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PROJECT TITTLE: STANDARDIZATION OF THE CGMP PLANT DESIGN, COMMISSIONING AND QUALIFICATION

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ABSTRACT:

Title of the thesis: **STANDARDIZATION OF THE CGMP PLANT DESIGN, COMMISSIONING AND QUALIFICATION.**

By

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It would have a significant impact in the GMP regulated industries and in our society. The industries can have a readily available proven standard, which would be followed consistently and make pure product for the end user, human being. Establishing a new standard by projects, is time consuming and costs a fortune. Sometimes some company make it conveniently, which can be wrong, as a result, the outcome hurts the end user, and when it is recognized by the regulatory authorities, the company absorbs a huge opportunity cost. A proven, regulatory authority accepted readily available CGMP standard would help the company to maintain the business and the end user could enjoy the right quality product. It will open a new horizon in the GMP industries.

The standard guideline is based on the current regulatory requirements, and accepted standard practices in the industries. The author can be contacted for any update or clarification at ncs777@gmail.com, or nsaha@ncspharma.com, phone: 1-732-816-0831.

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I feel so fortunate and grateful to my friends, relatives, my family, my wife Jaba Saha, my son Narattam Saha, and my daughter Sonia Saha for their moral support and cooperation for allowing me to have the opportunity to work on the thesis.

This work is dedicated with respect and love to my parents.

By

Nikhil C. Saha.

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1.0 INTRODUCTION:

The purpose of this document is to establish a standard general guidelines based on CGMP (Current Good Manufacturing Practices) for the GMP regulated industries in the Company wide successful implementation of Capital Projects. This guideline provides a consistent and uniform approach to executing all Capital Projects company wide. All Capital Projects should be planned, coordinated, documented and executed in an efficient manner, utilizing the best practices outlined by this guideline.

2.0 SCOPE:

This document describes the process, which should be followed for properly executing a Capital Project in the company wide in the GMP regulated industries. This process accomplishes the following objectives:

- Identifies the lifecycle of a Capital Project
- Better alignment with business needs
- Improved financial performance
- Proper control, communication, and involvement by all stakeholders
- Responsibilities of stakeholders
- Project execution that is timely and effective and meets CPA (Capital Project Appropriation) objectives

The list mentioned above is not intended to be all-inclusive; instead, it is an overview of what can be attained by implementing the above practices.

3.0 RESPONSIBILITIES:

Architectural & Engineering (A/E) Firm – Provides a design that meets all project objectives. Integrates communicated Company user requirements, best practices, standards, and properly accounts for existing conditions to produce a constructible KISS (Keep It Safe and Simple) based, and cost-effective design. Design engineers are usually contractors. Typically, the A/E's Project Manager is responsible for coordinating all the design activities.

Automation Liaison – Provides knowledge and expertise on process-specific control systems and ensures integration of new and existing control systems. Must also balance degree of control and automation with process requirements, efficiency, and operability. Serves as the communication link between the automation group and the project team. Manages the

automation aspects of the project under the overall management of the Company Project Manager.

Company Construction Manager (CM) – Provides design and planning input relative to constructability issues. Manages all construction phase activities, schedules field labor, controls field costs, and maintains adherence to construction schedules. Responsible for construction sub-account budgets.

Maintenance Liaison – Provides design input relative to equipment accessibility and maintainability. Establishes spare-parts inventories, maintenance schedules and equipment files. Serves as the communication link between the maintenance group and the project team.

Manager/Project Team Leader (TL) – Responsible for ensuring that each PM is properly trained in the use of this guideline and the CPT Manual.

Operations Liaison – Provides input on business justification, process knowledge, technical design input and operability as well as operating personnel needs and capabilities. Serves as the communication link between the operating group and the project team. Shares mutual accountability with PM for project success.

Company Project Manager (PM) - Responsible for planning, leading and managing all activities associated with a Capital Project. Accountable for overall project success and meeting of communicated CPA objectives, as well as overall project safety, quality, cost, and schedule performance. Shares mutual accountability for meeting CPA objectives with Operations Liaison.

4.0 GUIDELINE:

The US Area Capital Project Management Team (USCPMT) has identified nine phases within the lifecycle of a Capital Project. The nine phases that comprise of the project lifecycle are as follows:

- Project Identification
- Conceptual Design
- Preliminary Design
- Detailed Design
- Procurement
- Construction and Installation
- Commissioning and Qualification
- Close Out

- Project Controls (An additional "phase" which spans throughout the lifecycle of a Capital Project.)

This document will provide a description, key deliverables, entry and exit points and gate-keeping review checklist for each of the phases mentioned above. Additionally, this document will discuss project control techniques utilized during the lifecycle of a Capital Project. For further detailed information (e.g., templates, example of project documents, deliverables, etc.) about each of the phases within the lifecycle of a Capital Project, see in the appendix, or/and the author can be contacted for any detail current information or clarification. The guideline would be updated periodically overtime based on the current information.

4.1 Project Identification:

4.1.1 Description of Phase:

The purpose of the Project Identification Phase is to document the business needs that call for the development of a Capital Project and communicate those needs to the appropriate project sponsors. The Project Identification Phase ensures that Capital Projects support the objectives of the business. The business objectives, which are the foundation of all project activity, should be recorded, understood, and accepted by owner representatives and site leadership, including Operations, Finance, and Engineering. They form the basis and driver for the project objectives, which in turn form the basis for front-end design and all project activity that follows.

4.1.2 Key Deliverables:

The lists below are typical key deliverables generated during the Project Identification Phase:

A. General Engineering:

- Updated master project plan
- Updated master project tracking and planning database
- Project objectives documented
- Capital budget/forecast (Order of Magnitude)
- Initial milestone schedule
- Business justification documented
- Initial resource plan
- Scope development for Conceptual Design Phase

4.1.3 Entry Point:

The entry point for the Project Identification Phase is identifying and documenting the business need(s). The following are typical examples of business needs:

- Product/capacity expansion or enabling requirements
- Maintenance/replacement
- Environmental, health and safety (EH&S) improvements
- Infrastructure/utility upgrade or expansion
- Cost reductions
- Regulatory requirements (FDA, OSHA, EPA, DEP, etc.)
- Process and equipment technology/strategic investments

This process is led by the Team Leader, and typically includes the following activities:

A. Quarterly capital planning meetings between the CPT (Capital Project Team) and customer departments.
B. Monthly site project steering committee meetings.
C. Annual capital budget and operational review meetings (ORM's).
D. Special project meetings with Company Global Engineering (CGE) or other Company leadership as needed.
E. Quarterly project coordination meetings.

4.1.4 Exit Point:

The exit point for the Project Identification Phase is approval from site or divisional leadership for the business need(s) that lead to the initiation of conceptual design activities, with consequent update to capital planning database tools.

4.1.5 Gate-Keeping Review Checklist:

1. Have all key stakeholders put all their needs/requirements in the proposed project plan?

2. Does the proposed Capital Project have an effect on the remainder of the site, plant operating budget or other CPA's, and has it been properly accounted for?
3. Is there alignment with CGE regarding the proposed Capital Project?
4. Have stakeholder requirements been challenged to ensure they meet business and divisional objectives?
5. Has site leadership endorsed the proposed project?
6. Has the impact on the approved site capital and expense budget been reviewed and accepted by site Finance?
7. Have the master project plan and master project tracking database tools been updated?
8. Have master site plan and existing strategy impacts been identified?

4.2 Conceptual Design:

4.2.1 Description of Phase:

The purpose of the Conceptual Design Phase is to: (1) document business need(s), (2) develop sound, technical and business alternatives aligned with the business need(s), (3) analyze the technical and business alternatives, and (4) select the best project basis from the technical and business alternatives and document the design basis.

The Conceptual Design Phase provides Company with project concepts and strategies early enough in the planning cycle to allow the business to make informed decisions about whether to pursue Capital Projects while minimizing the cost of developing these concepts and strategies. The Capital Projects should be characterized from a technical, financial, and schedule viewpoint. The decisions can include the potential outcomes of:

- Perform further analysis (conceptual design studies) prior to deciding to proceed.
- Proceed with the project.
- Defer the project until a later time.
- Abandon the project.

The end product of the conceptual design process form the project basis, which enables the business to decide whether to proceed with a particular Capital Project. It is important to note that the Conceptual Design Phase is a highly iterative and interactive process that requires a series of conceptualization, alignment with evolving business need(s), and revisions and refinements of concepts.

The following alternatives can be utilized to fund a conceptual design study:

- Perform with Company internal resources.
- Fund outside A/E Firm via a low cost expense purchase order (PO) that is charged against the CPT budget.
- For larger Capital Projects, a Conceptual Design CPA may be utilized.

4.2.2 Key Deliverables:

The lists below are typical key deliverables generated during the Conceptual Design Phase:

A. Process and Equipment:
- Process flow diagrams (PFD's)
- Major process and utility equipment list
- Utilities summary
- Incremental utilities impact
- Material and energy balances

B. Process Controls and Instrumentation:
- Automation strategy

C. Piping and Layout:
- Concept equipment arrangement alternatives
- Personnel, equipment and material (PEM) flow diagrams

D. HVAC:
- HVAC classification drawings

E. General Engineering, Commissioning and Qualification:
- Level-one schedule
- ±30% order of magnitude estimate (OME) with estimate basis

- User requirements specification (URS)
- Design CPA per company CPA guideline
- Alternatives analysis
- Documented and developed business justification
- Review and/or update site master plan and affected strategy documents

4.2.3 Entry Point:

The entry point for the Conceptual Design Phase is an identified project that has received site leadership endorsement to proceed to the next stage of development.

4.2.4 Exit Point:

The exit point for the Conceptual Design Phase is a Design CPA that identifies the recommended technical and business alternative, which ultimately forms the project basis.

4.2.5 Gate-Keeping Review Checklist:

1. Are the business need(s) documented and fully understood by all key stakeholders involved in the Capital Project?
2. Has the A/E Firm developed an OME for each of the proposed alternatives?
3. Has the site master plan and associated strategies been reviewed and/or updated based on impact of the project?
4. Have all appropriate business alternatives been identified?
5. Has a proper analysis of alternatives been completed, and are the conclusions properly supported by sound analysis and logic?
6. Does the recommended alternative solve the business need(s)?
7. Has key Company leadership/management agreed to the recommended alternative that solves the business need(s)?
8. Has a conceptual design basis, estimate basis, and a properly documented OME been completed for the recommended alternative?

4.3 Preliminary Design:

4.3.1 Description of Phase:

The purpose of the Preliminary Design Phase is to: (1) develop and finalize the project design basis and associated discipline documents and (2) develop a definitive level cost estimate for final funding of the Capital Project.

The Preliminary Design Phase takes the input from the Conceptual Design Phase, completes the scope of work, and assembles sufficient design to allow preparation of a CPA quality cost estimate (±10%). The end product of the Preliminary Design Phase is a package of project specific information that is called the Project Design Basis (PDB). A quality PDB contains all pertinent information to achieve the Detailed Design Phase of the Capital Project with minimal or no change. It is the completeness and firmness of the information in the PDB that is important, not the percentage of engineering/design complete. However, on most Capital Projects, 20% to 50% engineering/design (overall) is typically completed to produce a quality PDB.

Funding for the Preliminary Design Phase of a Capital Project is typically achieved via a Design CPA. For schedule-critical projects, the Design CPA may also include funding for continuation of design during the Definitive CPA approval cycle (e.g., beginning of Detailed Design Phase). For fast-track projects, a Design and Long-Lead Procurement CPA may be used, which also includes pre-purchase of long-lead equipment.

4.3.2 Key Deliverables:

The lists below are typical key deliverables generated during the Preliminary Design Phase:

A. Process and Equipment:

- Piping and instrumentation diagrams (P&ID's)
- Update process and utility equipment list
- Process data sheets for equipment
- Pressure safety valve and control valve data sheets
- Specification of critical long-lead equipment and quotations for purchase

B. Process Controls and Instrumentation:

- Instrument list
- DCS equipment purchase specifications and quotations
- Control system architecture

C. Piping and Layout:

- Piping material specifications
- Line list
- Plot plans
- Piping routing drawings
- Tie-in list (coordinating transition plan for shutdown schedule)
- Updated PEM flow diagrams
- Equipment arrangement drawings

D. HVAC:

- Updated HVAC classification and pressurization diagrams
- Specifications for HVAC equipment
- HVAC air flow diagrams

E. Electrical:

- Electrical area classification drawings
- Electrical one-line diagrams
- Underground grounding plans

F. Civil, Structural and Architectural:

- Site plan
- Geo-technical surveys
- Steel and concrete drawings
- Permits (building and environmental)
- Room finishes schedule
- Building floor and roof plans
- Life safety egress drawing

G. General Engineering, Commissioning and Qualification:

- Detailed schedule
- HAZOP report
- ±10% definitive cost estimate with estimate basis

- Project commissioning and qualification plan (PCQP)
- System level impact assessment
- Master turnover package (TOP) matrix (refer to the appendix)
- cGMP/GEP checklist (refer to the appendix) review
- URS review
- Material and equipment inspection plan
- Enhanced design review summary report
- Updated URS

4.3.3 Entry Point:

The entry point for the Preliminary Design Phase is an approved Design CPA or Design and Long-Lead Procurement CPA.

4.3.4 Exit Point:

The exit point for the Preliminary Design Phase is an approved Definitive CPA.

4.3.5 Gate-Keeping Review Checklist:

1. Has a HAZOP been performed?
2. Has the Maintenance Liaison reviewed the instrument list?
3. Has the Maintenance Liaison reviewed the equipment list and equipment arrangement drawings, plus long-lead equipment specifications?
4. Does the A/E Firm have all applicable Company standards, best practices and guidelines?
5. Has the A/E Firm prepared a definitive cost estimate with a detailed estimate basis?
6. Has the project schedule been reviewed by the A/E Firm, CM and Owner to ensure the schedule is realistic?
7. Has the CM reviewed the cost estimate generated by the A/E Firm?
8. Has the CM performed a constructability review?
9. Have preliminary design basis documents been updated to reflect the results of the following:

    - HAZOP
    - cGMP/GEP checklist review
    - URS review

10. Has the environmental checklist been completed for the Definitive CPA package?
11. Have permit requirements been established and incorporated into the plan?
12. Has a system level impact assessment been performed and PCQP prepared and approved?
13. Has the A/E Firm assigned proper instrument and equipment tag numbers per Company tag number procedures?
14. Has the A/E Firm developed P&ID's in the Company format?
15. Has the A/E Firm developed a procurement plan for the Capital Project?
16. Has the Operations Liaison reviewed the tie-in schedule to ensure it is aligned with the shutdown schedule?

4.4 Detailed Design:

4.4.1 Description of Phase:

The purpose of the Detailed Design Phase is to develop the results of the Preliminary Design Phase into high quality "Issue for Construction" documents in a timely manner supporting the project schedule. The documents must be sufficient to cost-effectively construct the Capital Project in accordance with the agreed design basis and user requirements.

During the Detailed Design Phase, the PDB package is developed into completed design documents, specifications, and equipment procurement for field installation. The CM defines and assembles the construction bid packages for a Capital Project with support from the A/E Firm. The construction bid packages are comprised of drawings, specifications, models, and reports that are used to erect, install, and commission a Capital Project.

4.4.2 Key Deliverables:

The lists below are the typical deliverables generated during the Detailed Design Phase:

A. Process and Equipment:

- Finalize P&ID's
- Finalize process data sheets for equipment
- Finalize utilities summary

- Emergency relief calculations
- Equipment specifications for purchase
- Process calculations/line sizing

B. Process Controls and Instrumentation:

- Finalize instrument list
- Instrument specifications for purchase
- Instrument loop diagrams
- Instrument installation details
- Instrument location drawings
- I/O assignments

C. Piping and Layout:

- Finalize tie-in list and line list
- Isometric drawings
- Piping layout drawings
- Pipe stress and support design
- Pipe support details
- Piping material requisitions for purchase
- Installation and testing specifications

D. HVAC:

- Finalize HVAC classification/pressurization diagram
- Finalize HVAC air flow diagrams
- HVAC system zoning diagrams
- HVAC control diagram and specifications
- HVAC equipment arrangement drawings
- HVAC equipment schedules
- HVAC ductwork plans, layouts and sections
- Installation and testing specifications

E. Electrical:

- Lighting layout plans
- Finalize electrical one-line diagrams
- Finalize electrical area classification drawings
- Electrical panel schedules
- Instrument wiring diagrams
- Cable tray layouts

- Power, lighting and grounding plans and details
- Telephone, communication and fire alarm system layouts
- Load study calculations
- Emergency power specifications and plans
- System security specifications
- Electrical installation details
- Installation and testing specifications

F. Civil, Structural and Architectural:

- Site plan
- Steel framing plans, sections and details
- Concrete foundation plans, sections and details
- Slab on grade plans and details
- Finalize architectural floor and roof plans
- Architectural finish schedule
- Door and hardware schedule
- Reflected ceiling plans
- Architectural details
- Building elevations and sections
- Laboratory and office furniture specifications
- Finalize life safety egress drawings

G. General Engineering, Commissioning and Qualification:

- Requisitions for purchase
- Level-2 construction schedule
- Component level impact assessment
- Begin assembly of TOP files
- Detailed TOP matrix
- Develop commissioning test plans by system
- Develop factory acceptance test (FAT) plans
- Develop installation and operational (IOQ) protocols by system
- Update PCQP
- Design reports to document resolution of significant technical issues as appropriate

4.4.3 Entry Point:

The entry point for the Detailed Design Phase is a completed design basis and approved Definitive CPA.

4.4.4 Exit Point:

The exit point for the Detailed Design Phase is at the completion of the assembly, bid and award cycle of the construction bid packages.

4.4.5 Gate-Keeping Review Checklist:

1. Have the "Issue for Construction" drawings been signed-off by the Design Manager and PM?
2. Are the loop diagrams in Company format, and using approved Company templates?
3. Has the A/E Firm reviewed all instrumentation on skid-type equipment?
4. Has the CM developed quality and safety plans?
5. Has the A/E Firm participated in the development of the construction bid packages?
6. Has the A/E Firm documented all process calculations, including calculations for emergency relief devices?
7. Has a Component Level Impact Assessment been performed?
8. Has a project execution plan been developed by the CM with support from the PM?
9. Has the Automation Liaison generated I/O assignments?
10. Has a tie-in schedule been coordinated with the Operations Liaison?
11. Have the FAT plans been approved?
12. Have the TOP files for design documents been compiled?

4.5 Procurement:

4.5.1 Description of Phase:

The purpose of the Procurement Phase is to: (1) develop high quality bid packages, (2) solicit competitive bids, (3) perform effective commercial and technical bid analysis supporting buy-out of the project's various material and construction requisitions in an efficient and cost-effective manner meeting the project schedule requirements, and (4) perform quality and timely processing and

review of vendor/contractor submittals supporting the project schedule, and (5) to effectively manage vendor documents.

Typically, during the Procurement Phase of a Capital Project, the A/E Firm will perform commercial and technical bid analysis for specialized items such as process equipment (e.g., reactors, heat exchangers, pumps, etc.), process controls, instrumentation, pre-purchased piping spools and specialty items, and HVAC equipment. For smaller Capital Projects, the PM and CM may collaborate to handle this activity in lieu of the A/E Firm. For bulk, non-specialized items such as conduit, wire, concrete and structural steel, the CM will initiate procurement activities via the contract construction bid packages. The CM handles procurement of all field construction bid packages.

4.5.2 Key Deliverables:

The lists below are typical key deliverables generated during the Procurement Phase:

A. General Engineering, Commissioning and Qualification:

- Bid analysis
- Scopes of work
- Vendor drawings and calculations submittals
- Performance test certificates
- Develop site acceptance test (SAT) plans
- Requisition status reports
- PO status reports
- Updated schedule
- Compilation of procurement section of the TOP files

4.5.3 Entry Point:

With the exception of the early phase procurement of engineering services, the entry point for the Procurement Phase is an approved Design and Long-Lead Procurement CPA or Definitive CPA.

4.5.4 Exit Point:

The exit point for the Procurement Phase is at the completion of the Commissioning and Qualification Phase of a Capital Project.

4.5.5 Gate-Keeping Review Checklist:

1. Has the bidders list for specialized items been reviewed and approved by the Maintenance and Operations Liaisons and Procurement Department?
2. Has the Procurement Department participated in deciding what specialized items will be purchased by Company versus by the contractors?
3. Has the Maintenance and Operation Liaisons and Procurement Department reviewed and approved all bid analysis pertaining to specialized items?
4. Have all vendor drawings pertaining to specialized items been reviewed by the Maintenance and Operations Liaisons prior to fabrication?
5. Has the Procurement Manager, Site CM, and TL reviewed and approved all bid analysis pertaining to the construction bid packages?
6. Have justifications for any required single-source contracts/PO's been developed, and approved by the Site CM, TL, and Procurement Manager?
7. Has a contracting plan been developed, and approved by the Site CM, Procurement Manager, and TL?
8. Has a bidders list for construction been approved by the Procurement Manager?
9. Have all new contractors and vendors been properly pre-qualified by the Procurement Department?
10. Has the material and equipment inspection plan been executed as agreed, and results documented?
11. Has the project execution plan been updated?
12. Have all appropriate vendors/contractors received Company specific requirements via the construction bid packages? These include the following:

    - Post-construction cleaning requirements
    - FAT/SAT documentation/plan requirements
    - Documentation submittal requirements per the detailed TOP matrix
    - Commissioning phase documentation responsibilities per the commissioning test plans

4.6 Construction and Installation:

4.6.1 Description of Phase:

The purpose of the Construction and Installation Phase is to: (1) execute the proper installation of the A/E Firm's design, in a safe, efficient, and cost-effective manner (2) verify construction is in conformance with the design documents.

Company constructs most Capital Projects via the CM method (typically CM by Company), using multiple construction bid packages. Construction bid packages have well-defined boundaries and may be executed by several contractual methods, most typically lump sum competitive bid in accordance with the CPT's procurement guidelines.

The CM works with the A/E Firm to define the construction bid packages, which include definition of the scopes of work, in accordance with the agreed contracting plan for the project.

The CM manages the construction phase under the overall direction of the PM. The CM works closely with the Procurement Manager and Site CM to execute the construction bid package buy-out. The CPT CM procedures are described in more detail in CPT-SOP.

4.6.2 Key Deliverables:

The lists below are typical key deliverables generated during the Construction and Installation Phase:

A. Construction:

- Develop and execute logistics plan, including temporary facilities, mobilization, access, storage, contractor support facilities, etc.
- Complete permit applications, receive permits
- Develop and execute contractor safety plans
- Develop and execute construction quality plan
- Execute contractor rigging plans
- Update and execute construction schedule
- Process contractor submittals
- Manage subcontractor field construction activities per the project schedule

- Coordinate activities between contractors, Company Operations, and other projects to achieve safety and schedule goals

B. Commissioning and Qualification:

- Execute FAT plans
- Plan and schedule completion of construction on a system basis
- Completed mechanical completion by contract and by system
- Finalize commissioning test plans by system
- Finalize IOQ protocols by system
- Plan resources for Commissioning and Qualification Phase

4.6.3 Entry Point:

The entry point for the Construction and Installation Phase is an approved Definitive CPA.

4.6.4 Exit Point:

The exit point for the Construction and Installation Phase is at the conclusion of the mechanical completion milestone during the Commissioning Phase.

4.6.5 Gate-Keeping Review Checklist:

1. Have all warranties been received?
2. Are all schedules of values items and contract deliverables verified complete?
3. Has the mechanical completion certificate for each contract been signed-off?
4. Are all punch-list items relating to construction contractor scopes closed out and complete?
5. Are all contractor and temporary facilities demobilized?
6. Are all contractor submittals, including as-built drawings in the TOP file?
7. Are all contracts and PO's zeroed-out and closed?
8. Are all invoices fully paid?

4.7 Commissioning and Qualification:

4.7.1 Description of Phase:

The purpose of the Commissioning and Qualification Phase is to: (1) properly document that the systems were constructed and can operate in accordance with

all design and user specifications, and (2) to successfully start-up and turnover facilities, systems, and equipment to the end-user, resulting in a safe and functional Capital Project that meets established user, design and applicable regulatory requirements.

Commissioning and qualification is the culmination of all project activities. Significant events include: mechanical completion by system, commissioning, and qualification.

There are numerous activities that occur during this phase of a Capital Project. They are as follows:

- Commissioning (All Systems):
  - Inspection and testing phase
  - Mechanical completion
  - Regulation, adjustment and setting-to-work phase
  - Functional run test phase

- Qualification (Direct Impact Systems Only):
  - Execute IOQ protocols
  - Execute PQ protocols
  - Final qualification summary report

4.7.2 Key Deliverables:

The lists below are typical key deliverables generated during the Commissioning and Qualification Phase:

A. Commissioning and Qualification:
- Executed commissioning test plans by system, including SAT's
- Executed post-construction cleaning
- Mechanical completion certificates issued and signed
- Executed IOQ protocols by system (direct impact systems only)
- Executed PQ protocols
- Complete final qualification summary reports by system
- Assemble TOP's per the detailed TOP matrixes

4.7.3 Entry Point:

Although the commissioning and qualification activities span essentially the entire project lifecycle (beginning with the URS in the Conceptual Design Phase), the actual entry point of the Commissioning and Qualification Phase of the project is the beginning of the inspection and testing phase of commissioning. Note there is an overlap with the Construction and Installation Phase, as inspection and testing and mechanical completion are also the final activities to conclude the contractor scopes and construction.

4.7.4 Exit Point:

The exit point for the Commissioning and Qualification Phase is the executed commissioning test plans, IOQ protocols, PQ protocols (as applicable), and the completed final qualification summary report.

4.7.5 Gate-Keeping Review Checklist:

1. Has the CM walked-down the system with the Operations and Maintenance Liaisons?
2. Has the CM transmitted a copy of the redlined critical documents to the A/E Firm for final CAD edit?
3. Have copies of the redlined critical documents been turned-over via the Maintenance Liaison to the Critical Document Coordinator per CPT-SOP?
4. Have all IOQ protocol deviations been closed out and approved by Quality Operations?
5. Have all critical instruments been calibrated?
6. Have all systems installed or modified been commissioned?
7. Have all direct impact systems installed or modified been qualified by IQ and OQ?
8. Were all commissioning test plans and IOQ protocols approved both pre- and post-execution and completed signatures verified?
8. Were final qualification summary reports written and approved for all direct impact systems?
9. Are the original versions of all commissioning test plans, reports, IOQ protocols and final qualification summary reports filed in the Engineering Archive TOP?
10. Are all FAT and SAT plans and reports complete and filed in the TOP's?
11. Are all punch-list items completed and closed out?

4.8 Close Out:

4.8.1 Description of Phase:

The purpose of the Close Out Phase is to provide and turnover all the agreed necessary documentation and information to the applicable stakeholders, namely Operations, Maintenance and Engineering Archives Departments. It is important to note that implementing the Close Out Phase of a Capital Project encompasses both physical completion and financial closing.

4.8.2 Key Deliverables

The lists below are typical key deliverables generated during the Close Out Phase:

A. General Engineering
- Completed punch-list
- Completed TOP's transmitted to Engineering Archives, Operations and Maintenance
- Completed project close out forms, including financial and physical completion sections
- As-built drawings

4.8.3 Entry Point

The entry point for the Close Out Phase is at the conclusion of the Commissioning and Qualification Phase.

4.8.4 Exit Point

The exit point for the Close Out Phase is when the project close out form has been completed.

4.8.5 Gate-Keeping Review Checklist

1. Are the three (3) turnover packages completed and transmitted to Operations, Maintenance and Engineering Archives Departments?
2. Are all punch-list items closed?

3. Are all critical documents CAD/updated to as-built status, and both hard copy and electronic versions transmitted to Engineering Archives?
4. Has a lessons-learned meeting been conducted with key stakeholders from the project (as applicable)?
5. Are all HAZOP action items reviewed and verified closed?
6. Are all CPA commitments reviewed and met?
7. Are all EHS and Quality action items from the CPA approval process reviewed and completed?
8. Is the CPA closed in project cost management system (PCMS)?
9. Are all the estimated-to-completes (ETC's) and PO balances zeroed-out?
10. Are all invoices paid?
11. Are all PO's closed and contracts closed out via procurement, lien waivers on file?

8.9 Project Controls

4.9.1 Overview of Project Control Process

Company has developed and successfully implemented a Project Management and Control methodology that is founded on the principles of baseline management, objective performance measurement, early identification of potential changes, timely reporting, use of "estimate to complete" concept for cost forecasting, analysis and open communication throughout the lifecycle of the Capital Project. The following outlines the recommended approach pertaining to Project Controls for Capital Projects.

1. Establish the Project's Baseline

   There are two baselines generated for a Capital Project, each of which includes scope, cost and schedule. These are: (1) conceptual design basis, and OME estimate and schedule, and (2) preliminary design basis, and definitive cost estimate and schedule (e.g., Definitive CPA). Scope, cost, and schedule are interrelated, and changing one typically changes the others. The scope of work should be established first and then the cost and schedule to achieve the work is determined. A key element in establishing these baselines is stakeholder input. Since scope drives cost and schedule, the establishment of the project's scope is critical.

2. Monitoring, Analyzing and Controlling Progress, Performance and Scope

   Once the baseline is established and work on the project begins the PM should monitor the actual cost and schedule performance against the project's baselines as the point of comparison. The actual cost is monitored utilizing PCMS. Additionally, the ETC's should be reviewed and updated periodically (approximately every two weeks) by the PM. Schedule performance is monitored by deliverables as well as by evaluating the overall critical path schedule. During this time period, scope can be refined. The key is to manage any scope change and understand that the cost and schedule impact of changes should be known before any changes are made. Cost and schedule performance needs to be monitored, analyzed and controlled even when there are no scope changes.

   The PM is responsible for maintaining ETC's for cost areas; design, equipment and bulk purchase in PCMS. The CM is responsible for maintaining ETC's for cost of construction. Area sub-account for overhead and CM services are under the control of the TL and Site CM respectively, and should be assumed by the PM to be fully committed unless specifically approved by the TL.

3. Reporting

   The PM should report the results of the scope, cost and scheduling process throughout a Capital Project to all key stakeholders in accordance with company's CPA reporting requirements. This encompasses work in all phases of a Capital Project. The primary purpose of reporting is to eliminate surprises and to keep Company management informed of possible deviations from the project's baseline in a timely manner. This also enables Company management to participate in the decision making process.

4. Estimating

   The establishment of a meaningful estimate at a level of detail that enables the collection, analysis and forecasting of costs is an important step. At the conclusion of the Conceptual Design Phase, a ±30% OME should be developed for the Capital Project. This estimate should be used for the subsequent monitoring, analyzing and controlling of cost. The estimate produced in the Conceptual Design Phase should be used to monitor the cost

during the Preliminary Design Phase. At the conclusion of the Preliminary Design Phase and before release of a Definitive CPA for approval a ±10% estimate and detailed estimate basis should be provided that forms the basis for cost trending throughout the remainder of the project.

5. Change Control

   Change control is a vital element to managing Capital Projects. Company places emphasis on the early identification of change by requiring key stakeholders to understand the project's scope baseline. It is important to note that any required major changes should be communicated to Company management for approval.

   The PM is not authorized to make changes from communicated CPA scope, to make changes, which would result in a communicated CPA objective not being met, or which would result in the CPA requiring use of CPA contingency. The TL must be informed of any such issues as soon as the PM becomes aware of the issue, so that a plan to address IT can be developed and approved by Company leadership. The CM Group will maintain a field change log during the Construction and Installation Phase to assist in the management of field changes.

4.9.2 Gate-Keeping Review Checklist

1. Has the A/E Firm provided a ±10% definitive cost estimate with a detailed basis of estimate (e.g., material and labor take-offs) for all required disciplines?
2. Has the definitive cost estimate been reviewed by the CM and the TL prior to submitting a Definitive CPA?
3. Has the ETC's been updated on PCMS every two weeks?
4. If schedule allows, has the CM collected all bids for each of the construction bid packages prior to release of the Definitive CPA?
5. Is the A/E Firm developing project status reports?
6. Are there monthly meetings with the CM to review cost and schedule of the project?
7. For larger Capital Projects, has a third party provided a cost estimate at the conclusion of the Preliminary Design Phase?
8. Has the CM generated a baseline project schedule, and has the schedule been reviewed by the appropriate stakeholders?

5.0 CONCLUSION

Considering above, the standard guideline would be company-wide consistent, a-well established and proven standard based on the current regulatory requirements for the GMP industries, which would be automatic, safe, and cost effective. The author strongly recommend to consider KISS (Keep It Safe and Simple) principle, and Pharm.MACT (Maximum Achievable Control Technology in the pharmaceutical industries for the environmental issues) philosophy for the design.

The GMP regulated industry is a major factor in our personal level as well as in the business level globally. The most important factor in the GMP industry is to follow and maintain CGMP regulation to produce the product for the end user, which is the most important creature created by God on the surface of the earth. Without a good health, we may not have that much left in our life. The industry produces the products, which helps to maintain our good health. Most of the times, many companies fail because of not having a consistent regulatory authority accepted CGMP standard company wide. A proven, regulatory authority accepted readily available CGMP standard would help the company to maintain the business and the end user could enjoy the right quality product. Based on the history, and experience in the industry, it is safe to say that the major successful players in the industry have and maintain a consistent regulatory requirements company wide. Many companies do not have, or companies do not share the regulatory standards they have in place, which is confidential from the business point of view. Having access in a well-proven accepted standard would be cost effective, and the industry and the end user could enjoy the outcome. Initial implementation can be an issue, but once the benefits are realized, it will be well receipt. Based on the history, the end users may not realize the benefits of the product initially but the producer can educate the end users, which is proven in the high tech industry for instant Apple's product, the Apple became the most successful company in the world. The current trend in the high tech industries is that the producer driven market place has been proven better than the consumer driven one. It will open a new horizon in the GMP industries.

The standard guideline is based on the current regulatory requirements, and accepted standard practices in the industries. The author can be contacted for any update or clarification at ncs777@gmail.com, or nsaha@ncspharma.com, phone: 1-732-816-0831.

6.0 APPENDIX

A.1 APPENDIX: NOMENCLATURE, **DEFINITIONS AND ABBREVIATIONS**

A key requirement for consistent practice is the adoption of a standard set of terminology. The purpose of this Guideline is to define terms associated with the process for new and modified equipment, utilities, and utilities systems used in the US GMP Area Manufacturing plants.

Benefits of a common set of terms include:

- Avoids confusion and misinterpretation
- Defines clear expectations of desired outcome
- Beneficial in benchmarking
- Promotes consistency between operating units and alignment across the industry.

A.1.1 **DEFINITION OF THE TERMS AND ACRONYMS**

ACCEPTANCE CRITERIA:
The set of conditions determined prior to the test, which when met, will constitute acceptance of the successful completion of the test.

ACTIVE PHARMACEUTICAL INGREDIENT (API):
The ingredient in the drug, which prevent disease.

A/E:
Architectural and Engineering Firm.

BOD:
Basis of Design, the philosophy of the design, which direct the life-cycle of the design activities.

BIDDER:
Any individual, firm or corporation submitting a priced proposal for the scope of work set forth in the RFP.

BRACKETING:
The extremes in the sample for an experiment.

CM:
Construction Manager.

C & Q:
Commissioning & Qualification

CPA:
Capital Project Appropriation.

CALIBRATION:
The process to standardizing a unit to operate within a range based on a reference standard unit.

cGMP:
Current Good Manufacturing Practice as defined in 21CFR210 and 211 (US), or other regional / global regulatory bodies having jurisdiction over the US manufacturing sites (e.g.: MCA, ICH, etc.)

CHANGE CONTROL SYSTEM:
A formal system involving the appropriate Quality Unit, a group of expert responsible, and manages and maintains regulatory compliance in the facilities.

CHANGE CONTROL SYSTEM:
A formal system involving the appropriate Quality Unit, managed by a qualified team responsible to maintain regulatory standard quality for changes.

CHANGE MANAGEMENT:

A formal qualified management controls and manages the changes during design and planning stages following regulatory guidelines and meeting the pre-determined acceptance criteria

COMMISSIONING:
A standard engineering practice to confirm and verify the system based on the design, operates based on the operational specification, URS, which precedes Qualification, and includes three phases:
- Inspection and Testing
- Regulation, Adjustment and Setting to Work

- Functional/Run Testing

CAD:
Computer – Aided Design.

CONCURRENT VALIDATION:
Qualification activities during operation of production.

CONTROL STRATEGY:

A set of items planned to be controlled/monitored in the process.

CORRECTIVE ACTION (C/A):
An action taken to control based on monitored a critical parameter.

CRITICAL:

Parameter, which has direct impact on the product/process.

CRITICAL COMPONENT:
An item, which has a direct impact on the product quality.

CRITICAL CONTROL POINT (CCP):

A point, which can be considered to control to minimize impact in product quality and safety hazards.

CGE:
Company Global Engineering.

CRITICAL INSTRUMENT:
An instrument, which has a direct impact on product quality. (e.g.: A critical component)

CPT:
Capital Project Team.

CRITICAL VARIABLE STUDY:
The study of the parameters, which have direct impact on the operation and product quality.

DESIGN QUALIFICATION (DQ):

Qualifying process, which evaluates the design satisfying the regulatory requirements and following the Good Manufacturing Practices.

DESIGN SPACE:

A combination of inputs provides quality assurance.

DEVIATION:
Any test result obtained while executing a Qualification Protocol that does not meet the Acceptance Criteria. Also includes Protocol errors or documentation changes required to be corrected/made during execution of a Protocol. All Deviations must be properly resolved and closure documented and approved by designated approvers.

DCS:
Distributed Control System.

DEP:
Department of Environmental Protection.

DIRECT IMPACT SYSTEM (DI/D):
A system, which has direct impact on the product quality based on the impact assessment for cGMP compliance.

DRUG MASTER FILE (DMF):

The information provided to the regulatory authorities by the producer to be authorized to market.

ENGINEERING CHANGE CONTROL:
An engineering process under Good Engineering Practice, to manage changes to a design and related documents. Includes use of appropriate and qualified reviewers and document revision control systems.

ENHANCED DESIGN REVIEW (EDR):
An engineering process intended to assure that a design meets its intended purpose, and that it meets Good Engineering Practice and cGMP requirements. Includes:

- A structured cGMP review of the design
- A structured review of the design for Good Engineering Practice
- A structured review of the design against the User Requirements Specification
- A summary of the above reviews

EH&S:
Environment Health and Safety.

EPA:
Environmental Protection Agency.

ETC:
Estimated to Complete.

FACTORY ACCEPTANCE TEST (FAT):
Static and/or dynamic testing to support the qualification efforts should be conducted and documented at the supplier site.

FINISHED PHARMACEUTICAL PRODUCT (FPP):

The drug product ready, and authorized to market for consumer.

GAP ANALYSIS:

Evaluation, or assessment of the critical items existence at the receiving unit compare to the sending unit.

FDA:
Food and Drug Administration.

GUARANTEED MAXIMUM COSTS (GMC):
The fixed maximum amount in a negotiated contract within which the scope of work will be achieved on a reimbursable basis. Bidder assumes full responsibility to complete the agreed scope of work within the GMC amount in a timely manner.

GOOD ENGINEERING PRACTICE (GEP):
A body of knowledge representing generally recognized techniques, standards, methods and concepts, representing sound engineering practice. Includes technical design discipline elements, as well as means and methods elements. Examples include project management and design management processes/systems, use of registered Professional Engineers for design of systems, document and controls systems, use of pre-approved engineering specifications and standards, and structured design review processes.

GOOD LABORATORY PRACTICES (GLP):
The analytical industry standards, which is accepted by the regulatory authorities.

GUIDELINE:
A document which provides suggested methodology for accomplishing a specific task. Guidelines are typically non-binding.

HAZOP:
Hazard and Operability study.

HVAC:
Heating, Ventilation and Air Conditioning.

I/O:
Input/Output is the communication between an information processing systems.

INSTALLATION QUALIFICATION (IQ):
A well-documented verification for installation based on the design maintaining acceptance criteria.

IN-PROCESS CONTROL (IPC):

Monitored parameters, which is controlled to meet the specifications.

IOQ:
Installation and Operational Qualification.

INDIRECT IMPACT SYSTEM (II/I):
A system, which has an indirect impact on the product quality.

INSTRUMENT:
Any non-computer device which is used to measure and / or store and / or display a value of a variable which has been acquired directly or by controlling an associated piece of equipment.

IMPACT ALTERING CHANGE:
Any change made during the course of a project, from the time of the initial Impact Assessment, through completion of Qualification, which has the effect of altering the product quality impact of a system or component therein. Impact Altering Changes may change the nature of a System from or to Direct Impact, Indirect Impact, or No Impact status, or may change the nature of a Component within a Direct Impact System from or to Critical or Non-Critical status. Particular care must be given also to changes which could change a component within an Indirect or No Impact System to "Critical" status, which would require that the system be re-classified as Direct Impact.

IMPACT ASSESSMENT:
A standard process to assess the impact of the item on the product quality, which includes:
- System Level Impact Assessment
- Component Level Impact Assessment

ICH:
International Conference of Harmonisation.

INSTRUMENT:
Any non-computer device which is used to measure and / or store and / or display a value of a variable which has been acquired directly or by controlling an associated piece of equipment.

I.S.P.E.:
International Society for Pharmaceutical Engineers

IT:
Information Technology.

KEY MILESTONES:
Milestones associated with specific time periods and/or dates as set forth in the RFP.

KEY PERSONNEL:
Individuals considered essential to the scope of engineering services performed or to be performed by, or on behalf of the Engineer.

MODIFICATION:
A revision to a Protocol, typically to correct errors or modify criteria.

LUMP-SUM:
A fixed contract price to complete the agreed scope of work.

MCA:
UK Medicine Control Agency.

MT:
Maintenance Technician.

NO IMPACT SYSTEM (NI/N):
A system, which has no impact on the product quality

NMT:
Not More Than.

NON-CRITICAL COMPONENT:
An item, which has no impact on the product quality.

OME:
Order of Magnitude Estimate.

ORM:
Operational Review Meeting.

OSHA:
Occupational Safety and Health Administration.

OPERATIONAL QUALIFICATION (OQ):
A well-documented verification for the operation based on functional specification meeting acceptance criteria.

PROCEDURE:
A formal written document that spells out the agreed methodology to carry out an activity or function. Procedures are typically binding.

PCMS:
Project Cost Management System.

PFD:
Process Flow Diagram.

PROJECT COMMISSIONING AND QUALIFICATION PLAN (PCQP):
A summary level document that describes a manufacturing site's plan for establishing and executing a commissioning and qualification program for a capital project adding or modifying equipment, facilities, or utilities.

PEM:
Personnel, Equipment and Material Flow Diagram.

PM:
Project Manager.

PROPOSAL:
The written document, which the Engineer submits in conformance with the Request for Proposal.

PO:
Purchase Order.

PERFORMANCE QUALIFICATION (PQ):
A well-documented verification of the item for performance meeting pre-determined acceptance criteria.

PLANT FUNCTIONAL SPECIFICATIONS:
The designed functional specification of any item for operation by qualified team.

P&ID:
Piping and Instrumentation Diagram. Engineering design drawings, which show system along with controls, flows in detail at some extent.

PRE-DETERMINED ACCEPTANCE CRITERIA:
The acceptance criteria determined by qualified team following regulatory requirements and meeting regulatory compliances beforehand for qualification.

PDB:
Project Design Basis.

PROTOCOL:
A written document describing in detail, the method and acceptance criteria for qualifying a process, equipment unit, or system. It will also describe the system, its function, and identification of those who will be responsible for the qualification efforts and the test methodology employed. After approval of the protocol, it requires later execution in order to amass the raw data (documented evidence) required for establishing and approving the qualified status of the system.

PROCESS VALIDATION:
A well-documented verification process, which qualifies the item's consistency in reproducibility meeting pre-determined acceptance criteria.

PROSPECTIVE VALIDATION:
A well-documented verification process, which follows the pre-determined qualification plan.

QUALIFICATION:
The standard practice of validation based on the predetermined specifications. Also may refer to the phase of a project following Commissioning, and includes IQ, OQ, and PQ.

QUALITY ASSURANCE (QA):

The system, which manages the consistency of the product quality.

QUALITY CONTROL (QC):

The process, which controls the products according to the specifications.

QUALITY PLANNING:

A set of objectives set by the management to maintain the quality based on the specification.

QUALITY POLICY:

Developed and accepted by the upper management to maintain quality based on the specification and the regulatory compliances.

QUALITY RISK MANAGEMENT (QRM):

A process to assess, and maintain the quality and minimize risk during the product life.

QUALIFICATION PRACTICES:

A set of enhanced review, approval, and documentation practices involving the designated Quality Unit for the site or facility, which are intended to provide assurance that those Critical Components and Direct Impact systems which affect product quality are appropriately installed, qualified, and documented in accordance with cGMP requirements.

QUALIFICATION SUMMARY REPORT:

A document that summarizes the qualification test results, addressing any deviations discovered during the execution, and states the validation status of the system.

QUALIFIED SYSTEM:

A Qualified System is any system that is used in conjunction with regulated activities, and that itself has been appropriately qualified for its intended purpose.

RFP:

Request for Proposal.

RETROSPECTIVE VALIDATION:

The qualification process based on the accumulated past working information for existing items.

RE-VALIDATION:
A process of qualification, which re-evaluate the item based on the pre-determined acceptance criteria following the regulatory requirements.

SITE ACCEPTANCE TEST (SAT):
Testing of a system or equipment unit, conducted at the location of installation.

SOP:
Standard Operating Procedure.

SIP:
Steam-In-Place.

SUB-CONSULTANT:
Any organization, which is subcontracted by a selected consultant for the work defined in the RFP.

SYSTEM BOUNDARY:
A boundary of the system, the items it would cover for certain activities.

TEST EQUIPMENT:
Instrument or device, which is calibrated used to calibrate other instruments or to perform one-time C&Q testing.

TL:
Team Leader.

TIME AND MATERIAL WITH A NOT TO EXCEED (NTE):
The Bidder is paid for the actual amount of labor expended on a project with a NTE value incorporated into the contract. The work is managed under the NTE amount, but bidder is not liable to complete the full, required scope of work under the NTE amount. However, bidder may not exceed authorized purchase order amount in terms of resources expended nor in terms of invoicing without owner's written permission and receipt of a purchase order change increasing the NTE amount. Bidder is expected to exercise good judgment and management in the performance of the work, making a good faith effort to complete the work within the NTE amount.

TURNOVER PACKAGE (TOP):
A pre-defined set of documentation representing the details of a facility or system, and which is turned over and transmitted upon system completion to an end user, maintenance group, or site archive.

USER REQUIREMENT SPECIFICATION (URS):
A written document that defines the minimum requirements for performance of a system or facility.

USCPMT:
US area Capital Project Management Team.

VALIDATION:

A well-documented evaluation confirming the process, system, item is consistent,

and meets acceptance criteria.

VALIDATION MASTER PLAN (VMP):

A living document, which direct the overall project philosophy throughout the life-cycle maintaining regulatory compliances, and meeting the specifications.

VALIDATION PROTOCOL (or PLAN) (VP):

A well written document/plan, which qualify a process, system based on the

validation master plan satisfying the acceptance criteria.

VALIDATION REPORT (VR):

A final validation summary report, which documents the validation outcome, and resolution of any deviation.

VALUE MANAGEMENT WORKSHOP:
A structured review of the project design basis against the project business objectives with the objective of identifying cost-effective alternatives to achieve the optimum project value (delivered results for capital expended). This review typically is conducted during the Preliminary Design Phase, and includes not only manufacturing objectives, but other areas as well, including environmental performance, energy efficiency, etc.

WORK BREAKDOWN STRUCTURE:
The Engineer's written plan for organizing, scheduling, and monitoring the progress of the design deliverables.

A.2 APPENDIX: TOP (TURNOVER PACKAGE), ENHANCED DOCUMENTATION

A.2.1 INTRODUCTION

This document contains the methodology and tools for developing and compiling the system- and non-system based files for the 3 stake-holder group Turnover Packages (Maintenance, Operations, and Archive). Turnover Packages will be developed for each system. These packages will contain design, procurement, fabrication, construction, commissioning, qualification and project documentation. Documentation from the Turnover Packages will be used to support commissioning and qualification activities. Following handover of the systems to manufacturing, turnover packages will provide a history of the system for ongoing maintenance, operations, and quality functions.

This procedure should be used for capital projects executed within GMP manufacturing sites.

A.2.2 PURPOSE

This guideline is established to provide a planned, organized and consistent approach to the development and compiling of turnover packages for capital projects executed in the GMP manufacturing sites. Turnover packages will be planned and compiled utilizing this procedure and the templates included with this procedure.

A.2.3 SCOPE

Turnover packages will be compiled to capture design, procurement, construction, commissioning (including inspection and testing, regulation, adjustment, and setting to work, and functional run testing) qualification, and overall project management documentation to support new and renovated pharmaceutical manufacturing operations within GMP regulated industries.

TOP Matrices are tools used to generate the master project document index, which indicate the content of the Turn-Over Packages. There are two TOP Matrices that need to be created:

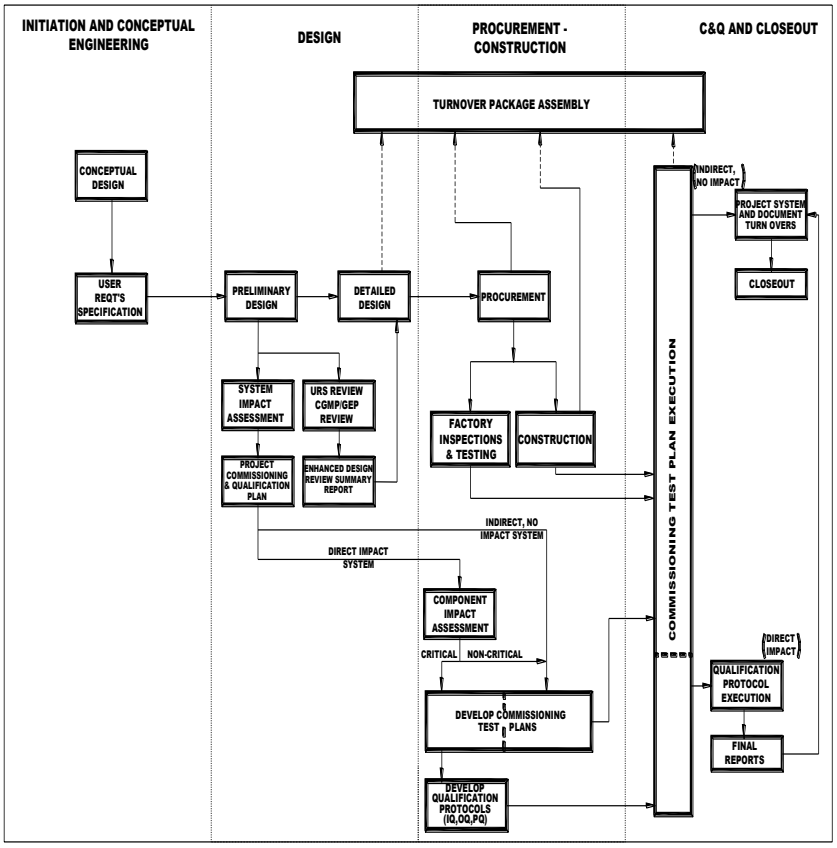
- Master TOP Matrix (Refer to the Appendix)
- Final TOP Matrix (Refer to the Appendix)

The scope of this procedure includes the necessary templates, instructions, and other information

to allow project teams to develop the Master TOP Matrix, Final TOP Matrix, and Turn Over Packages.

A.2.4 GMP PROJECT FRAME-WORK

The typical GMP Project follows the following Frame-Work;



A.2.5 DEFINITIONS & ABBREVIATIONS

For a full listing and terms, definitions, and acronyms, refer to the nomenclature section of this document.

A.2.6 RESPONSIBILITIES

The Project Manager is responsible for ensuring that the TOP Matrices are developed and associated TOPs are compiled. The project team will tailor the pre-formatted Master TOP Matrix template for the project to communicate the documentation requirements to vendors, A/E firms, construction management, and contractors for proper and timely delivery to the project.

Generally, the A/E or CM will be responsible for completing the Final Turnover Package Matrix and compiling the TOP files. This decision will be made by the Project Manager and communicated to the project team.

Additionally, the Master TOP Matrix, Final TOP Matrix, Turn-Over Packages (including Non System Based files and System Based files) will be reviewed by the project team to ensure that appropriate documentation is indicated and that the packages are complete. Recommended participants may include:

- Manufacturing Representative
- Project Team Representative
- Technical Experts (design, operation, automation, etc.)
- Quality Assurance/Validation Representative (for direct impact systems)

A.2.7 PROCEDURE FOR DEVELOPING THE MASTER TURNOVER PACKAGE MATRIX

The Master TOP matrix contains a listing of required project documents. This matrix will be completed during the project preliminary design phase and attached to the Project Commissioning and Qualification Plan (PCQP).

The Master TOP Matrix will identify:

- The major documents to be generated during the project and the party responsible for generation
- The documents to be included in the “Non-System Based files” (described below)

- The documents to be included in the "System Based files" (described below)
- Identification of the contents of the three (3) TOPS (Maintenance, Operations, Archive).

The following sections describe the content and required input data to be used for generating the Master TOP using excel template form.

A.2.7.1 Master TOP Matrix Header

Indicate the Project Title, CPA Number, Master TOP Matrix Revision, and Date in the header of the excel template.

A.2.7.2 Non System Based Documents File

Turnover Packages will be compiled for every system identified in the PCQP. However, certain documents will be more project based than system based (for example the design basis, URS, General Arrangements, Line Lists, Tie In Lists, etc.). Items such as these will be compiled into the "Non System Based" documents file.

The attached Master TOP Matrix indicates the typical documentation included in the Non System Based TOP.

A.2.7.3 System Based Documents File

Enter the system name and number in the third row of the TOP Matrix (these are listed as system #1 through system #3, n based on the number of system on the attached Master Turnover Package Matrix template).

Examples of documents filed on a system basis include: P&ID's, owner manuals, commissioning test plans/reports, Qualification Protocols, etc.

A.2.7.4 System Impact Classification

Enter the System Impact classification in the second row of the matrix. (Refer to the Impact Assessment).

Each System will be classified as:

- DI- Direct Impact
- II- Indirect Impact

- NI- No Impact

Only direct impact systems will require "enhanced documentation" to support qualification activities.

A.2.7.5 The Three (3) Turn Over Packages

Three TOP's are indicated in the Master TOP Matrix:

- Maintenance TOP
- Operations TOP
- Archive TOP

Indicate the documents to be included in each of the three TOP's with a Y (Yes) or N (No) on the matrix spreadsheet. Note that all original documents should be included in the "Archive TOP." Typically, the Maintenance and Operations TOP's would include copies.

The attached Master Turnover Package Matrix template indicates the typical documents to be included in each of the 3 TOPs. This should be reviewed/updated based on individual project requirements.

A.2.7.6 Project Phase/Discipline/File Number/Document Type

The Master TOP Matrix indicates the documents required through each project phase in the first column of the Matrix. The project phases include:

- Design- The A/E is generally responsible for delivering these documents. These would include final design documents and as built drawings (P&IDs, Flow Diagrams, Loop Diagrams, Undergrounds, Fire Protection, etc.). Typically, critical documents are updated to as-built status by the A/E, whereas non-critical documents may be archived in red-line status. For the interim period between turn-over to manufacturing and the completion of CAD as-built documents, red-lined documents are acceptable for inclusion in the TOP files.

- Procurement (PO/Requisition Based Files): The A/E, PM, and/or CM are generally responsible for delivering these documents, depending on procurement responsibility. These would include final vendor documents, bid analyses, purchase orders, and "as built" vendor drawings, as-purchased specifications, etc. as indicated in the attached template.

- Construction (PO/Contract Based Files): The CM is responsible for delivering these documents. These include submittals, construction contracts, etc.

- Commissioning: These files will consist primarily of Commissioning Test Plans and reports. The data which is used for records-review based check-sheets will typically reside in another of the files (such as Construction or Procurement). The majority of these items will be generally be delivered by the Commissioning & Qualification (C&Q) Team and CM.

- Qualification: This includes documentation required to support qualification activities, as well as qualification documents. Enhanced documentation items specifically apply to direct impact systems. These typically include protocols and other qualification documents as defined in Project Commissioning and Qualification Guideline. These items are indicated with an asterisk (*) in the TOP Matrix. These items will generally be turned over by the C&Q Team or contracted C&Q support firm.

- Project Management: These include general, non-system specific, project documents.

Listed next to each project phase is the discipline responsible for generation of the document, file number (to be used for the index in the compiled TOPs) and Document Type.

These four columns are preformatted and do not require modification. Depending on the size and complexity of the project, the listed documents may or may not be required.

The Master TOP matrix template also gives guidance as to the party responsible for delivering the indicated documents for each TOP. This will vary based on the specific project scope and responsibilities.

A.2.7.7 Approval of the Master TOP Matrix

This Master TOP Matrix will be completed during the project preliminary design phase and attached to the Project Commissioning and Qualification Plan (PCQP). By approving the PCQP, the Master Turnover Package Matrix is also approved.

A.2.8 PROCEDURE FOR DEVELOPING THE FINAL TOP MATRIX AND COMPILING THE TOPS

The Final TOP Matrix contains a detailed listing of the required project documents, and the method for recording the location/revision of the documents. The Final TOP will be created during the detailed design phase.

The following sections describe the content and required input data to be used for generating the Final TOP Matrix using the attached excel template form, and compiling the individual TOPs.

A.2.8.1 Final TOP Matrix Header*:*

Indicate the Project Title, CPA Number, Final TOP Matrix Revision, and Date in the header of the template.

A.2.8.2 Completing the Final TOP Matrix*:*

The Final TOP Matrix is the same as the Master Turnover Package Matrix, with the addition of eight (8) columns:

- Document Number
- Revision Number
- Revision Status
- Quality Critical Component ID Number
- Required Document (Yes/No)
- In File (Yes/No)
- Initial (of the person verifying the documents)
- Date

As the turnover packages are compiled, these additional columns will be filled out by the party responsible for compiling and or reviewing/accepting the TOPs. This will generally be the A/E or CM, depending on the size of the project.

Definitions of above terms:

- Quality Critical Component ID Number: Of the total documents in a project file, only a sub-set actually are associated with Critical Components within Direct Impact Systems. Identification of these documents is a priority from a QA/Validation perspective. Therefore, in order to identify which documents

within the TOP's are associated with Critical Components, this field is used to record the tag# of any critical component associated with each document, thereby identifying all such documents.

- The remaining required data listed above should be self-explanatory.

A.2.8.3 Approval of TOP Files

A System Level Commissioning Plan will be developed and executed for each system. A review and verification that the required documents are present in each of the three (3) turnover packages (maintenance, operations, and archive) is included in the system level commissioning plan. By approving the executed system level commissioning plan, the TOP files are approved.

A.2.8.4 Approval of the Completed Final Turnover Package Matrix

Each page of the Completed Final TOP Matrix includes a signature /date line in the bottom footer. The matrix will be reviewed by the Project Manager or designee to ensure that required documents have been located and referenced.

The Completed Final TOP Matrix will reside with the Archive Non-System Specific TOP.

A.2.9 MASTER TURNOVER PACKAGE MATRIX

System Impact Classifications					N/A						
Project Phase	**Discipline**	**File Number**	**Document Type**	**Engineering Drawings (11x17 or larger)**	**Non-System Based Documents File**	**System #1 File**	**System #2 File**	**System #3 File**	**Maintenance TOP**	**Operations TOP**	**Archives TOP**
									Yes or No Required		
1.0 DESIGN	**1.1 Equipment**	**1.1.1**	Design Basis		**A/E**				**Y**	**Y**	**Y**
		1.1.2	Equipment Data Sheets		**A/E**				**Y**	**Y**	**Y**
		1.1.3	Calculations		**A/E**				**N**	**N**	**Y**
		1.1.4	Filter List		**A/E**				**N**	**N**	**Y**
		1.1.5	Functional Requirements Specification		**A/E**				**N**	**Y**	**Y**
		1.1.6	Equipment List		**A/E**				**N**	**N**	**Y**

	1.2 Process	**1.2.1**	Process & Utility Flow Diagrams	4		**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		1.2.2	Piping & Instrumentation Diagrams (P&ID's)*	4		**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		1.2.3	Design Basis		**A/E**				**Y**	**Y**	**Y**
		1.2.4	Process Calculations		**A/E**				**N**	**N**	**Y**
		1.2.5	Material & Energy Balances		**A/E**				**N**	**N**	**Y**
		1.2.6	Process Data Sheets			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		1.2.7	Utility Summary Report		**A/E**				**N**	**N**	**Y**
		1.2.8	Pressure Safety & Control Valve Data Sheets			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
	1.3 Piping & Layout	**1.3.1**	Piping Material Specifications*		**A/E**				**N**	**N**	**Y**
		1.3.2	Line List		**A/E**				**N**	**N**	**Y**
		1.3.3	Piping Plans		**A/E**				**N**	**N**	**Y**
		1.3.4	Tie-In List		**A/E**				**N**	**N**	**Y**
		1.3.5	General Arrangement Drawings		**A/E**				**N**	**N**	**Y**
		1.3.6	Isometric Drawings with Material Listing	4		**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		1.3.7	Pipe Support Drawings and Details	4	**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.3 Piping & Layout**	**1.3.8**	Stress Calculations		**A/E**				**N**	**N**	**Y**
		1.3.9	Design Basis		**A/E**				**N**	**N**	**Y**
		1.3.10	Plot Plans	4	**A/E**				**N**	**N**	**Y**
		1.3.11	Material Take-Off List		**A/E**				**N**	**N**	**Y**

		1.3.12	Steam Tracing Schedules & Details		**A/E**				**N**	**N**	**Y**
	1.4 Electrical	**1.4.1**	Single-Line Diagrams*	4	**A/E**				**Y**	**Y**	**Y**
		1.4.2	Hazardous Area Classification Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.3	MCC Schedules	4	**A/E**				**Y**	**N**	**Y**
		1.4.4	Power and Grounding Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.5	Conduit and Cable Routing Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.6	Switch Room and Substation Layout Drawing	4	**A/E**				**N**	**N**	**Y**
		1.4.7	Cable Schedule		**A/E**				**N**	**N**	**Y**
		1.4.8	Lighting Calculations		**A/E**				**N**	**N**	**Y**
		1.4.9	Lighting & Small Power Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.10	Data Sheets For Electrical Equipment	4	**A/E**				**N**	**N**	**Y**
		1.4.11	Cable Location Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.12	MCC & Equipment Room General Arrangement Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.13	Motor Data Sheets	4	**A/E**				**N**	**N**	**Y**
		1.4.14	Electrical Schematic Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.15	Electrical Heat Tracing Schedules & Details		**A/E**				**N**	**N**	**Y**
		1.4.16	Distribution Board Schedules		**A/E**				**N**	**N**	**Y**

1.0 DESIGN	**1.4 Electrical**	**1.4.17**	Cathodic Protection Drawings	4	**A/E**				**N**	**N**	**Y**
		1.4.18	Material Take-Off List		**A/E**				**N**	**N**	**Y**
		1.4.19	Design Basis		**A/E**				**Y**	**N**	**Y**
	1.5 Instrument & Controls	**1.5.1**	Loop Diagrams*	4		**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		1.5.2	Instrument List		**A/E**				**Y**	**N**	**Y**
		1.5.3	Control/Relief Valve Calculations*		**A/E**				**N**	**N**	**Y**
		1.5.4	Instrument Data Sheets			**A/E**	**A/E**	**A/E**	**Y**	**N**	**Y**
		1.5.5	I/O Assignments		**IT**				**N**	**N**	**Y**
		1.5.6	Control Room/Equipment Room Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.5.7	DCS Specifications		**A/E**				**N**	**N**	**Y**
		1.5.8	Control System Architecture		**A/E**				**N**	**N**	**Y**
		1.5.9	Instrument Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.5.10	Control Panel Drawings	4	**A/E**				**N**	**N**	**Y**
		1.5.11	Tubing/Junction Box Schedules		**A/E**				**N**	**N**	**Y**
		1.5.12	Functional Requirements Specification		**A/E**				**N**	**N**	**Y**
		1.5.13	Instrument Utility Requirements Summary		**A/E**				**N**	**N**	**Y**
		1.5.14	Instrument Installation Drawings	4	**A/E**				**N**	**N**	**Y**

		1.5.15	Material Take-Off List		**A/E**				**N**	**N**	**Y**
		1.5.16	Design Basis		**A/E**				**Y**	**N**	**Y**
1.0 DESIGN	**1.6 HVAC**	**1.6.1**	HVAC Calculations		**A/E**				**N**	**N**	**Y**
		1.6.2	HVAC Area Schedule		**A/E**				**N**	**N**	**Y**
		1.6.3	HVAC Flow Diagrams*	4		**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		1.6.4	HVAC Equipment Room Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.6.5	HVAC Control Schedules & Specifications		**A/E**				**N**	**N**	**Y**
		1.6.6	HVAC Ducting & Equipment Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.6.7	HVAC Calculations		**A/E**				**N**	**N**	**Y**
		1.6.8	Data Sheets For HVAC Equipment		**A/E**				**Y**	**N**	**Y**
		1.6.9	Utility Requirements Summary		**A/E**				**N**	**N**	**Y**
		1.6.10	Material Take-Off List		**A/E**				**N**	**N**	**Y**
		1.6.11	Design Basis		**A/E**				**Y**	**N**	**Y**
	1.7 Civil/Structural	**1.7.1**	Soils Report		**A/E**				**N**	**N**	**Y**
		1.7.2	Topographical Report		**A/E**				**N**	**N**	**Y**
		1.7.3	Earthworks & Grading Drawings	4	**A/E**				**N**	**N**	**Y**
		1.7.4	Site Plan	4	**A/E**				**N**	**N**	**Y**
		1.7.5	Roads & Paving Drawings	4	**A/E**				**N**	**N**	**Y**

		1.7.6	Piling Layout Drawings & Pilecap Details	4	**A/E**				**N**	**N**	**Y**
		1.7.7	Underground Drawings	4	**A/E**				**N**	**N**	**Y**
		1.7.8	Foundation Loading Drawings	4	**A/E**				**N**	**N**	**Y**
		1.7.9	Foundation Drawings & Bar Bending Schedules	4	**A/E**				**N**	**N**	**Y**
		1.7.10	Above Ground Concrete Drawings & Bar Bending Schedules	4	**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.7 Civil/ Structural**	**1.7.11**	Structural Steel Arrangement Drawings	4	**A/E**				**N**	**N**	**Y**
		1.7.12	Structural Steel Fabrication Drawings	4	**A/E**				**N**	**N**	**Y**
		1.7.13	Material Take-Off List		**A/E**				**N**	**N**	**Y**
		1.7.14	Design Basis		**A/E**				**N**	**N**	**Y**
	1.8 Architectural	**1.8.1**	Architectural Specifications		**A/E**				**N**	**N**	**Y**
		1.8.2	Schedule of Room Finishes	4	**A/E**				**N**	**N**	**Y**
		1.8.3	Architectural Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.8.4	Architectural & Building Detail Drawings	4	**A/E**				**N**	**N**	**Y**
		1.8.5	Building Regulation Documentation		**A/E**				**N**	**Y**	**Y**
		1.8.6	Material-Take-Off List		**A/E**				**N**	**N**	**Y**
		1.8.7	Design Basis		**A/E**				**Y**	**Y**	**Y**

	1.9 Fire Protection	**1.9.1**	Fire Protection Calculations		**A/E**				**N**	**N**	**Y**
		1.9.2	Fire Protection Control Schedule & Specification		**A/E**				**N**	**N**	**Y**
		1.9.3	Data Sheets For Equipment		**A/E**				**Y**	**Y**	**Y**
		1.9.4	Fire Protection Layout Drawings	4	**A/E**				**N**	**N**	**Y**
		1.9.5	Fire Protection Detail Drawings*	4	**A/E**				**N**	**N**	**Y**
		1.9.6	Material Take-Off List		**A/E**				**N**	**N**	**Y**
		1.9.7	Design Basis		**A/E**				**Y**	**Y**	**Y**
2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.1 Equipment**	**2.1.1**	Material Requisitions			**A/E**	**A/E**	**A/E**	**Y**	**N**	**Y**
		2.1.2	Bid Analysis			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.1.3	Request For Purchase/Purchase Orders			**PM**	**PM**	**PM**	**N**	**N**	**Y**
		2.1.4	Vendor Submittals / Drawings	4		**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.1.5	Welder Certification Records			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.1.6	Receipt Inspection Forms			**CM**	**CM**	**CM**	**N**	**N**	**Y**
		2.1.7	Recommended Spare Parts List			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.1.8	Recommended Lubrication List			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.1.9	O&M Manuals			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.2.1	Material Requisitions		**A/E**				**N**	**N**	**Y**

	2.2 Piping & Layout	**2.2.2**	Bid Analysis		**A/E**				**N**	**N**	**Y**
		2.2.3	Request For Purchase/Purchase Orders		**PM**				**N**	**N**	**Y**
		2.2.4	Vendor Submittals / Drawings	4	**A/E**				**N**	**N**	**Y**
		2.2.5	Receipt Inspection Forms		**CM**				**N**	**N**	**Y**
	2.3 Electrical	**2.3.1**	Material Requisitions		**A/E**				**N**	**N**	**Y**
		2.3.2	Bid Analysis		**A/E**				**N**	**N**	**Y**
		2.3.3	Request For Purchase/Purchase Orders		**PM**				**N**	**N**	**Y**
		2.3.4	Vendor Submittals / Drawings	4	**A/E**				**N**	**N**	**Y**
		2.3.5	Receipt Inspection Forms		**CM**				**N**	**N**	**Y**
2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.4 Instrument & Controls**	**2.4.1**	Material Requisitions			**A/E**	**A/E**	**A/E**	**Y**	**N**	**Y**
		2.4.2	Bid Analysis			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.4.3	Request For Purchase/Purchase Orders			**PM**	**PM**	**PM**	**N**	**N**	**Y**
		2.4.4	Vendor Submittals / Drawings	4		**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.4.5	O&M Manuals			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.4.6	Recommended Spare Parts List			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.4.7	Receipt Inspection Forms			**CM**	**CM**	**CM**	**N**	**N**	**Y**
	2.5 HVAC	**2.5.1**	Material Requisitions			**A/E**	**A/E**	**A/E**	**Y**	**N**	**Y**
		2.5.2	Bid Analysis			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.5.3	Request For Purchase / Purchase Orders			**PM**	**PM**	**PM**	**N**	**N**	**Y**

		2.5.4	Vendor Submittals / Drawings	4		**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		2.5.5	O&M Manuals			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.5.6	Recommended Spare Parts List			**A/E**	**A/E**	**A/E**	**Y**	**Y**	**Y**
		2.5.7	Receipt Inspection Forms			**CM**	**CM**	**CM**	**N**	**N**	**Y**
	2.6 Civil/Structural	**2.6.1**	Material Requisitions	4	**A/E**				**N**	**N**	**Y**
		2.6.2	Bid Analysis		**A/E**				**N**	**N**	**Y**
		2.6.3	Request For Purchase/Purchase Orders		**PM**				**N**	**N**	**Y**
		2.6.4	Vendor Submittals / Drawings	4	**A/E**				**N**	**N**	**Y**
		2.6.5	Receipt Inspection Forms		**CM**				**N**	**N**	**Y**
2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.7 Architectural**	**2.7.1**	Material Requisitions		**A/E**				**N**	**N**	**Y**
		2.7.2	Bid Analysis		**A/E**				**N**	**N**	**Y**
		2.7.3	Request For Purchase/Purchase Orders		**PM**				**N**	**N**	**Y**
		2.7.4	Vendor Submittals	4	**A/E**				**N**	**N**	**Y**
		2.7.5	Receipt Inspection Forms		**CM**				**N**	**N**	**Y**
	2.8 Fire Protect-ion	**2.8.1**	Material Requisitions		**A/E**				**Y**	**N**	**Y**
		2.8.2	Bid Analysis		**A/E**				**N**	**N**	**Y**

		2.8.3	Request For Purchase/Purchase Orders		**PM**				**N**	**N**	**Y**
		2.8.4	Vendor Submittals / Drawings	4	**A/E**				**N**	**N**	**Y**
		2.8.5	Receipt Inspection Forms		**CM**				**N**	**N**	**Y**
3.0 CONSTRUCTION (PO/CONTRACT-BASED FILE)	**3.1 Equipment Installation**	**3.1.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.1.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.1.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.1.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.1.5	Submittals		**CM**				**N**	**N**	**Y**
	3.2 Piping Installation	**3.2.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.2.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.2.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.2.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.2.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**
		3.2.6	Welder Certification Records		**CM**				**N**	**N**	**Y**
3.0 CONSTRUCTION (PO/CONTRACT-ION BASED FILE)	**3.3 Electrical Installation**	**3.3.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.3.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.3.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.3.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.3.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**

	3.4 Instrument & Controls Installation	**3.4.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.4.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.4.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.4.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.4.5	Submittals		**CM**				**N**	**N**	**Y**
	3.5 HVAC Installation	**3.5.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.5.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.5.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.5.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.5.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**
	3.6 Civil/Structural Installation	**3.6.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.6.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.6.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.6.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.6.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**

3.0 CONSTRUCTION (PO/CONTRACT-BASED FILE)	**3.7 Architectural Installation**	**3.7.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.7.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.7.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.7.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.7.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**
	3.8 Fire Protection Installation	**3.8.1**	Scope of Work Documents		**CM**				**N**	**N**	**Y**
		3.8.2	Bid Analysis		**CM**				**N**	**N**	**Y**
		3.8.3	Request For Purchase/Purchase Orders		**CM**				**N**	**N**	**Y**
		3.8.4	Construction Contracts		**CM**				**N**	**N**	**Y**
		3.8.5	Submittals / Drawings	4	**CM**				**N**	**N**	**Y**
4.0 COMMISSIONING	**4.1 General**	**4.1.1**	Commissioning Plans with Check-Sheets (CP-1000)			**CM**	**CM**	**CM**	**N**	**N**	**Y**
5.0 QUALIFIC-ATION	**5.1 General**	**5.1.1**	User Requirement Specifications / URS Review			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		5.1.2	Project Commissioning & Qualification Plan*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**

		5.1.3	GEP/GMP Checklist Review			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		5.1.4	Enhanced Design Review Summary Report			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
5.0 QUALIF-ICATION	**5.1 General**	**5.1.5**	System Level Impact Assessment*			**A/E**	**A/E**	**A/E**	**N**	**N**	**Y**
		5.1.6	Component Level Impact Assessment*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
		5.1.7	Installation Qualification Protocols*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
		5.1.8	Operational Qualification Protocols*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
		5.1.9	Performance Qualification Protocols*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
		5.1.10	Training Records/Plans For Qualification Activities			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
		5.1.11	Final Qualification Summary Reports*			**A/E**	**A/E**	**A/E**	**N**	**Y**	**Y**
6.0 PROJECT MANAGEMENT	**6.1 General**	**6.1.1**	CPA		**PM**				**N**	**N**	**Y**
		6.1.2	Schedules		**PM**				**N**	**N**	**Y**
		6.1.3	Cost Reports		**PM**				**N**	**N**	**Y**
		6.1.4	Conceptual Design Reports		**PM**				**N**	**Y**	**Y**
		6.1.5	Preliminary Design Reports		**PM**				**N**	**Y**	**Y**
		6.1.6	Service Contracts, PO Records		**PM**				**N**	**N**	**Y**
		6.1.7	Correspondence		**PM**				**N**	**N**	**Y**
		6.1.8	HAZOP Reports*		**PM**				**N**	**Y**	**Y**

A.2.10 FINAL TURNOVER PACKAGE MATRIX

												System Impact Classifications							
													N/A						
Project Phase	**Discipline**	**File Number**	**Document Type**	**Document Number**	**Revision Number**	**Revision Status**	**Quality Critical Component ID Number**	**Required**	**In File?**	**Initial**	**Date**	**Engineering Drawings (11x17 or larger)	**Non-System Based Documents File**	**System #1 File**	**System #2 File**	**System #3 File**	**Maintenance TOP**	**Operations TOP**	**Archives TOP**
								Yes or No	**Yes or No**								**Yes or No Required**		
1.0 DESIGN	**1.1 Equipment**	**1.1.1**	**Design Basis**																
			1.1.1.1										**A/E**				**Y**	**Y**	**Y**
			1.1.1.2										**A/E**				**Y**	**Y**	**Y**
		1.1.2	**Equipment Data Sheets**																
			1.1.2.1										**A/E**				**Y**	**Y**	**Y**
			1.1.2.2										**A/E**				**Y**	**Y**	**Y**
		1.1.3	**Calculations**																

			1.1.3.1										A/E				N	N	Y
			1.1.3.2										A/E				N	N	Y
		1.1.4	**Filter List**																
			1.1.4.1										A/E				N	N	Y
			1.1.4.2										A/E				N	N	Y
		1.1.5	**Functional Requirements Specification**																
			1.1.5.1										A/E				N	Y	Y
			1.1.5.2										A/E				N	Y	Y
		1.1.6	**Equipment List**																
			1.1.6.1										A/E				N	N	Y
			1.1.6.2										A/E				N	N	Y
	1.2 Process	**1.2.1**	**Process & Utility Flow Diagrams**																
			1.2.1.1									4		A/E			Y	Y	Y
			1.2.1.2									4			A/E		Y	Y	Y
		1.2.2	**Piping & Instrumentation Diagrams (P&ID's)***																
			1.2.2.1											A/E			Y	Y	Y
			1.2.2.2												A/E		Y	Y	Y

		1.2.3	**Design Basis**																	
			1.2.3.1										**A/E**				**Y**	**Y**	**Y**
			1.2.3.2										**A/E**				**Y**	**Y**	**Y**
		1.2.4	**Process Calculations**																	
			1.2.4.1										**A/E**				**N**	**N**	**Y**
			1.2.4.2										**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.2 Process**	**1.2.5**	**Material & Energy Balances**																	
			1.2.5.1										**A/E**				**N**	**N**	**Y**
			1.2.5.2										**A/E**				**N**	**N**	**Y**
		1.2.6	**Process Data Sheets**																	
			1.2.6.1											**A/E**			**Y**	**Y**	**Y**
			1.2.6.2												**A/E**		**Y**	**Y**	**Y**
		1.2.7	**Utility Summary Report**																	
			1.2.7.1										**A/E**				**N**	**N**	**Y**
			1.2.7.2										**A/E**				**N**	**N**	**Y**
		1.2.8	**Pressure Safety & Control Valve Data Sheets**																	
			1.2.8.1											**A/E**			**N**	**Y**	**Y**
			1.2.8.2												**A/E**		**N**	**Y**	**Y**

	1.3 Piping & Layout	**1.3.1**	**Piping Material Specifications***																	
			1.3.1.1										**A/E**				**N**	**N**	**Y**
			1.3.1.2										**A/E**				**N**	**N**	**Y**
		1.3.2	**Line List**																	
			1.3.2.1										**A/E**				**N**	**N**	**Y**
			1.3.2.2										**A/E**				**N**	**N**	**Y**
		1.3.3	**Piping Plans**																	
			1.3.3.1										**A/E**				**N**	**N**	**Y**
			1.3.3.2										**A/E**				**N**	**N**	**Y**
		1.3.4	**Tie-In List**																	
			1.3.4.1										**A/E**				**N**	**N**	**Y**
			1.3.4.2										**A/E**				**N**	**N**	**Y**
		1.3.5	**General Arrangement Drawings**																	
			1.3.5.1										**A/E**				**N**	**N**	**Y**
			1.3.5.2										**A/E**				**N**	**N**	**Y**
		1.3.6	**Isometric Drawings with Material Listing**																	
			1.3.6.1									4	**A/E**				**N**	**N**	**Y**
			1.3.6.2									4	**A/E**				**N**	**N**	**Y**

1.0 DESIGN	**1.3 Piping & Layout**	**1.3.7**	**Pipe Support Drawings and Details**																	
			1.3.7.1									4	**A/E**				**N**	**N**	**Y**
			1.3.7.2									4	**A/E**				**N**	**N**	**Y**
		1.3.8	**Stress Calculations**																	
			1.3.8.1										**A/E**				**N**	**N**	**Y**
			1.3.8.2										**A/E**				**N**	**N**	**Y**
		1.3.9	**Design Basis**																	
			1.3.9.1										**A/E**				**N**	**N**	**Y**
			1.3.9.2										**A/E**				**N**	**N**	**Y**
		1.3.10	**Plot Plans**																	
			1.3.10.1									4	**A/E**				**N**	**N**	**Y**
			1.3.10.2									4	**A/E**				**N**	**N**	**Y**
		1.3.11	**Material Take-Off List**																	
			1.3.11.1										**A/E**				**N**	**N**	**Y**
			1.3.11.2										**A/E**				**N**	**N**	**Y**
		1.3.12	**Steam Tracing Schedules & Details**																	
			1.3.12.1										**A/E**				**N**	**N**	**Y**
			1.3.12.2										**A/E**				**N**	**N**	**Y**

	1.4 Electrical	**1.4.1**	**Single-Line Diagrams***																	
			1.4.1.1									4	**A/E**				**Y**	**Y**	**Y**
			1.4.1.2									4	**A/E**				**Y**	**Y**	**Y**
		1.4.2	**Hazardous Area Classification Drawings**																	
			1.4.2.1									4	**A/E**				**N**	**N**	**Y**
			1.4.2.2									4	**A/E**				**N**	**N**	**Y**
		1.4.3	**MCC Schedules**																	
			1.4.3.1									4	**A/E**				**Y**	**N**	**Y**
			1.4.3.2									4	**A/E**				**Y**	**N**	**Y**
		1.4.4	**Power and Grounding Drawings**																	
			1.4.4.1									4	**A/E**				**N**	**N**	**Y**
			1.4.4.2									4	**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.4 Electrical**	**1.4.5**	**Conduit and Cable Routing Drawings**																	
			1.4.5.1									4	**A/E**				**N**	**N**	**Y**
			1.4.5.2									4	**A/E**				**N**	**N**	**Y**
		1.4.6	**Switch Room and Substation Layout Drawing**																	
			1.4.6.1									4	**A/E**				**N**	**N**	**Y**

			1.4.6.2									4	A/E				N	N	Y
		1.4.7	**Cable Schedule**																
			1.4.7.1										A/E				N	N	Y
			1.4.7.2										A/E				N	N	Y
		1.4.8	**Lighting Calculations**																
			1.4.8.1										A/E				N	N	Y
			1.4.8.2										A/E				N	N	Y
		1.4.9	**Lighting & Small Power Drawings**																
			1.4.9.1									4	A/E				N	N	Y
			1.4.9.2									4	A/E				N	N	Y
		1.4.10	**Data Sheets For Electrical Equipment**																
			1.4.10.1									4	A/E				N	N	Y
			1.4.10.2									4	A/E				N	N	Y
		1.4.11	**Cable Location Drawings**																
			1.4.11.1									4	A/E				N	N	Y
			1.4.11.2									4	A/E				N	N	Y
		1.4.12	**MCC & Equipment Room General**																

			Arrangement Drawings																	
			1.4.12.1								4	**A/E**				**N**	**N**	**Y**
			1.4.12.2								4	**A/E**				**N**	**N**	**Y**
		1.4.13	**Motor Data Sheets**																	
			1.4.13.1								4	**A/E**				**N**	**N**	**Y**
			1.4.13.2								4	**A/E**				**N**	**N**	**Y**
		1.4.14	**Electrical Schematic Drawings**																	
			1.4.14.1								4	**A/E**				**N**	**N**	**Y**
			1.4.14.2								4	**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.4 Electrical**	**1.4.15**	**Electrical Heat Tracing Schedules & Details**																	
			1.4.15.1									**A/E**				**N**	**N**	**Y**
			1.4.15.2									**A/E**				**N**	**N**	**Y**
		1.4.16	**Distribution Board Schedules**																	
			1.4.16.1									**A/E**				**N**	**N**	**Y**
			1.4.16.2									**A/E**				**N**	**N**	**Y**
		1.4.17	**Cathodic Protection Drawings**																	

			1.4.17.1									4	A/E				N	N	Y
			1.4.17.2									4	A/E				N	N	Y
		1.4.18	**Material Take-Off List**																
			1.4.18.1										A/E				N	N	Y
			1.4.18.2										A/E				N	N	Y
		1.4.19	**Design Basis**																
			1.4.19.1										A/E				Y	N	Y
			1.4.19.2										A/E				Y	N	Y
	1.5 Instrument & Controls	**1.5.1**	**Loop Diagrams***																
			1.5.1.1									4		A/E			Y	Y	Y
			1.5.1.2									4			A/E		Y	Y	Y
		1.5.2	**Instrument List**																
			1.5.2.1										A/E				Y	N	Y
			1.5.2.2										A/E				Y	N	Y
		1.5.3	**Control/Relief Valve Calculations***																
			1.5.3.1										A/E				N	N	Y
			1.5.3.2										A/E				N	N	Y

		1.5.4	**Instrument Data Sheets**																	
			1.5.4.1											**A/E**			**Y**	**N**	**Y**
			1.5.4.2												**A/E**		**Y**	**N**	**Y**
1.0 DESIGN	**1.5 Instrument & Controls**	**1.5.5**	**I/O Assignments**																	
			1.5.5.1									**IT**					**N**	**N**	**Y**
			1.5.5.2									**IT**					**N**	**N**	**Y**
1.0 DESIGN		**1.5.6**	**Control Room/Equipment Room Layout Drawings**																	
			1.5.6.1								4	**A/E**					**N**	**N**	**Y**
			1.5.6.2								4	**A/E**					**N**	**N**	**Y**
		1.5.7	**DCS Specifications**																	
			1.5.7.1									**A/E**					**N**	**N**	**Y**
			1.5.7.2									**A/E**					**N**	**N**	**Y**
		1.5.8	**Control System Architecture**																	
			1.5.8.1									**A/E**					**N**	**N**	**Y**
			1.5.8.2									**A/E**					**N**	**N**	**Y**

		1.5.9	**Instrument Layout Drawings**																	
			1.5.9.1									4	**A/E**				**N**	**N**	**Y**
			1.5.9.2									4	**A/E**				**N**	**N**	**Y**
		1.5.10	**Control Panel Drawings**																	
			1.5.10.1									4	**A/E**				**N**	**N**	**Y**
			1.5.10.2									4	**A/E**				**N**	**N**	**Y**
		1.5.11	**Tubing/Junction Box Schedules**																	
			1.5.11.1										**A/E**				**N**	**N**	**Y**
			1.5.11.2										**A/E**				**N**	**N**	**Y**
		1.5.12	**Functional Requirements Specification**																	
			1.5.12.1										**A/E**				**N**	**N**	**Y**
			1.5.12.2										**A/E**				**N**	**N**	**Y**
		1.5.13	**Instrument Utility Requirements Summary**																	
			1.5.13.1										**A/E**				**N**	**N**	**Y**
			1.5.13.2										**A/E**				**N**	**N**	**Y**

1.0 DESIGN	**1.5 Instrument & Controls**	**1.5.14**	**Instrument Installation Drawings**																	
			1.5.14.1									4	**A/E**				**N**	**N**	**Y**
			1.5.14.2									4	**A/E**				**N**	**N**	**Y**
		1.5.15	**Material Take-Off List**																	
			1.5.15.1										**A/E**				**N**	**N**	**Y**
			1.5.15.2										**A/E**				**N**	**N**	**Y**
		1.5.16	**Design Basis**																	
			1.5.16.1										**A/E**				**Y**	**N**	**Y**
			1.5.16.2										**A/E**				**Y**	**N**	**Y**
	1.6 HVAC	**1.6.1**	**HVAC Calculations**																	
			1.6.1.1										**A/E**				**N**	**N**	**Y**
			1.6.1.2										**A/E**				**N**	**N**	**Y**
		1.6.2	**HVAC Area Schedule**																	
			1.6.2.1										**A/E**				**N**	**N**	**Y**
			1.6.2.2										**A/E**				**N**	**N**	**Y**
		1.6.3	**HVAC Flow Diagrams***																	
			1.6.3.1									4		**A/E**			**Y**	**Y**	**Y**
			1.6.3.2									4			**A/E**		**Y**	**Y**	**Y**

		1.6.4	**HVAC Equipment Room Layout Drawings**																	
			1.6.4.1									4	**A/E**				**N**	**N**	**Y**
			1.6.4.2									4	**A/E**				**N**	**N**	**Y**
		1.6.5	**HVAC Control Schedules & Specifications**																	
			1.6.5.1										**A/E**				**N**	**N**	**Y**
			1.6.5.2										**A/E**				**N**	**N**	**Y**
		1.6.6	**HVAC Ducting & Equipment Layout Drawings**																	
			1.6.6.1									4	**A/E**				**N**	**N**	**Y**
			1.6.6.2									4	**A/E**				**N**	**N**	**Y**
		1.6.7	**HVAC Calculations**																	
			1.6.7.1										**A/E**				**N**	**N**	**Y**
			1.6.7.2										**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.6 HVAC**	**1.6.8**	**Data Sheets For HVAC Equipment**																	
			1.6.8.1										**A/E**				**Y**	**N**	**Y**
			1.6.8.2										**A/E**				**Y**	**N**	**Y**

		1.6.9	**Utility Requirements Summary**																	
			1.6.9.1										**A/E**				**N**	**N**	**Y**
			1.6.9.2										**A/E**				**N**	**N**	**Y**
		1.6.10	**Material Take-Off List**																	
			1.6.10.1										**A/E**				**N**	**N**	**Y**
			1.6.10.2										**A/E**				**N**	**N**	**Y**
		1.6.11	**Design Basis**																	
			1.6.11.1										**A/E**				**Y**	**N**	**Y**
			1.6.11.2										**A/E**				**Y**	**N**	**Y**
	1.7 Civil/Structural	**1.7.1**	**Soils Report**																	
			1.7.1.1										**A/E**				**N**	**N**	**Y**
			1.7.1.2										**A/E**				**N**	**N**	**Y**
		1.7.2	**Topographical Report**																	
			1.7.2.1										**A/E**				**N**	**N**	**Y**
			1.7.2.2										**A/E**				**N**	**N**	**Y**
		1.7.3	**Earthworks & Grading Drawings**																	
			1.7.3.1									4	**A/E**				**N**	**N**	**Y**
			1.7.3.2									4	**A/E**				**N**	**N**	**Y**

		1.7.4	**Site Plan**																
			1.7.4.1									4	**A/E**				**N**	**N**	**Y**
			1.7.4.2									4	**A/E**				**N**	**N**	**Y**
		1.7.5	**Roads & Paving Drawings**																
			1.7.5.1									4	**A/E**				**N**	**N**	**Y**
			1.7.5.2									4	**A/E**				**N**	**N**	**Y**
		1.7.6	**Piling Layout Drawings & Pilecap Details**																
			1.7.6.1									4	**A/E**				**N**	**N**	**Y**
			1.7.6.2									4	**A/E**				**N**	**N**	**Y**
1.0 DESIGN	**1.7 Civil/ Structural**	**1.7.7**	**Underground Drawings**																
			1.7.7.1									4	**A/E**				**N**	**N**	**Y**
			1.7.7.2									4	**A/E**				**N**	**N**	**Y**
		1.7.8	**Foundation Loading Drawings**																
			1.7.8.1									4	**A/E**				**N**	**N**	**Y**
			1.7.8.2									4	**A/E**				**N**	**N**	**Y**
		1.7.9	**Foundation Drawings & Bar Bending Schedules**																
			1.7.9.1									4	**A/E**				**N**	**N**	**Y**

			1.7.9.2									4	**A/E**				**N**	**N**	**Y**
		1.7.10	**Above Ground Concrete Drawings & Bar Bending Schedules**																
			1.7.10.1									4	**A/E**				**N**	**N**	**Y**
			1.7.10.2									4	**A/E**				**N**	**N**	**Y**
		1.7.11	**Structural Steel Arrangement Drawings**																
			1.7.11.1									4	**A/E**				**N**	**N**	**Y**
			1.7.11.2									4	**A/E**				**N**	**N**	**Y**
		1.7.12	**Structural Steel Fabrication Drawings**																
			1.7.12.1									4	**A/E**				**N**	**N**	**Y**
			1.7.12.2									4	**A/E**				**N**	**N**	**Y**
		1.7.13	**Material Take-Off List**																
			1.7.13.1										**A/E**				**N**	**N**	**Y**
			1.7.13.2										**A/E**				**N**	**N**	**Y**
		1.7.14	**Design Basis**																
			1.7.14.1										**A/E**				**N**	**N**	**Y**

			1.7.14.2										A/E				N	N	Y
	1.8 Architectural	1.8.1	**Architectural Specifications**																
			1.8.1.1										A/E				N	N	Y
			1.8.1.2										A/E				N	N	Y
1.0 DESIGN	1.8 Architectural	1.8.2	**Schedule of Room Finishes**																
			1.8.2.1									4	A/E				N	N	Y
			1.8.2.2									4	A/E				N	N	Y
		1.8.3	**Architectural Layout Drawings**																
			1.8.3.1									4	A/E				N	N	Y
			1.8.3.2									4	A/E				N	N	Y
		1.8.4	**Architectural & Building Detail Drawings**																
			1.8.4.1									4	A/E				N	N	Y
			1.8.4.2									4	A/E				N	N	Y

		1.8.5	**Building Regulation Documentation**																	
			1.8.5.1										**A/E**				**N**	**Y**	**Y**
			1.8.5.2										**A/E**				**N**	**Y**	**Y**
		1.8.6	**Material-Take-Off List**																	
			1.8.6.1										**A/E**				**N**	**N**	**Y**
			1.8.6.2										**A/E**				**N**	**N**	**Y**
		1.8.7	**Design Basis**																	
			1.8.7.1										**A/E**				**Y**	**Y**	**Y**
			1.8.7.2										**A/E**				**Y**	**Y**	**Y**
	1.9 Fire Protection	**1.9.1**	**Fire Protection Calculations**																	
			1.9.1.1										**A/E**				**N**	**N**	**Y**
			1.9.1.2										**A/E**				**N**	**N**	**Y**
		1.9.2	**Fire Protection Control Schedule & Specification**																	
			1.9.2.1										**A/E**				**N**	**N**	**Y**
			1.9.2.2										**A/E**				**N**	**N**	**Y**

1.0 DESIGN	**1.9 Fire Protection**	**1.9.3**	**Data Sheets For Equipment**																
			1.9.3.1										**A/E**				**Y**	**Y**	**Y**
			1.9.3.2										**A/E**				**Y**	**Y**	**Y**
		1.9.4	**Fire Protection Layout Drawings**																
			1.9.4.1									4	**A/E**				**N**	**N**	**Y**
			1.9.4.2									4	**A/E**				**N**	**N**	**Y**
		1.9.5	**Fire Protection Detail Drawings***																
			1.9.5.1									4	**A/E**				**N**	**N**	**Y**
			1.9.5.2									4	**A/E**				**N**	**N**	**Y**
		1.9.6	**Material Take-Off List**																
			1.9.6.1										**A/E**				**N**	**N**	**Y**
			1.9.6.2										**A/E**				**N**	**N**	**Y**
		1.9.7	**Design Basis**																
			1.9.7.1										**A/E**				**Y**	**Y**	**Y**
			1.9.7.2										**A/E**				**Y**	**Y**	**Y**

2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.1 Equipment**	**2.1.1**	**Material Requisitions**																			
			2.1.1.1													**A/E**			**Y**	**N**	**Y**
			2.1.1.2														**A/E**		**Y**	**N**	**Y**
		2.1.2	**Bid Analysis**																			
			2.1.2.1													**A/E**			**N**	**N**	**Y**
			2.1.2.2														**A/E**		**N**	**N**	**Y**
		2.1.3	**Request For Purchase/Purchase Orders**																			
			2.1.3.1													**PM**			**N**	**N**	**Y**
			2.1.3.2														**PM**		**N**	**N**	**Y**
		2.1.4	**Vendor Submittals**																			
			2.1.4.1											4		**A/E**			**N**	**N**	**Y**
			2.1.4.2											4			**A/E**		**N**	**N**	**Y**
2.0 PROCUREMENT (PO/REQUISITION-	**2.1 Equipment**	**2.1.5**	**Welder Certification Records**																			
			2.1.5.1													**A/E**			**N**	**N**	**Y**
			2.1.5.2														**A/E**		**N**	**N**	**Y**
		2.1.6	**Receipt Inspection Forms**																			

			2.1.6.1											CM			N	N	Y
			2.1.6.2												CM		N	N	Y
		2.1.7	**Recommended Spare Parts List**																
			2.1.7.1											A/E			Y	Y	Y
			2.1.7.2												A/E		Y	Y	Y
		2.1.8	**Recommended Lubrication List**																
			2.1.8.1											A/E			Y	Y	Y
			2.1.8.2												A/E		Y	Y	Y
		2.1.9	**O&M Manuals**																
			2.1.9.1											A/E			Y	Y	Y
			2.1.9.2												A/E		Y	Y	Y
	2.2 Piping & Layout	2.2.1	**Material Requisitions**																
			2.2.1.1										A/E				N	N	Y
			2.2.1.2										A/E				N	N	Y
		2.2.2	**Bid Analysis**																
			2.2.2.1										A/E				N	N	Y
			2.2.2.2										A/E				N	N	Y

		2.2.3	**Request For Purchase/Purchase Orders**																	
			2.2.3.1										**PM**				**N**	**N**	**Y**
			2.2.3.2										**PM**				**N**	**N**	**Y**
		2.2.4	**Vendor Submittals**																	
			2.2.4.1									4	**A/E**				**N**	**N**	**Y**
			2.2.4.2									4	**A/E**				**N**	**N**	**Y**
2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.2 Piping & Layout**	**2.2.5**	**Receipt Inspection Forms**																	
			2.2.5.1										**CM**				**N**	**N**	**Y**
			2.2.5.2										**CM**				**N**	**N**	**Y**
	2.3 Electrical	**2.3.1**	**Material Requisitions**																	
			2.3.1.1										**A/E**				**N**	**N**	**Y**
			2.3.1.2										**A/E**				**N**	**N**	**Y**
		2.3.2	**Bid Analysis**																	
			2.3.2.1										**A/E**				**N**	**N**	**Y**
			2.3.2.2										**A/E**				**N**	**N**	**Y**
		2.3.3	**Request For Purchase/Purchase Orders**																	
			2.3.3.1										**PM**				**N**	**N**	**Y**

			2.3.3.2										PM				N	N	Y
		2.3.4	**Vendor Submittals**																
			2.3.4.1									4	A/E				N	N	Y
			2.3.4.2									4	A/E				N	N	Y
		2.3.5	**Receipt Inspection Forms**																
			2.3.5.1										CM				N	N	Y
			2.3.5.2										CM				N	N	Y
	2.4 Instrument & Controls	**2.4.1**	**Material Requisitions**																
			2.4.1.1											A/E			Y	N	Y
			2.4.1.2												A/E		Y	N	Y
		2.4.2	**Bid Analysis**																
			2.4.2.1											A/E			N	N	Y
			2.4.2.2												A/E		N	N	Y
		2.4.3	**Request For Purchase/Purchase Orders**																
			2.4.3.1											PM			N	N	Y
			2.4.3.2												PM		N	N	Y
		2.4.4	**Vendor Submittals**																

			2.4.4.1											A/E			N	N	Y
			2.4.4.2												A/E		N	N	Y
2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	2.4 Instrument & Controls	2.4.5	O&M Manuals																
			2.4.5.1											A/E			Y	Y	Y
			2.4.5.2												A/E		Y	Y	Y
		2.4.6	Recommended Spare Parts List																
			2.4.6.1											A/E			Y	Y	Y
			2.4.6.2												A/E		Y	Y	Y
		2.4.7	Receipt Inspection Forms																
			2.4.7.1											CM			N	N	Y
			2.4.7.2												CM		N	N	Y
	2.5 HVAC	2.5.1	Material Requisitions																
			2.5.1.1											A/E			Y	N	Y
			2.5.1.2												A/E		Y	N	Y
		2.5.2	Bid Analysis																
			2.5.2.1											A/E			N	N	Y
			2.5.2.2												A/E		N	N	Y

		2.5.3	**Request For Purchase/Purchase Orders**																		
			2.5.3.1												**PM**				**N**	**N**	**Y**
			2.5.3.2													**PM**			**N**	**N**	**Y**
		2.5.4	**Vendor Submittals**																		
			2.5.4.1												**A/E**				**N**	**N**	**Y**
			2.5.4.2													**A/E**			**N**	**N**	**Y**
		2.5.5	**O&M Manuals**																		
			2.5.5.1												**A/E**				**Y**	**Y**	**Y**
			2.5.5.2													**A/E**			**Y**	**Y**	**Y**
		2.5.6	**Recommended Spare Parts List**																		
			2.5.6.1												**A/E**				**Y**	**Y**	**Y**
			2.5.6.2													**A/E**			**Y**	**Y**	**Y**

2.0 PROCUREMENT (PO/REQUISITION-BASED FILE)	**2.5 HVAC**	**2.5.7**	**Receipt Inspection Forms**																
			2.5.7.1											**CM**			**N**	**N**	**Y**
			2.5.7.2												**CM**		**N**	**N**	**Y**
	2.6 Civil/Structural	**2.6.1**	**Material Requisitions**																
			2.6.1.1										**A/E**				**N**	**N**	**Y**
			2.6.1.2										**A/E**				**N**	**N**	**Y**
		2.6.2	**Bid Analysis**																
			2.6.2.1										**A/E**				**N**	**N**	**Y**
			2.6.2.2										**A/E**				**N**	**N**	**Y**
		2.6.3	**Request For Purchase/Purchase Orders**																
			2.6.3.1										**PM**				**N**	**N**	**Y**
			2.6.3.2										**PM**				**N**	**N**	**Y**

	2.6 Civil/Structural	**2.6.4**	**Vendor Submittals**																	
			2.6.4.1										**A/E**				**N**	**N**	**Y**
			2.6.4.2										**A/E**				**N**	**N**	**Y**
		2.6.5	**Receipt Inspection Forms**																	
			2.6.5.1										**CM**				**N**	**N**	**Y**
			2.6.5.2										**CM**				**N**	**N**	**Y**
	2.7 Architectural	**2.7.1**	**Material Requisitions**																	
			2.7.1.1										**A/E**				**N**	**N**	**Y**
			2.7.1.2										**A/E**				**N**	**N**	**Y**
2.0 PROCUREMENT	**2.7 Architectural**	**2.7.2**	**Bid Analysis**																	
			2.7.2.1										**A/E**				**N**	**N**	**Y**
			2.7.2.2										**A/E**				**N**	**N**	**Y**

		2.7.3	**Request For Purchase/Purchase Orders**																	
			2.7.3.1										**PM**				**N**	**N**	**Y**
			2.7.3.2										**PM**				**N**	**N**	**Y**
		2.7.4	**Vendor Submittals**																	
			2.7.4.1									4	**A/E**				**N**	**N**	**Y**
			2.7.4.2									4	**A/E**				**N**	**N**	**Y**
		2.7.5	**Receipt Inspection Forms**																	
			2.7.5.1										**CM**				**N**	**N**	**Y**
			2.7.5.2										**CM**				**N**	**N**	**Y**
	2.8 Fire Protection	**2.8.1**	**Material Requisitions**																	
			2.8.1.1										**A/E**				**Y**	**N**	**Y**
			2.8.1.2										**A/E**				**Y**	**N**	**Y**
		2.8.2	**Bid Analysis**																	
			2.8.2.1										**A/E**				**N**	**N**	**Y**

			2.8.2.2										A/E				N	N	Y
		2.8.3	**Request For Purchase/Purchase Orders**																
			2.8.3.1										PM				N	N	Y
			2.8.3.2										PM				N	N	Y
		2.8.4	**Vendor Submittals**																
			2.8.4.1									4	A/E				N	N	Y
			2.8.4.2									4	A/E				N	N	Y
2.0 PROCUREMENT (PO/REQUISITION-BASED)	**2.8 Fire Protection**	**2.8.5**	**Receipt Inspection Forms**																
			2.8.5.1										CM				N	N	Y
			2.8.5.2										CM				N	N	Y
3.0 CONSTRUCTION (PO/CONTRACTION	**3.1 Equipment Installation**	**3.1.1**	**Scope of Work Documents**																
			3.1.1.1										CM				N	N	Y
			3.1.1.2										CM				N	N	Y
		3.1.2	**Bid Analysis**																

			3.1.2.1										**CM**				**N**	**N**	**Y**
			3.1.2.2										**CM**				**N**	**N**	**Y**
		3.1.3	**Request For Purchase/Purchase Orders**																
			3.1.3.1										**CM**				**N**	**N**	**Y**
			3.1.3.2										**CM**				**N**	**N**	**Y**
		3.1.4	**Construction Contracts**																
			3.1.4.1										**CM**				**N**	**N**	**Y**
			3.1.4.2										**CM**				**N**	**N**	**Y**
		3.1.5	**Submittals**																
			3.1.5.1										**CM**				**N**	**N**	**Y**
			3.1.5.2										**CM**				**N**	**N**	**Y**
	3.2 Piping Installation	**3.2.1**	**Scope of Work Documents**																
			3.2.1.1										**CM**				**N**	**N**	**Y**
			3.2.1.2										**CM**				**N**	**N**	**Y**
		3.2.2	**Bid Analysis**																
			3.2.2.1										**CM**				**N**	**N**	**Y**
			3.2.2.2										**CM**				**N**	**N**	**Y**

		3.2.3	**Request For Purchase/Purchase Orders**																	
			3.2.3.1										**CM**				**N**	**N**	**Y**
			3.2.3.2										**CM**				**N**	**N**	**Y**
3.0 CONSTRUCTION (PO/CONTRACT-BASED FILE)	**3.2 Piping Installation**	**3.2.4**	**Construction Contracts**																	
			3.2.4.1										**CM**				**N**	**N**	**Y**
			3.2.4.2										**CM**				**N**	**N**	**Y**
		3.2.5	**Submittals**																	
			3.2.5.1									4	**CM**				**N**	**N**	**Y**
			3.2.5.2									4	**CM**				**N**	**N**	**Y**
		3.2.6	**Welder Certification Records**																	
			3.2.6.1										**CM**				**N**	**N**	**Y**
			3.2.6.2										**CM**				**N**	**N**	**Y**
	3.3 Electrical Installation	**3.3.1**	**Scope of Work Documents**																	
			3.3.1.1										**CM**				**N**	**N**	**Y**
			3.3.1.2										**CM**				**N**	**N**	**Y**
		3.3.2	**Bid Analysis**																	
			3.3.2.1										**CM**				**N**	**N**	**Y**
			3.3.2.2										**CM**				**N**	**N**	**Y**

		3.3.3	**Request For Purchase/Purchase Orders**																	
			3.3.3.1										**CM**				**N**	**N**	**Y**
			3.3.3.2										**CM**				**N**	**N**	**Y**
		3.3.4	**Construction Contracts**																	
			3.3.4.1										**CM**				**N**	**N**	**Y**
			3.3.4.2										**CM**				**N**	**N**	**Y**
		3.3.5	**Submittals**																	
			3.3.5.1									4	**CM**				**N**	**N**	**Y**
			3.3.5.2									4	**CM**				**N**	**N**	**Y**
	3.4 Instrument & Controls	**3.4.1**	**Scope of Work Documents**																	
			3.4.1.1										**CM**				**N**	**N**	**Y**
			3.4.1.2										**CM**				**N**	**N**	**Y**
3.0 CONSTRUCTION (PO/CONTRACT-BASED	**3.4 Instrument & Controls Installation**	**3.4.2**	**Bid Analysis**																	
			3.4.2.1										**CM**				**N**	**N**	**Y**
			3.4.2.2										**CM**				**N**	**N**	**Y**
		3.4.3	**Request For Purchase/Purchase Orders**																	
			3.4.3.1										**CM**				**N**	**N**	**Y**

			3.4.3.2										CM				N	N	Y
		3.4.4	**Construction Contracts**																
			3.4.4.1										CM				N	N	Y
			3.4.4.2										CM				N	N	Y
		3.4.5	**Submittals**																
			3.4.5.1										CM				N	N	Y
			3.4.5.2										CM				N	N	Y
	3.5 HVAC Installation	**3.5.1**	**Scope of Work Documents**																
			3.5.1.1										CM				N	N	Y
			3.5.1.2										CM				N	N	Y
		3.5.2	**Bid Analysis**																
			3.5.2.1										CM				N	N	Y
			3.5.2.2										CM				N	N	Y
		3.5.3	**Request For Purchase/Purchase Orders**																
			3.5.3.1										CM				N	N	Y
			3.5.3.2										CM				N	N	Y
		3.5.4	**Construction Contracts**																
			3.5.4.1										CM				N	N	Y
			3.5.4.2										CM				N	N	Y

		3.5.5	**Submittals**															
			3.5.5.1									4	**CM**				**N**	**N**	**Y**
			3.5.5.2									4	**CM**				**N**	**N**	**Y**
3.0 CONSTRUCTION (PO/CONTRACT-BASED FILE)	**3.6 Civil/Structural Installation**	**3.6.1**	**Scope of Work Documents**															
			3.6.1.1										**CM**				**N**	**N**	**Y**
			3.6.1.2										**CM**				**N**	**N**	**Y**
		3.6.2	**Bid Analysis**															
			3.6.2.1										**CM**				**N**	**N**	**Y**
			3.6.2.2										**CM**				**N**	**N**	**Y**
		3.6.3	**Request For Purchase/Purchase Orders**															
			3.6.3.1										**CM**				**N**	**N**	**Y**
			3.6.3.2										**CM**				**N**	**N**	**Y**
		3.6.4	**Construction Contracts**															

			3.6.4.1										CM				N	N	Y
			3.6.4.2										CM				N	N	Y
		3.6.5	**Submittals**																
			3.6.5.1									4	CM				N	N	Y
			3.6.5.2									4	CM				N	N	Y
	3.7 Architectural Installation	3.7.1	**Scope of Work Documents**																
			3.7.1.1										CM				N	N	Y
			3.7.1.2										CM				N	N	Y
3.0 CONSTRUCTION (PO/CONTRACT-BASED FILE)	3.7 Architectural Installation	3.7.2	**Bid Analysis**																
			3.7.2.1										CM				N	N	Y
			3.7.2.2										CM				N	N	Y
		3.7.3	**Request For Purchase/Purchase Orders**																
			3.7.3.1										CM				N	N	Y
			3.7.3.2										CM				N	N	Y
		3.7.4	**Construction Contracts**																

			3.7.4.1										CM				N	N	Y
			3.7.4.2										CM				N	N	Y
		3.7.5	**Submittals**																
			3.7.5.1									4	CM				N	N	Y
			3.7.5.2									4	CM				N	N	Y
	3.8 Fire Protection Installation	**3.8.1**	**Scope of Work Documents**																
			3.8.1.1										CM				N	N	Y
			3.8.1.2										CM				N	N	Y
		3.8.2	**Bid Analysis**																
			3.8.2.1										CM				N	N	Y
			3.8.2.2										CM				N	N	Y
		3.8.3	**Request For Purchase/Purchase Orders**																
			3.8.3.1										CM				N	N	Y
			3.8.3.2										CM				N	N	Y
		3.8.4	**Construction Contracts**																
			3.8.4.1										CM				N	N	Y
			3.8.4.2										CM				N	N	Y

	3.8 Fire Protection Installation	**3.8.5**	**Submittals**																
			3.8.5.1									4	**CM**				**N**	**N**	**Y**
			3.8.5.2									4	**CM**				**N**	**N**	**Y**
4.0 COMMISSIONING	**4.1 General**	**4.1.1**	**Commissioning Check Sheets (CP-1000)**																
			4.1.1.1											**CM**			**N**	**N**	**Y**
			4.1.1.2												**CM**		**N**	**N**	**Y**
5.0 QUALIFICATION	**5.1 General**	**5.1.1**	**User Requirement Specifications**																
			8.1.1.1											**A/E**			**N**	**N**	**Y**
			8.1.1.2												**A/E**		**N**	**N**	**Y**
		5.1.2	**User Requirement Specifications Review**																
			8.1.2.1											**A/E**			**N**	**N**	**Y**

			8.1.2.2											A/E			N	N	Y
		5.1.3	**Project Commissioning & Qualification Plan***																
			8.1.3.1										A/E				N	Y	Y
			8.1.3.2											A/E			N	Y	Y
		5.1.4	**GEP/GMP Checklist Review**																
			8.1.4.1										A/E				N	N	Y
			8.1.4.2											A/E			N	N	Y
		5.1.5	**Enhanced Design Review Summary Report**																
			8.1.5.1										A/E				N	Y	Y
			8.1.5.2											A/E			N	Y	Y
		5.1.6	**System Level Impact Assessment***																
			8.1.6.1										A/E				N	N	Y
			8.1.6.2											A/E			N	N	Y

5.0 QUALIFICATION	**5.1 General**	**5.1.7**	**Component Level Impact Assessment***																				
			8.1.7.1													**A/E**			**N**	**Y**	**Y**
			8.1.7.2														**A/E**		**N**	**Y**	**Y**
		5.1.8	**Installation Qualification Protocols***																				
			8.1.8.1													**A/E**			**N**	**Y**	**Y**
			8.1.8.2														**A/E**		**N**	**Y**	**Y**
		5.1.9	**Operational Qualification Protocols***																				
			8.1.9.1													**A/E**			**N**	**Y**	**Y**
			8.1.9.2														**A/E**		**N**	**Y**	**Y**
		5.1.10	**Performance Qualification Protocols***																				
			8.1.10.1													**A/E**			**N**	**Y**	**Y**
			8.1.10.2														**A/E**		**N**	**Y**	**Y**
		5.1.11	**Training Records/Plans For Qualification Activities**																				
			8.1.11.1													**A/E**			**N**	**Y**	**Y**
			8.1.11.2														**A/E**		**N**	**Y**	**Y**

		5.1.12	**Final Qualification Summary Reports***																	
			8.1.12.1											**A/E**				**N**	**Y**	**Y**
			8.1.12.2												**A/E**			**N**	**Y**	**Y**
6.0 PROJECT MANAGEMENT	**6.1 General**	**6.1.1**	**CPA**																	
			9.1.1.1										**PM**					**N**	**N**	**Y**
			9.1.1.2										**PM**					**N**	**N**	**Y**
		6.1.2	**Schedules**																	
			9.1.2.1										**PM**					**N**	**N**	**Y**
			9.1.2.2										**PM**					**N**	**N**	**Y**
		6.1.3	**Cost Reports**																	
			9.1.3.1										**PM**					**N**	**N**	**Y**
			9.1.3.2										**PM**					**N**	**N**	**Y**
6.0 PROJECT MANAGEMENT	**6.1 General**	**6.1.4**	**Conceptual Design Reports**																	
			9.1.4.1										**PM**					**N**	**Y**	**Y**
			9.1.4.2										**PM**					**N**	**Y**	**Y**

		6.1.5	**Preliminary Design Reports**																	
			9.1.5.1										**PM**				**N**	**Y**	**Y**
			9.1.5.2										**PM**				**N**	**Y**	**Y**
		6.1.6	**Service Contracts, PO Records**																	
			9.1.6.1										**PM**				**N**	**N**	**Y**
			9.1.6.2										**PM**				**N**	**N**	**Y**
		6.1.7	**Correspondence**																	
			9.1.7.1										**PM**				**N**	**N**	**Y**
			9.1.7.2										**PM**				**N**	**N**	**Y**
		6.1.8	**HAZOP Reports***																	
			9.1.8.1										**PM**				**N**	**Y**	**Y**
			9.1.8.2										**PM**				**N**	**Y**	**Y**

A.3 APPENDIX: CGMP/GEP REVIEW, ENHANCED DESIGN REVIEW

A.3.1 INTRODUCTION

This document contains the methodology for conducting cGMP and GEP design reviews using the attached checklists.

A.3.2 PURPOSE

The GMP regulated industries should follow this cGMP/GEP Checklist Procedure to verify and document that the expectations of regulatory authorities as well as manufacturing requirements have been met in the system design.

Completed cGMP and GEP checklists, along with the User Requirements Specification Review form the Enhanced Design Review, also referred to in some regions as Design Qualification.

A.3.3 SCOPE

This procedure describes the methodology for completing the cGMP and GEP Checklist review using the attached checklists.

A.3.4 RESPONSIBILITIES:

The Project Manager is responsible for implementing this procedure during the preliminary design phase of the project. (Refer to Project Commissioning and Qualification Guideline). Supporting teams involved in completing the review may include:

- Quality Assurance/Validation
- Contracted engineering design or validation services consultants.
- User group or owner (e.g. manufacturing)
- Specialized equipment vendors

A.3.5 PROCEDURE FOR DOCUMENTING THE cGMP/GEP CHECKLIST REVIEW

The following sections describe the content and required input data to be used in completing the cGMP/GEP checklist review using the attached template form.

A.3.5.1 Cover and Signature Page

This is a standard-form page, which includes the project data (plant, project title, number, etc.), an approval block, and a revision history block. Note that the completed checklists must be approved after conducting the design review.

A.3.5.2 Documenting the Design Review

The design review will be documented using the attached checklists. The checklists are for different engineering disciplines. Disciplines include:

- Architectural
- HVAC
- Electrical
- Process and Utilities
- Process Equipment
- Instrumentation
- Process and Security Control

When completing the review indicate the individuals involved in the checklist review on the header of each sheet (Reviewed by), and the date of the review.

Listed within each checklist are a number of cGMP/GEP requirements applicable to that particular category. Each requirement has been assigned an ID number for reference, a group of keywords, and the appropriate discipline responsible for ensuring that the requirement is specified in the design.

During the design review, each requirement will be examined. The following information will be recorded in the appropriate column of the check sheet during the design review:

Checklist Column Heading	Required Input During Design Review
Part of Design Basis (Y/N/NA or On Hold)	Indicate yes, no, not applicable, or on hold in this column based on the particular requirement.
Design Documents and Sect. Nos.	Indicate the design document and section that satisfies the cGMP/GEP requirement.
Action Required, if not Addressed	Indicate the action which will take place to ensure the cGMP/GEP requirement is addressed in the design. This may include P&ID updates, updates to the equipment or instrument specifications, updates to layout drawings, etc.
Completion Initials/Date	Initial and date this column, indicating that the required action was completed.

Each page should be independently reviewed by a second, qualified person who should sign and date each page in the appropriate blocks in the upper, left-hand corner.

A.3.5.3 Approving and Updating the cGMP/GEP Checklists

After completion of the design review using the checklists, the completed checklists are approved using the cover page attached to this document.

Open items should be noted in the Enhanced Design Review (EDR) Summary Report.

As the project progresses, the checklists may require additional review if there are major changes to the design. Adding systems or components, changes to how systems/components are utilized, the reclassification of manufacturing areas, and other factors could trigger an update to the checklist review, and/or an additional review. It is the responsibility of the Project Manager to schedule additional reviews as required.

A.3.5.4 Archiving the Completed cGMP/GEP Checklists

The completed checklist review is filed in the project Turn-Over Package, as specified in the Turn-Over Package Matrix.

A.3.6 ARCHITECTURE CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
1	Area cleanliness - bio containment	Identify levels of cleanliness and bio containment for all areas (See HVAC Table)				
2	Area cleanliness - Finish	Finishes should be in accordance with designated cleanliness levels				
3	Area cleanliness - Finish - Cleaning	Provide readily accessible and cleanable surfaces in accordance with designated cleanliness levels				
4	Area definitions	Core areas include manufacturing areas from subdivision through filling				
5	Area definitions	Support areas include secondary functions (i.e. materials receiving, storage, packing, shipping, laboratories, offices, dressing rooms, housekeeping support, etc.)				
6	Area definitions	Service areas are for piping, ducts, accessory/utility equipment, and other services for adjacent process modules				
7	Cold Rooms - Cleaning - wipe downs	Cold room interior walls should be designed for cleaning wipe downs.				

8	Cold Rooms - Doors - Coolers - Freezers - Warehouses	Provide rapid roll doors (preferred) or air curtains to reduce warm air infiltration for coolers and freezers in the warehouse				
9	Cold Rooms - Floors - Coolers - Freezers - Warehouses	Isolate floors for coolers and freezers to prevent cooling adjacent floors in the warehouse				
10	Document review and approval for direct impact systems	Ensure that Quality Operations reviews and approves the URS, the impact assessment, the commissioning plans, the protocols, and final reports for qualification				
11	Drains - Bio containment - kill tanks - kill vessels - biological inactivation	All drains coming from a bio contained area should go to a kill tank (for biological inactivation system).				
12	Drains - cross contamination - bio containment - process	Drains should be designed to prevent cross contamination between bio-contained drains and process drains.				
13	Drains - cross contamination - sanitary waste - air break - clean utilities - sterile utilities	Drains of pharmaceutical equipment should be designed to prevent contamination to sanitary waste system. Drains of sterile utilities (i.e. clean steam condensate, WFI) should be through an air break.				
14	Drains - double containment piping - inspection	Contaminated drains should be capable of inspection or other means of ensuring that leaks cannot contaminate the environment. For hazardous & toxic materials, use double containment pipes (outer pipe open and draining into contained area), if buried.				
15	Drains - Floors - Floor drains	Floor drains should be avoided in subdivision modules, but may be located away from the subdivision modules in the staging areas				
16	Drains - Floors - Floor drains	Top surface of drains should be flush with finished floor				

17	Drains - Floors - Floor drains - Chemical Resistance - Cleaning	Stainless steel and other materials for drains should be resistant to chemical attack by disinfectants and sanitizing agents				
18	Drains - Floors - Floor drains - Covers - Plugs -Aseptic	Floor drains should have smooth internal surface, solid air tight cover, & gasketed screw-on internal plug. Use polished finishes in Aseptic areas				
19	Drains - Floors - Floor drains - Grates - Manufacturing	Grates should be provided for floor drains in wet applications for manufacturing modules				
20	Drains - Floors - Floor drains - Manufacturing - Aseptic	Floor drains should be avoided, or otherwise kept to a minimum in Manufacturing Dry Process and Aseptic areas				
21	Drains - Floors - Floor drains - Traps	Provide a trap to maintain water seal prior to its connection to drain line header				
22	Drains - Floors - Floor drains - Warehouses	Drains should be avoided, if possible, in the warehouse. If required, they should be accessible, but not located in aisle ways				
23	Drains - Floors - Floor drains - Warehouses - Tanks - Collection tanks - Reservoir tanks	Route drain lines to dedicated reservoir for containment/testing prior to discharge to plant effluent from the warehouse. Address any requirements for treatment based on proposed testing that will be used.				
24	Drains - Hubs - Drain Hubs - Backflow preventers - Manufacturing - Aseptic	When equipment is permanently connected to drain hub, a closed connection with backflow preventer and capability for carrying out periodic sanitization should be provided in manufacturing modules or sanitization in aseptic modules				

25	Drains - Hubs - Drain Hubs - Covers - Manufacturing - Aseptic - Primary packaging	Open drain hubs should be internally threaded and use threaded and gasketed flanged cap for airtight seal in manufacturing, aseptic, or primary packaging modules				
26	Drains - Hubs - Drain Hubs - Manufacturing - Aseptic - Primary packaging	Drain hubs should be located in the service area, or if this is not possible, then located in walls at height of 150 mm from the floor in manufacturing, aseptic, or Primary packaging modules				
27	Drains - Hubs - Drain Hubs - Traps - Manufacturing - Aseptic - Primary packaging	Drain traps should installed as close as possible to the hub opening to provide a water trap in manufacturing, aseptic, or Primary packaging modules				
28	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
29	Explosion relief panels	Explosion relief panels should be mounted flush w/interior wall				
30	Explosion relief panels	Explosion relief panels should have dust covers provided for any ledges				
31	Explosion relief panels	There should be no physical barriers inside/outside of rooms for panel relief				
32	Finish - Ceiling - Cleaning	Ceilings should be easily cleanable with a smooth, impervious surface				
33	Finish - Ceilings	Ceilings should be a monolithic, flat durable surface				
34	Finish - Ceilings - Cleaning	Ceilings should be resistant to chemical attack and discoloration by fumigants, cleaning agents & process materials that are used in that area				

35	Finish - Ceilings - Cleaning - Ceiling Height	Ceiling heights, which should be dictated by the equipment in the area, should also be kept to a minimum to facilitate cleaning				
36	Finish - Ceilings - Joint - Corners - Coves	Joints between walls and ceilings should be rounded to a radius identical to the wall corners				
37	Finish - Ceilings - Penetrations	Gaps, joints, & penetrations should be sealed for moisture/vapor & fire				
38	Finish - Ceilings - Penetrations	All penetrations should have a metal frame/sleeve				
39	Finish - Ceilings - Penetrations	Provide curbed penetrations above ceilings and floors				
40	Finish - Ceilings - Secondary Packaging	Ceiling finishes should be identical to the walls; or a suspended ceiling using a concealed or exposed 2-directional grid with appropriately fitted ceiling panels for Secondary Packaging areas				
41	Finish - Ceilings - Secondary Packaging	Ceiling panels should be static-free and specially impregnated, coated, or treated to guarantee that particulate generation will not occur at exposed edges or edge surfaces created when panels are cured or formed for Secondary Packaging areas				
42	Finish - Ceilings - Subdivision - Manufacturing - Aseptic - Material Sampling - Primary Packaging	Ceiling finishes shall be identical to walls for Subdivision, Aseptic, Manufacturing, Material Sampling & Primary Packaging modules				
43	Finish - Doors - Air curtains - Warehouses	Air curtains should be provided for exterior doors that are opened for more than several minutes for the warehouse				
44	Finish - Doors - Cleaning	All door hardware should be easily cleanable				

45	Finish - Doors - Cleaning - Chemical Resistance	Door hardware should be resistant to chemical attack from fumigants, cleaning, and sanitizing agents				
46	Finish - Doors - Emergency Exits - Warehouses	Emergency exits should be provided per local building and safety codes for the warehouse.				
47	Finish - Doors - Fire doors - Fire walls - Warehouses	Fire doors should be provided with same ratings as firewalls for the warehouse				
48	Finish - Doors - Manufacturing -Aseptic - Primary Packaging - Secondary Packaging	All door hardware should be sanitary for Manufacturing, Aseptic, and Packaging areas				
49	Finish - Doors - Panels	Door panels should be flush and smooth faced				
50	Finish - Doors - Panels - Clearances	Minimize clearance between doors panels & floor (~6-8 mm)				
51	Finish - Doors - Panels - Door closers	Automatic door closers should be recessed within door panels with minimum of protruding parts				
52	Finish - Doors - Panels - Door Closers	Provide automatic door closers				
53	Finish - Doors - Panels - Door Closers - Warehouses	Door closers should have hold-open features, if required, but not if door connects to area of different cleanliness standard from the warehouse				
54	Finish - Doors - Panels - Frames	Door panels and frames should be welded with joints properly filled to eliminate cracks, crevices, or pinholes				
55	Finish - Doors - Panels - Frames	Door frames should be the same depth as the wall thickness where they are installed				

56	Finish - Doors - Panels - Locks	Doors should have built-in locking devices				
57	Finish - Doors - Panels - Locks	To control access where this is necessary, provide locking devices that are electronic or similar type that can be activated by some type of code reader or card; or provide keyed lock				
58	Finish - Doors - Panels - Roll-up Doors - Manufacturing - Primary packaging	Roll-up doors may be used for material airlocks for material movement for manufacturing or Primary packaging modules				
59	Finish - Doors - Panels - Sliding Doors	Slide doors should not have a guide mechanism at floor level that requires a groove or projecting edge along the door opening				
60	Finish - Doors - Panels - Sliding Doors	Avoid the use of pocket type sliding doors that have sliding space built into the wall thickness				
61	Finish - Doors - Panels - Sliding Doors - Cleaning	Sliding door gear should be covered to give a cleanable surface				
62	Finish - Doors - Panels - Swing Doors	Provide spring loaded latches to keep the door closed to maintain proper room pressurization				
63	Finish - Doors - Panels - Swing Doors	Provide large handle on hinged side face of the door				
64	Finish - Doors - Panels - Swing Doors - Aseptic	Swing doors should be used in aseptic areas				
65	Finish - Doors - Panels - Swing Doors - Door swing	Doors should swing in the direction of air flow, except where mandated otherwise for safety reasons				
66	Finish - Doors - Panels - Swing Doors - Hinges	Door hinges should have self-lubricated thrust bushings or bearings				

67	Finish - Doors - Panels - Swing Doors - Sliding Doors - Subdivision - Manufacturing - Material sampling - Primary packaging - Secondary packaging	Swing or slide doors should be used in subdivision, manufacturing. Material sampling, or packaging areas				
68	Finish - Doors - Panels - Width	Doors should be wide enough to minimize damage from any material handling equipment that would pass through				
69	Finish - Doors - Panels - Windows	Doors should have a large viewing panel in the upper half of the door to provide a clear view into the room				
70	Finish - Doors - Panels - Windows	Door vision panels should be flush fitted with the door surface or centrally located in the door panel with beveled sides leading to door panel face				
71	Finish - Doors - Panels - Windows - Glass	Door vision panels should be laminated safety glass				
72	Finish - Doors - Pressure retention - Explosion relief	Doors should meet pressure retention requirements for modules with explosion relief				
73	Finish - Doors - Seals	Door seals should be provided to minimize room air loss				
74	Finish - Doors - Seals - Gaskets - Weather tight - Warehouses	Gasketing and weather seals should be provided for external doors for the warehouse				
75	Finish - Floors	Floors should be level, smooth, free of pores, and anti-static				
76	Finish - Floors	Floors should be resistant to chipping and wear				
77	Finish - Floors	Floors should be cast as a level monolithic surface over a clean dry structurally stable sub-floor				
78	Finish - Floors	Monolithic floor should extend up the wall surface to a min. height of 100 mm while forming a cove with a min. radius of 50 mm				

79	Finish - Floors - Chemical resistance - Cleaning	Floors should be resistant to chemical attack and discoloration by fumigants, cleaning agents & process materials that are used in that area				
80	Finish - Floors - Curbs - Coves - Warehouses	If curbing is required (i.e. for sprinkler water retention, etc.), it should be cast integrally with the floor in the warehouse. Joints between the curb and floor should be coved with minimum radius of 20 mm for cleaning.				
81	Finish - Floors - Materials - Warehouses	Floors should be poured concrete in the warehouse				
82	Finish - Floors - Protection - Pests - Insects - Rodents - White strips - Warehouses	A white strip (38 cm min.) of enamel or epoxy paint should be provided along the walls (46 cm min. height) and floors (38 cm min.) at the outside walls to aid detection of pests in the warehouse				
83	Finish - Floors - Slope - Floor drains	Floors should pitch gently toward drains				
84	Finish - Floors - Slope - Floor drains - Warehouses	Avoid pitching of floors to drains in the warehouse				
85	Finish - Floors - Surface coatings - Chemical resistance - Anti-static - Sealer - Warehouses	Floor surface coatings can be provided for chemical resistance & static/dust prevention, as required, in the warehouse				
86	Finish - Floors - Surface coatings - Hardener - Sealer - Warehouses	Floors should be finished w/surface hardener & sealer to prevent dusting & liquids penetration in the warehouse.				

87	Finish - Floors - Vapor barrier	Floors at ground level should have a reliable vapor barrier				
88	Finish - Floors - Wear Resistance - Hardness - Floor Traffic - Fork Lift Trucks - Warehouses	Floors should be finished to a hardness to provide adequate wear resistance and flatness compatible with the type of fork lift trucks or vehicles that are to be used in the warehouse				
89	Finish - Roofs - Warehouses	Roofs should be designed for local climatic (weather tight) & natural calamities for the warehouse				
90	Finish - Roofs - Warehouses	Roofs should be well draining & free of leaks for the warehouse				
91	Finish - Roofs - Warehouses - Gutters	Avoid central storm water gutters for the warehouse roof. Design gutters to prevent overflow into the warehouse.				
92	Finish - Roofs - Warehouses - Insulation	Roofs should be provided with insulation to conserve heat/cold & reduce solar heating for the warehouse				
93	Finish - Roofs - Warehouses - Maintenance	Roofs should be designed for low maintenance for the warehouse				
94	Finish - Roofs - Warehouses - Penetrations	Minimize roof penetrations for the warehouse. When required, provide curbed penetrations w/flashing to exclude outside air/water/dust				
95	Finish - Roofs - Warehouses - Safety Rails - Peripheral walls	Safety rails or peripheral walls should be provided for fall prevention for the roof for the warehouse				
96	Finish - Roofs - Warehouses - Walkway	Well demarcated/supported walkways should be provided for non-load bearing roofs for the warehouse				

97	Finish - Roofs - Warehouses - Walkways	Roof walkways should minimize wear from personnel/equipment traffic for the warehouse				
98	Finish - Sloping surfaces - Cleaning	Avoid horizontal surfaces in the core areas. Surfaces should be sloped to facilitate cleaning and avoidance of dirt accumulation				
99	Finish - Walls	Walls should be smooth surfaced				
100	Finish - Walls - Cleaning	Walls should have impervious washable surface and be resistant to chemical attack and discoloration by fumigants, cleaning agents & process materials that are used in that area				
101	Finish - Walls - Dividing partitions	Removable or fixed-in-place dividing partitions should be rigidly fixed to the floor between Secondary Packaging lines				
102	Finish - Walls - Dividing partitions - Secondary Packaging	Dividing partitions with no gap between the floor should be provided up to a minimum height of 1.8M between Secondary Packaging lines				
103	Finish - Walls - Floors	Lowest 100 mm of the wall should be formed monolithically w/floor				
104	Finish - Walls - Joint - Corners - Coves	Intersections of walls should have a coved radius of 35-50 mm				
105	Finish - Walls - Openings - Pass Throughs - Manufacturing - Aseptic - Primary Packaging	Wall openings should be kept to minimum possible dimension based on serving the required material handling function for manufacturing Aseptic, and Primary packaging modules				
106	Finish - Walls - Openings - Pass Throughs - Manufacturing - Aseptic - Primary Packaging	Air tight covers for wall openings for pass through should be provided for closing openings that are not in use, whenever possible, for manufacturing, Aseptic, and Primary Packaging modules				

107	Finish - Walls - Openings - Pass Throughs - Manufacturing - Aseptic - Primary Packaging	A system of adjustable gates or interchangeable forms/templates should be provided for wall opening pass throughs for opening that need to vary in size at different times for Manufacturing, aseptic, and Primary packaging module				
108	Finish - Walls - Openings - Pass Throughs - Windows - Manufacturing - Aseptic - Primary Packaging	A window view panel should be provided in close proximity of wall opening pass through for manufacturing, Aseptic, and Primary packaging modules				
109	Finish - Walls - Penetrations	Gaps, joints, & penetrations should be sealed for moisture/vapor & fire				
110	Finish - Walls - Penetrations	All penetrations should have a metal frame/sleeve				
111	Finish - Walls - Plinths - Manufacturing - Aseptic - Primary Packaging	Base of the walls must be a plinth that is at least 150 mm high and placed on the sub-floor for Manufacturing, Aseptic, and Primary Packaging Modules				
112	Finish - Walls - Warehouses	External walls should be designed for local climatic (weather tight) & natural calamities for the warehouse				
113	Finish - Walls - Warehouses - External - Firewalls - Fire rating	External walls should have a fire rating of 2 hours or as required by local authorities for the warehouse				
114	Finish - Walls - Warehouses - External - Insulation	External walls should have insulation to conserve heat/cold in the warehouse & provide interior barrier/cover				

115	Finish - Walls - Warehouses - External - Insulation	Insulation should not be exposed in the exterior walls in the warehouse. Insulation should be protected with a light colored interior jacket cover (rigid, not flexible) suitable for wiping/cleaning or a pre-painted/finished metal panel (preferred) on both sides.				
116	Finish - Walls - Warehouses - External - Maintenance	External wall surfaces should be designed for low maintenance for the warehouse				
117	Finish - Walls - Warehouses - External - Openings	Exterior wall openings, entries, & exits should be minimized for essential functions for the warehouse. Exhaust fan &HVAC duct openings should be located in the exterior walls instead of the roof, when possible.				
118	Finish - Walls - Warehouses - External - Openings - Protection - Security	All exterior building openings should be sealed and/or screened. Consider grills for security, where appropriate, for the warehouse				
119	Finish - Walls - Warehouses - External - Protection - Pests - Insects - Rodents	External walls should provide protection against infiltration by insects, rodents, & pests for the warehouse				
120	Finish - Walls - Warehouses - External - Protection - Security - Unauthorized personnel	External walls should provide protection against entry by unauthorized personnel in the warehouse				
121	Finish - Walls - Warehouses - External - Weather tight	Exterior walls should be sealed at floor/roof interfaces & between panels to keep the building weather-tight, prevent exterior light penetration, and prevent entrance of pests for the warehouse				

122	Finish - Walls - Warehouses - External - Windows	Avoid windows in the external walls. If required, avoid windows that open in in the warehouse.				
123	Finish - Walls - Warehouses - External - Windows	Dirt catching horizontal ledges (bevel edges down) should be minimized for any windows in the warehouse				
124	Finish - Walls - Warehouses - External - Windows	Consider blocking off windows in existing/leased facilities for the warehouse. If windows open, use security bars for protection & screens against insects/pests				
125	Finish - Walls - Warehouses - Internal - Firewalls	Firewalls should be used for separation from core areas for the warehouse				
126	Finish - Walls - Warehouses - Internal - Protection - Security - Unauthorized personnel	Internal walls should provide physical security against entry by unauthorized personnel for the warehouse				
127	Finish - Walls - Warehouses - Structural Members - Exposed	Hollow box sections should be considered for warehouse structural members instead of open sections, such as joists, channels, or angles in the warehouse				
128	Finish - Walls - Warehouses - Structural Members - Exposed	Horizontal surfaces for warehouse structural members should be sloped downward to minimize dust settlement, whenever practical				
129	Finish - Walls - Warehouses - Structural Members - Exposed - Cleaning	Warehouse columns, beams, and other structural members shall have readily cleanable surfaces				

130	Finish - Walls - Warehouses - Structural Members - Exposed - Paint	Warehouse structural members should be primed/painted to prevent corrosion & ease cleaning. Finish coat up to height of 8-10 ft. is acceptable.				
131	Finish - Walls - Windows	Windows should be sized to provide a clear view into the modules				
132	Finish - Walls - Windows	Window frames should be welded and provide smooth flat surface				
133	Finish - Walls - Windows	Windows should be flush fit with the wall or use beveled sill on both/single side				
134	Finish - Walls - Windows	Windows should use tempered, laminated (safety) glass of appropriate thickness (typically 5-6 mm)				
135	Finish - Walls - Windows	Windows should use double glazing, which is factory assembled whenever available				
136	Finish - Walls - Windows	Windows should not be located in exterior walls of subdivision, manufacturing, aseptic, and Primary packaging areas				
137	Finishes Platforms - Stairs - Metal - Perforated metal	Metal platforms and stairs should not use perforated decking or stair treads				
138	Finishes Platforms - Stairs curbs - cleaning - skid proof	Platforms should be provided with solid, easily cleanable, skid proof surfaces. Solid curbs should be provided to prevent liquid spills or solids dropping over the edge				
139	Layout - Airlocks	Airlock design should be integrated with gowning rooms for entry into the process areas with the higher cleanliness level.				
140	Layout - Airlocks	Airlocks should be provided for entry/exit of all personnel and materials from support areas to core processing areas.				
141	Layout - Airlocks	Airlocks should be provided when provisions are made for entry/exit of personnel and materials between core processing areas of different cleanliness level ratings				

142	Layout - Carts - portable equipment - Material handling traffic - pharmaceutical equipment	Layout should allow for access and routes for trolleys, carts, mobiles portable tanks, etc. Layout should take into account their maneuverability in a normal production environment				
143	Layout - Change rooms	Primary change/dressing rooms should be located in close proximity to the building entrance to minimize tracking of dirt				
144	Layout - Core Areas	Core areas should be separated by walls, corridors, and airlocks from receiving/storage, shipping, & support areas				
145	Layout - Core Areas	None of the core area walls should be external walls of the building				
146	Layout - Core Areas	Corridors or other support areas should encircle Core areas				
147	Layout - dedicated areas - Separation - Containment - penicillin - cephalosporin - antibiotics - sterile - aseptic - flammables - explosives	Dedicated facility areas for manufacturing, processing and packaging should be separated and contained with walls and airlocks for: 1) Penicillin, cephalosporin, and antibiotics 2) Sterile products (aseptic areas) 3) Volatiles, flammables/explosives, reactives, etc.				
148	Layout - Equipment maintenance - equipment removal	Layout of the building should allow for pharmaceutical equipment to be easily removed for extensive repair or modifications.				
149	Layout - Gowning rooms	Secondary gowning areas should be provided for entry/exit of all personnel from support areas to core processing areas				

150	Layout - Laboratory - storage - staging - archives - test samples - cold rooms - refrigeration - freezers - coolers liquid nitrogen - washing - raw materials	Laboratory facility layout should be provided with adequately sized areas that are located based on material and personnel traffic flow evaluations for: 1) Receipt, identification, testing, documentation, staging, and disposal of tested samples for incoming materials, components and drug products. 2) Storage areas for supplies, reagents and reference standards Refrigeration should be provided for perishable materials. 3) Glassware and dirty equipment staging & washing areas 4) Archives for storage/retrieval of raw data, reports, samples & specimens 5) Storage of temperature liquids (i.e. Liquid Nitrogen), if required				
151	Layout - Material traffic - material flow - Personnel traffic - Personnel flow - maintenance - equipment set up	Room layouts should allow for equipment set-ups, maintenance, material traffic/flow, material staging, & personnel traffic/flow				
152	Layout - Spare Parts - Consumables	A dedicated storage area should be provided for spare parts and consumables.				
153	Layout - Subdivision	Sub-division/dispensing areas should be in close proximity to raw material storage & manufacturing core areas				
154	Layout - Subdivision - Airlocks	Entry/exit into subdivision/dispensing areas should be through separate airlocks for the pharmacy, raw material staging and batch staging areas				
155	Layout - Subdivision - Pharmacy	Pharmacy/storage area for raw materials should be provided with specialized/dedicated room(s), if required due to material properties or regulations (i.e. controlled substance, spoilage, etc.)				

156	Layout - Subdivision - Weigh rooms	Subdivision/dispensing area for weighing out materials should be located between raw material staging and weighed batch staging areas with separate access to each staging area. Consider recommended once-thru traffic pattern for raw material staging to weighing to batch staging to mfg.				
157	Layout - Subdivision - Weigh rooms - Downflow Booths	Weigh room(s) for subdivision/dispensing areas should be provided with downflow booth(s) where bulk containers are opened to extract samples.				
158	Layout - Warehouses	Warehouse location should be in close proximity to manufacturing and packaging core areas				
159	Layout - Warehouses	Separate areas should be provided for: 1) Raw materials; 2) Packaged materials; 3) Intermediate products (Work in Progress); 4) Finished products in the warehouse				
160	Layout - Warehouses - Sampling Room - Raw materials	Dedicated sampling room(s) should be provided for materials that need special handling due to operator safety or product exposure requirements (i.e. aseptic bulks, hygroscopic or temp./light sensitive materials, highly corrosive/toxic/potent materials, etc.)				
161	Layout - Warehouses - Sampling rooms	Sampling room(s) should be provided with gown-up areas, place for cleaning the exterior of containers, and airlock access.				
162	Layout - Warehouses - Sampling rooms - Packaging materials	Sampling, checking of physical properties, and simple tests of packaging materials should be done in designated sampling room(s) close to the truck receiving area, but separate from where materials are stored in the warehouse. Comprehensive and more complex testing can be performed in the Quality Control lab at the site				
163	Layout - Warehouses - Sampling rooms - Raw materials	Sampling room(s) for raw materials should be provided with downflow booth where bulk containers are opened to extract the samples.				

164	Layout - Warehouses - Sampling rooms - Raw materials	Sampling of raw materials should be in designated sampling room(s) close to the incoming materials staging area in the warehouse				
165	Layout - Warehouses - Securable areas	Separate/isolated, securable areas should be provided in the warehouse(s) for: 1) Quarantined materials; 2) Materials w/special temp. or humidity control requirements; 3) Cooler/Freezers; 4) Controlled substances; 5) Flammable, explosive, & hazardous materials; 6) Rejected goods; 7) Finished goods				
166	Layouts - Airlocks - Bio containment - Biotechnology	Airlocks should be provided at containment boundaries for BL3-LS biotechnology areas				
167	Layouts - Carts - storage	When pharmaceutical equipment requires carts to be stored outside the core area, provisions should be made for the safe storage of these carts				
168	Layouts - Portable equipment - Cleaning Equipment	There should be dedicated storage areas for portable equipment, including cleaning equipment.				
169	Materials of construction - Wood	Wood and other organic materials should not be used.				
170	Pallet racks - Warehouses	Pallet racks should have locked or bolted design to prevent uplift & detachment and safety bars to prevent misplaced pallets and loads from falling in the warehouse				
171	Pallet racks - Warehouses	Pallet racks should be located 450 mm (min.) from walls to allow for cleaning & pest detection in the warehouse				
172	Pallet racks - Warehouses	Use wide trays under conveyors that run overhead to prevent spilled materials on racks in the warehouse				
173	Pallet racks - Warehouses	Provide protection with sturdy guard rails for the underside of conveyors that run overhead to fork lift aisles in the warehouse				

174	Traffic flow -Material Traffic flow - Personnel traffic flow-aseptic	In aseptic areas, one way flows are preferred. If this is not possible, SOPs must prevent simultaneous flows through a common space. The transport of material or product to/from the processing area, or between processing operations, must be in closed containers or systems.				
175	Traffic flow -Material Traffic flow - Personnel traffic flow	In non-aseptic areas, one way product, material, or equipment flows are not required provided that appropriate methods are employed to prevent cross contamination. (for example, if materials are transported in closed containers and appropriate SOPs are in place to prevent mix ups)				
176	Traffic flow -Material Traffic flow - Personnel traffic flow-aseptic	Layouts should preclude normal entry/exit into an aseptic area, except through controlled methods which prevent unauthorized personnel from entering the area during processing operations. Controlled methods include airlocks and gowning areas with administrative controls, on way flow patterns, electronic door interlocks, and alarm systems.				
177	Traffic flow -Material Traffic flow - Personnel traffic flow	If exposure to an open process risks personnel or environmental safety, segregating entrances and exits is recommended to allow for special gowning or decontamination procedures.				
178	Traffic flow -Material Traffic flow - Personnel traffic flow	If the same exits and entrances are used, simultaneous entrances and exits should not occur. Methods of preventing this include administrative controls, interlocking of doors, signaling systems.				

A.3.7 HVAC CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
250	AHU - Coils - air handling units	Air handling unit coils should have no more than ten fins per inch and no more than eight rows in depth. If cooling capacities require more than eight rows, then two coils should be placed in series.				
251	AHU - Coils - air handling units	Air handling unit coils should be spaced a minimum of 24" apart and provided with maintenance access				
252	AHU - double wall construction - air handling units	Air handling units, which are outdoors or service core processing areas, should be double wall construction.				

254	AHU - Filters - HEPA filters - ULPA filters - air handling units	Final filters for air handling units should be HEPA or ULPA, as required, for primary supply air to the core processing areas.				
255	AHU - Filters - Prefilters - Intermediate filters - Filter efficiency ratings - air handling units	Air handling units, which service core processing areas, should be provided w/30% prefilters & 90% ASHRAE, or equivalent, intermediate filters				
256	Air flow - Aseptic - Grade A - laminar flow	Unless specified otherwise, in Grade A aseptic areas, air velocity should be unidirectional laminar flow of at least 90 feet per minute over the entire exit area.				
257	Air flow - Differential pressure	Air flow resulting from the differential pressure gradient should not compromise batch or product separation.				
258	Air flow - Once through - bio containment - BL3-LS	Once-through air circulation should be provided for each BL3-LS bio containment area.				
259	Air flow - Once through - explosion proof - flammable - explosive - Product cross contamination	Once-through room air circulation should be provided for areas rated for explosion-proof handling of flammable gases, vapors, or liquids (i.e. organic solvents, etc.) or where product cross contamination is a concern. Return air should be exhausted to outdoors.				
260	Air flow - Once through - explosion proof - powders - recirculation	Once-through room air circulation is not required for explosion-proof handling of powders and dusts (no flammable gases/vapors/liquids). Air may be recirculated based on adequate quality/efficiency of air filtration				
261	Air flow - Once through - fumigation - purge cycle	HVAC systems for areas with fumigation capabilities should be provided with a purge cycle that utilizes once-thru air circulation that maintains a minimum space temperature of 18C				
262	Air leakage - calculations	Air leakage calculations should be performed and consider each wall regardless of whether the room is interior or exterior. Leakage should be identified as inward or outward. Leakage calculation should				

		contain a safety factor to compensate for less than ideal construction for clearances around doors; room penetrations; walls/ceilings, etc.				
263	Airlocks - air showers	Air showers or other means should be provide to clean exterior of material containers inside of airlocks				
264	Airlocks - material transfer - sterilizing - aseptic	Material transfer airlocks may require appropriately designed sterilizing systems for aseptic areas				
265	As-built P and I D drawing verification	The system P and I D drawings must be reviewed, verified and updated as required to reflect the "as-built" condition of the system.				
266	Bio containment level	Bio containment levels (BL) for core areas should be clearly identified based upon the anticipated microorganisms.				
267	Classification Levels	Classification equivalents or EU grades and US Class based on airborne particle count. The levels are: Grade A- Class 100 at rest and Class 100 in Operation. Grade B- Class 100 at rest and Class 10,000 in operation. Class C is Class 10,000 at rest and Class 100,000 in operation. Grade D is Class 100,000 at rest and not defined in operation.				
268	Cleanliness level - bio containment level - plant approval	Cleanliness and bio containment levels and design criteria should be clearly defined and approved by the plant customer				
269	Cleanliness level - bio containment level - properties products - packaging components - plant approval	Air cleanliness and bio containment levels should also be based on properties of operating materials and exposed products. (Rationalize impact of closed processes and transfers on air classifications.)				
270	Cleanliness level - Grade B - aseptic	Minimum cleanliness level should be Grade B for general Aseptic areas				

271	Cleanliness level - Grade A - aseptic - microbiological testing	Minimum cleanliness level should be Grade A for work stations where product, immediate containers, aseptic packaging components, or microbiological testing component are exposed to the environment in the Aseptic core areas				
272	Cleanliness level - Grade A - laminar flow - aseptic	Grade A conditions should be achieved by use of laminar flow modules, which are installed over the equipment and/or working area where the product/containers/components are exposed in the Aseptic core areas				
273	Cleanliness level - Grade D - aseptic	Minimum cleanliness level should be Grade D for contiguous non-aseptic rooms (i.e. Stopper prep, tank farm, etc.) for aseptic areas				
274	Cleanliness level - Class 100,000 - subdivision - manufacturing - primary packaging	Minimum cleanliness level should be Class 100,000 design for non-aseptic subdivision, manufacturing, and primary packaging areas. Class 100,000 as defined by the Company Modular guidelines, is defined as 20 air changes and HEPA filtered.				
275	Containment hoods - air flow velocity - face velocity - Bio containment - BL3	Containment hoods should be sized for air flow face velocity range of 75-125 FPM for BL3 bio containment areas				
276	Dehumidifiers	Dehumidifiers should be provided, as required, to maintain humidity levels				
277	Dehumidifier coils-condensate pans	Dehumidification coils should have corrosion resistant condensate draining pans, to prevent viables from entering clean room environments.				
278	Dehumidifiers - coolers	Localized dehumidifiers and cooling can be provided for designated rooms w/special conditions that are different from remainder of the system				
279	Differential pressure - Downflow booths	Down flow booths should be at a slightly lower air pressure than the room where they are located				
280	Differential pressure - rooms - 15 pascals	Differential pressure between adjacent rooms/areas of different grades should be >15 pascals (0.06" water)				

281	Differential pressure - rooms - aseptic	Aseptic core areas where product is exposed should be at the highest differential pressure that will cascade down into the corridors, airlocks, gowning rooms, and then the airlocks adjoining the non-aseptic areas				
282	Differential pressure - rooms - aseptic - airlocks	For aseptic productions areas for powder products, airlocks should be installed between the corridor and the aseptic area. The airlock pressure should isolate the working room from the corridor to preclude migration of product materials				
283	Differential pressure - rooms - explosion proof - explosive - flammable - powders - dust	Modules rated for explosion-proof handling of powders and dusts and/or flammable gases/vapors/liquids should be maintained at a lower pressure to the corridor and adjacent areas.				
284	Differential pressure - rooms - high containment - high bio containment - airlocks	For high containment/bio containment modules for specific products, airlocks should be installed between corridor and the module. The airlock pressure should isolate the working rooms from the corridor to preclude migration of product materials				
285	Differential pressure - rooms - high containment - high bio containment - BL3-LS - airlocks	Bio containment BL3-LS areas should be maintained at a negative pressure to other areas.				
286	Differential pressure - rooms - manufacturing -existing areas	Upgrades of existing areas, where it is not possible to have a clean corridor outside a manufacturing area due to physical or other constraints, should have the manufacturing area positive to the general corridor				
287	Differential pressure - rooms - material sampling	Material sampling rooms should be at the highest differential pressure that will cascade down to down flow booths and adjacent areas				
288	Differential pressure - rooms - subdivision	Subdivision/dispensing rooms should be at the highest differential pressure that will cascade down to the down flow booths & staging areas; from staging areas to airlocks; and from airlocks to corridors or warehouse				

289	Document review and approval for direct impact systems	Ensure that Quality Operations reviews and approves the URS, the impact assessment, the commissioning plans, the protocols, and final reports for qualification				
290	Downflow booths - air flow - heat loads	HVAC systems should be designed for conditioned air flow rates and heat loading for down flow booths when the booths are operating and in the stand-by or shutdown mode				
291	Downflow booths - subdivision - weigh rooms - material sampling	Down flow booths should be used for weighing, subdivision, and dispensing operations with any open product containers				
292	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
293	Ductwork - air return - air filters	Dust entrapment filters in the air return system should be located outside the rooms				
294	Ductwork - air return - aseptic	Air return ductwork openings should be located in the lower wall (typically lower opening edge is 150-250 mm above floor level) for aseptic areas.				
295	Ductwork - air return - manufacturing - primary packaging	Air return ductwork openings should be located in lower wall (typically lower opening edge is 150-250 mm above floor level) for manufacturing areas. Openings should be located diagonally across from the entry/exit door.				
296	Ductwork - air return - material sampling	Air return ductwork openings should be located in the ceiling or lower wall (typically lower opening edge is 150 mm above floor level) for material sampling areas. Openings should be located diagonally across from the entry/exit door.				
297	Ductwork - air return - secondary packaging	Air return ductwork opening should be located in the ceiling and provide uniform air sweep/distribution for the secondary packaging areas				

298	Ductwork - air return - subdivision	Air return ductwork openings should be in ceilings across from air supply opening for most subdivision areas for air sweeps that will provide a uniform environment. Air returns for weigh rooms can be located in the wall at floor level depending on room equipment and logistics for the subdivision area				
299	Ductwork - air supply	HVAC air supply inlet openings should not be located directly above process/packaging equipment				
300	Ductwork - air supply - double deflector grilles - ceiling diffusers - subdivision - manufacturing - packaging -material sampling	Directional supply air devices should be used for air supply duct openings to create uniform air distribution for the subdivision, manufacturing, packaging, and material sampling areas.				
301	Ductwork - air supply - manufacturing, primary packaging	Air supply ductwork openings should be located in order to provide a diagonal uniform air sweep/distribution of the room from the wall with the entry door to the far wall for manufacturing & primary packaging areas				
302	Ductwork - air supply - subdivision - manufacturing - primary packaging - material sampling	Air supply ductwork openings should be in the ceiling or elevated height in the wall to provide a uniform air sweep/distribution for the room for the subdivision, manufacturing, primary packaging, and material sampling areas				
303	Ductwork - cleaning	Ductwork should be cleanable				
304	Ductwork - cleaning - materials - chemical attack - sanitizing - fumigants	Ductwork materials should be resistant to chemical attack by cleaning, sanitizing, and fumigant materials used in the designated areas				
305	Ductwork - concealment	Exposed ductwork should not be located in processing areas				
306	Ductwork - concealment - soffits - stainless	If required in core processing areas due to space constraints, provide stainless ductwork w/seamless construction in enclosed soffits in the room				

307	Ductwork - Intake air - Supply air -Exhaust air	Outdoor air intakes should be located as far away as possible from, and upstream of, air exhausts.				
308	Ductwork - materials - dissimilar metals	Connections between dissimilar metals should be gasketed flanged connections				
309	Ductwork - materials - lining - asbestos	Sound attenuating or other lining materials for ductwork; or materials containing asbestos should not be used for the HVAC systems				
310	Ductwork - materials - stainless	Air return ductwork should be stainless up to just above the room ceiling for the manufacturing areas, where the room is subject to wash down or is otherwise wet.				
311	Ductwork - round - exhaust fans - dust collectors - fume extraction - vapor extraction	Ducts associated with exhaust of dust, or fume/vapors should be round with smooth finishes.				
312	Ductwork - round - exhaust fans - dust collectors - fume extraction - vapor extraction	Ducts to exhaust fans, dust collectors, and fume/vapor extraction should be routed as straight and direct as possible and not be fitted with obstructive devices that can increase pressure drop and dust settlement				
313	Ductwork- Humidifiers- Corrosion Resistant	A section of corrosion resistant duct should follow in duct humidifiers to prevent corrosion, which could become an airborne contaminant.				
314	Dust Collection	Dust collection should be provided in media prep, sampling or any area where solids are handled.				
315	Environmental Conditions - Aseptic	Environmental Conditions for Aseptic: **- General/Wet Areas:** - Temp: 19°C, +/-2°C, - Rel. Humidity: 25-50%,-Air Changes: 30/hr. min. **- Powder filling or when powder is exposed:** - Temp: 19°C, +/-2°C, - Rel. Humidity: 30-40% - Air Changes: 30/hr. min. **- For drier environments for specific product/process:** - Temp: 19°C, +/-2°C, - Rel. Humidity: *%, - Air Changes: 30/hr. min.				

		* - Review on a case by case basis based on product requirements				
316	Environmental Conditions - Manufacturing - Primary Packaging	Environmental Conditions for Mfg. & Primary Packaging: **- General and Wet Areas:** - Temp: 20°C, +/-2°C, -Rel. Humidity :< 50%, - Air Changes: 20/hr. min. **- Solid Dosage Form:** - Temp: 20°C, +/-2°C, - Rel. Humidity :< 35% - Air Changes: 20/hr. min. **- For drier environments mandated by specific product/process:** - Temp: 20°C, +/-2°C, -*Rel. Humidity: 25%, -Air Changes: 20/hr. min. * - Review on a case by case basis if lower humidity is required				
317	Environmental conditions - outdoors - HVAC - ASHRAE	ASHRAE or site specific data should be used for design criteria for outdoor environment conditions				
318	Environmental conditions - plant approval	Environmental conditions (i.e. temp. humidity, air filtration, air velocities, etc.) should be clearly defined and approved by the plant customer				
319	Environmental Conditions - Secondary Packaging	Environmental Conditions for Secondary Packaging: - Temp: 22°C, +/-2°C, - Rel. Humidity: Uncontrolled, suitable for comfort - Air Changes: Minimum outdoor air of 34M³/hr. per person				

320	Environmental Conditions - Subdivision	Environmental Conditions for Subdivision: **- Pharmacy:** - Temp: 22°C, +/-2°C, - Rel. Humidity: Uncontrolled - Air Changes: Typical storage conditions **- Staging:** - Temp:20°C,+/-2°C, - Rel. Humidity:<35%, - Air Changes:20/hr. min. **- Subdivision/Dispensing/Weighing:** - Temp: 20°C, +/-2°C, - Rel. Humidity :< 35%, - Air Changes: 20/hr. min.				
321	Environmental Conditions - Warehouse	Environmental Conditions for Warehouse: **- General Storage:** - Temp: <30°C, +/-2°C, - Rel. Humidity: Uncontrolled - Air Changes: Typical storage conditions **- Finished Goods:** - Temp: <25°C - Rel. Humidity: Uncontrolled, - Air Changes: Typical storage conditions				
322	Fans - exhaust fans - variable frequency drives	Variable frequency drives can be provided for exhaust fans, as required				
323	Fans - variable frequency drives	Variable frequency drives should be provided for supply and return fans				
324	Filters - return air - - HEPA filters - testing - validation - Bio containment	When HEPA filters are installed in the return air, ensure provisions are made for installation and removal of filter from inside the room for aseptic and bio containment areas. Filter validation/testing, can be performed from the back of the filter outside of the core area.				
325	Filters - return air - exhaust air - HEPA filters - Bio containment - BL3-LS	For BL3-LS biotechnology areas, exhaust air should be provided with HEPA filters, which should be bag in, bag out type.				

326	Filters - return air - exhaust air - HEPA filters - dust collectors -Penicillin - antibiotics - cephalosporin	Room return air and dust collection exhausts should be HEPA filtered for penicillins, antibiotics, and/or cephalosporins.				
327	Filters - supply air - HEPA filters - AHU - core areas - Grade D - air handling units	HEPA filters should be provided at the Air Handler Unit(s) for supply air to core processing areas for Grade D				
328	Filters - supply air - HEPA filters - terminal filters - aseptic	All supply air inlets should be provided with terminal HEPA filters, that can be installed, tested, and removed from inside the room for Aseptic areas				
329	Filters - vacuum - HEPA filters - bio containment -	All vacuum lines serving BL3 bio containment areas should be protected with HEPA filters				
330	Humidification -Clean steam - Humidifiers	Clean steam should be provided for humidification, when required. Clean steam can be provided by vaporizing water of acceptable quality. Direct use of boiler steam containing chemicals that are not accepted by the FDA as food grade should not be utilized.				
331	HVAC control systems - manufacturing - aseptic - primary packaging	HVAC Control systems should preferably be field programmable microprocessors w/direct digital control/display for Manufacturing, aseptic, Primary packaging and Secondary Packaging areas				
332	HVAC Drawings - air flow diagrams	Airflow diagrams should be provided to show components in proper air flow sequences. This includes AHU's, flow measuring stations, reheat coils, control devices, air valves, filter locations, humidifiers, exhaust fans, etc. Control system may be shown or covered separately in other drawings.				
333	HVAC systems - dedicated - shared	HVAC systems for subdivisions areas can be dedicated, or shared with another core processing area, as required				
334	HVAC systems - Penicillin - antibiotics - cephalosporin	HVAC systems for the manufacture, processing and packing of penicillin, antibiotics and/or cephalosporin products should be completely independent and separate from those used for other products.				

335	Insulation - ductwork - sheathing - AHU - air handling units	Exposed insulation should be sheathed with a durable, non-shedding, and cleanable material				
336	Insulation - Type - Materials	Insulation/sheathing materials and type should be approved by plant customer.				
337	Monitoring - Air flows	A method should be provided to control and/or balance air flow in and out of pressurized spaces				
338	Monitoring - Air flows - BAS - Building Automation Systems	Air flow should be monitored by means of air flow measuring stations. Air flow rates should be recorded by a Building Automation System or other archiving system				
339	Monitoring - Alarms - BMS - Building management systems	Monitoring alarms should be tied into the Building Management System (BMS) for operator notification.				
340	Monitoring - differential pressure	Actively controlled relative differential pressure should be tracked against one common area rather than between each adjacent rooms				
341	Monitoring - differential pressure - alarms	Differential pressure monitoring systems should be provided with pressure sensors for each monitored room that electronically transmits to a remote monitoring panel and/or computer. The system should have recording & alarm features. It should have a time delay to prevent false alarms being activated by normal room operations.				
342	Monitoring - differential pressure - alarms - aseptic	Differential pressure monitoring should be alarmed to indicate migration from set ranges for aseptic areas				
343	Monitoring - differential pressure - manufacturing - primary packaging - aseptic	Direct reading differential pressure gauges or manometers may be provided for working rooms for manufacturing, primary packaging, and aseptic areas				
344	Monitoring - differential pressure - manufacturing, primary packaging - aseptic	Differential pressure monitoring is required for manufacturing, primary packaging and aseptic areas.				

345	Monitoring - differential pressure - subdivision	If Differential pressure between rooms is required to be recordable due to operational/validation requirements, it should be monitored and alarmed for subdivision areas				
346	Monitoring - particles - level of cleanliness - Grade C	Particle monitoring should be considered for Grade C and cleaner.				
347	Monitoring - probes - system mapping - temperature - relative humidity	Monitoring probes should be provided in warehouses at locations of extreme temperature or other specified conditions based on system mapping of the conditions in summer and winter after installation				
348	Monitoring - relative humidity - warehouses	When special environmental conditions (i.e. humidity, etc.) are specified, validatable monitoring/recording systems with alarms should be provided for those conditions for warehouses.				
349	Monitoring - Temperature - Humidity	Temperature and humidity should be monitored in controlled core areas. Recorder hardware should be installed outside sterile areas, or in "double walls"				
350	Monitoring - temperature - warehouses	Validatable temperature monitoring/recording systems with alarms should be provided for warehouses.				
351	Reheat Coils	Reheat coils should be heated with electricity (multi-stage or variable SCR {silicon controlled rectifier} controls) or hot water.				
352	Sound attenuators	Sound attenuators containing exposed attenuation fill should not be used. Sound attenuation should be achieved through proper system air flow and equipment design.				

A.3.8 ELECTRICAL CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
500	As-built P and I D drawing verification	The system P and I D drawings must be reviewed, verified and updated as required to reflect the "as-built" condition of the system.				
501	Cabinets	Electrical cabinets located in classified areas should have sloped roofs for easy cleaning. The top of the cabinet should be sloped a minimum of 15 degrees. Equipment mounted on the exterior of the cabinet should have minimum crevices and be easy to clean.				

502	Clocks - wall mounting - cleaning - core areas	If a clock system is installed in a core area, the clock displays should be recessed with cleanable and disinfectable surfaces.				
503	Conduit - cables - conceal - warehouse	Maximize concealment of cables in conduit that should be buried in the concrete floor, whenever possible, or routed at roof/rafter level for warehouse areas, whenever possible				
504	Conduit - layout - cleaning	Exposed conduit should be spaced away from walls to facilitate cleaning				
505	Distribution panels - location - warehouse	Electrical distribution panels may be located at strategic places throughout the warehouse in order to minimize long cable runs.				
506	Distribution switch boards - aseptic	Electrical distribution switch boards should not be located in aseptic areas				
507	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
508	Electrical Enclosures	All electrical enclosures should be suitably rated for their environment in accordance with governing codes.				
509	Electrical enclosures - chemically resistant - cleaning	Electrical hardware enclosures should be resistant to chemical attacks by cleaning, sanitization, and fumigant agents that are used in the area				
510	Emergency lighting - battery powered	Battery powered emergency lighting should be provided for personnel and material traffic guidance during power outages				
511	Emergency lighting - emergency communications - core areas	Provide emergency lighting, as well as emergency audible/visual communications, as appropriate.				
512	Emergency lighting - exit lights	Exit lights should be provided at all designated emergency exits				

513	Emergency power - manufacturing - equipment - HVAC - core areas	Provide a source of emergency power for equipment and controls that are critical for any identified process step or product. HVAC systems for critical production, stability, storage, laboratory, and containment areas should be on emergency electrical supply. A list of the critical systems to be powered by the emergency generator should be established.				
514	Grounding	Whole electrical systems (equipment and power outlets) should be grounded in accordance with applicable codes.				
515	Grounding - equipment - conceal	Equipment ground conductors, including grounding straps and cables, should be concealed in core areas.				
516	Grounding - grounding bus	For explosion proof rated areas (NEMA 7 or 9 or equivalent), provide a grounding bus with strategically located grounding terminal plates for core areas				
517	Grounding -equipment - conceal	Grounding plates should be installed recessed and flush mounted with walls so they do not project into the room				
518	Light fixtures - ceiling mounted	Light fixtures should be recessed and flush mounted & sealed in ceiling				
519	Light fixtures - ceiling mounted	If light fixtures can't be installed flush mounted in ceiling, then they must have smooth cleanable sides of minimum depth and a glazed diffuser panel that allows for maintenance access and relamping from within the room. Surfaces are to be free of rims, ridges, bends, and crevices.				
520	Light fixtures - Grade A	In Grade A areas, all lighting fixtures should be flush mounted, triple gasketed or of the tear drop type.				
521	Light fixtures - cleaning - warehouses	Lighting fixtures, which should be enclosed to facilitate cleaning, should be strategically located at or close to roof/ceiling levels in warehouses.				
522	Light fixtures - explosion proof - XP - ceiling mounted - cGMP - cleanroom - NEMA 7 - NEMA 9 - core areas	If explosion proof rated (NEMA 7 or 9, or equivalent) ceiling mounted fixtures are not available with cGMP cleanable and/or clean room design, then ceiling flush mounted, industrial explosion proof fixtures may be used. (Check with Company Global Engineering for guidance prior to proceeding with industrial type fixtures)				

523	Light fixtures - Fluorescent - ceiling mounted	Multiple fluorescent tube lamps should be provided for core areas				
524	Light fixtures -switches - cGMP - cleanroom - cleaning - NEMA - NEC - core areas - hazardous areas - aseptic	Light fixtures/switches should be water-tight, dust tight, designed for cGMP cleanability and/or clean rooms, and meet NEMA code ratings, or equivalent, for the area. For aseptic areas, fixtures must be rated for aseptic service. For hazardous areas, all electrical hardware meets the requirement of the National Electrical Code NFPA 70, article 500.				
525	Light switches - buttons - wall mounted - core areas - aseptic	Light switches and control buttons should be flush mounted with the wall surfaces. Use smooth face touch control type (i.e. diaphragm, membrane faced, or touch pad) for aseptic areas.				
526	Light switches - buttons - wall mounted - fascia plate - core areas - aseptic	Fascia plates for light switches and control button should be stainless and have a smooth surface with beveled edges.				
527	Light switches - Grade A	Clean rooms classified Grade A should have remote light switches, when possible				
528	Light switches - Grade A	If needed in Grade A areas, all light switches have completely sealed flexible covers, which can be sanitized.				
529	Lighting - light sensitive products - yellow lighting - special lighting	Special lighting (i.e. yellow lighting, etc.) should be provided for materials/products that are sensitive to standard lighting				
530	Lighting - safety showers - eye wash stations	All safety showers and eye wash stations should be illuminated.				
531	Lighting hardware - explosion proof - XP - ceiling mounted - cGMP - cleanroom - NEMA 7 - NEMA 9 - core areas	If explosion proof (NEMA 7 or 9, or equivalent) rated lighting hardware is not available with cGMP cleanable and/or clean room design, check with Company Global Engineering for guidance prior to proceeding w/industrial hardware.				

532	Lighting intensity - core areas	Lighting intensity at work surfaces should be 700 lumens/M² min. for core areas				
533	Lighting intensity - inspection areas - core areas	Lighting intensity at inspection surfaces should be 900 lumens/M² min. for core areas				
534	Lighting intensity - warehouses	Lighting intensity at work surfaces should be 300 lumens/M² min., generally, and 500 lumens/M² min. for areas where labels are read in warehouses				
535	Materials of construction -Conduit - finish - sanitary - aseptic	In core areas, wire runs for hook-ups to operating equipment in each module should be located inside a rectangular, light gauge, 304L SS or 316L SS watertight raceway with an exterior surface finish of 150 grit.				
536	Materials of constructions - Conduit - core areas	Exposed conduit or raceway systems/fittings should be Schedule 40 PVC or PVC coated conduit as appropriate for the exposure or area classification. Connections to equipment in clean rooms should be run in stainless conduit or raceway.				
537	Motors, gearboxes, drives, couplings	Motors, gearboxes, drives, and couplings should not be located over product contact surfaces that have the potential to be exposed during some part of the operation unless adequate protection for contamination is provided.				
538	Phone communications - explosion proof - XP - intrinsically safe	If phone communications are required in the core area, provide hardware with clean lines. For explosion proof areas, hardware should be explosion proof or intrinsically safe. For aseptic areas, provide a clean room rated, speaker phone with diaphragm or touch activated face.				
539	Plug receptacles - power receptacles - conceal - core areas	Minimize the number of non-dedicated power receptacles; receptacles should be concealed, flush mounted, sealed type that avoid projection into the core area rooms.				
540	Plug receptacles - power receptacles - stainless utility columns	If temporary/portable equipment is located some distance from the walls, a stainless utility column may be used for power receptacles. Column should be provided with smooth flat surfaces with rounded corners.				

541	Plug receptacles - power receptacles - warehouse	Adequate quantity of power receptacles should be provided to power cleaning and maintenance tools./equipment in the warehouse				
542	Power connections - power hook-ups - equipment	All permanently installed equipment should be provided with fixed power connections				
543	Supports	Supports are 304L Stainless Steel or better with sanitary design and plastic covered threads in clean rooms				
544	UPS - Uninterruptible power supply	There should be a UPS strategy to ensure no deviation in manufacturing.				
545	Variable speed controllers - enclosures - locations	Variable speed controllers should be located inside a properly controlled environment or proper enclosure				
546	Wiring - conduit - communications wiring - electrical wiring - warehouse	All electrical and communication wiring that are routed less than 10 ft. above the floor should be enclosed in conduit that should be protected or buried in the floor. Use separate conduit for communications and electrical wiring.				

A.3.9 PROCESS/UTILITIES CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
750	As-built P and I D drawing verification	The system P and I D drawings must be reviewed, verified and updated as required to reflect the "as-built" condition of the system.				
751	Check Valves	- The use of check valves for hygienic piping systems is not recommended. The use of check valves should be thoroughly examined for these applications.				
752	CIP Supply Piping	- CIP supply should be designed for a minimum of 5 fps velocity in the process piping. Velocities for cleaning piping should be designed to keep the lines fully flooded.				

753	CIP systems - cleaning - piping - equipment	- CIP system should be provided for cleaning vessels, piping, and equipment in the core areas. When a CIP system can't be installed, equipment should be easy to dismantle and accessible for manual cleaning and inspection.				
754	CIP systems - location - Mechanical area	- To prevent contamination in a core area room, the CIP system should be located in a separate mechanical area.				
755	CIP systems - Piping - line sizing - fluid velocity	- Line sizes have been checked for adequate CIP velocity.				
756	Compressed air - air conditions - air specs - oil free process air - instrument air - dryers	- Compressed air should be dry/oil-free. System should use downstream dryer w/prefilter. Compressed air should be suitable for process and/or instrument supply air (dryness should be a dew point of minus 40°C).				
757	Compressed Air/Nitrogen	- For product contact compressed air/nitrogen, distribution piping MOC should be consistent with the quality specification Acceptable materials are 304SS, 316SS, plastic or plastic lined steel and copper (with point of use filters) depending on the classification of the area.				
758	Compressed air - filters - sterile filters	- Compressed air distribution should be provided with filters that are appropriate for end user applications. 0.2 micron final sterile filters should be provided at point-of-use if in contact with product or product containers. Fibrous materials, such as cotton, should not be used for filter media.				
759	Compressed Air/Nitrogen	- For product contact compressed air/nitrogen, system design should allow for sampling during PQ and for operational reasons.				
760	Clean Steam	- Boiler additives should not be used unless specifically listed as a CFR approved additive.				
761	Condensate traps - drains - sanitary - sterilizing - utility lines	- Sterilizing points in sanitary utility lines should have condensate traps and the sterilized line should be drainable. The trap should be designed such that the normal mode of mechanical failure is in the open position.				

762	Diaphragm Valves	- Diaphragm valves are recommended for bioprocessing fluid applications.				
763	Document review and approval for direct impact systems	Ensure that Quality Operations reviews and approves the URS, the impact assessment, the commissioning plans, the protocols, and final reports for qualification				
764	Drains - Clean Utilities - condensate	- Clean utility systems should be provided with self-drainage so that condensate should not collect.				
765	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
766	Environmental conditions - outdoors - cooling towers	- Cooling tower design should be based on local meteorological conditions.				
767	Equipment - layout - Cleaning - Maintenance	- All equipment should be located to facilitate cleaning, maintenance and proper operations.				
768	Exchangers - tube sheets - drains - WFI	- Heat exchangers on WFI water system should be fully drainable. Double tube sheets should be provided.				
769	Filters - Quantity - filter changes - shutdown	- Main line filters (pre- and sterile) should be double or in parallel, so that a filter can be changed without shutting down, when required by the process.				
770	Filters - sterile filters - core areas - aseptic	- Sterile filters should be located in a sterile or aseptic area for proper changing of filters.				
771	Fire sprinkler heads - low profile - concealed type - ceiling - secondary packaging	- Sprinkler heads should be low profile or concealed type for location at ceiling level for secondary packaging areas				

772	Fire sprinkler heads - sanitary -ceiling - subdivision - manufacturing - aseptic - primary packaging	- Sprinkler heads, which should be concealed type with sanitary design, should be located in isolated pockets in the ceiling for subdivision, manufacturing, aseptic, and primary packaging areas. Pockets should be sized to facilitate cleaning and maintenance of the heads. Pockets should be closed with a flush mounted cover plate				
773	Fire sprinkler piping - layout - routing - conceal - core areas	- Fire sprinkler piping should be concealed in core areas				
774	Fire sprinklers - collection tanks - fire water	- Fire sprinkler collection tanks should be provided for retention of fire water prior to testing for compliance with plant effluent and then discharge to plant effluent				
775	Flexible connections - flexible hose connections - sanitary - core areas	- Flexible end and hose connections should be sanitary design, bonded to hoses in a crevice free manner, and fit for the operating service/purpose in core areas				
776	Flexible connections - flexible hoses - lengths - cleaning	- Flexible connections or hoses should be sanitary design for core areas. Components should be cleanable for designated utility/process services and for specified lengths. Length should be minimized & generally should not be longer than 20 ft. Avoid in CIP systems unless properly supported.				
777	Fluid velocity - Purified Water	- Fluid velocity for Purified Water lines should be 5 feet per second or a minimum velocity to achieve turbulent flow.				
778	Materials of construction - Piping - Utility piping - secondary packaging	- Utility piping should be compatible with the utility service and the external finish should be resistant to chipping, flaking or dusting for secondary packaging areas				
779	Materials of construction - Flexible connections - flexible hose connections	- Flexible connections and hoses should generally be stainless steel, Teflon or silicon.				
780	Materials of Construction - Piping - Sanitary - Utility Piping - Vessels - Utilities	- Critical sanitary utility piping and vessels should be 316L stainless steel.				

781	Materials of construction - Piping - Utility piping - Compressed Gases - end connections - core areas - sanitary	- All utility piping in the core areas should be welded 316L stainless steel with tri-clover "sanitary" type connections. Other materials may be appropriate (i.e. Kynar, etc.) if compatible with the service and allowed by local/Company guidelines.				
782	Materials of construction - Piping - Utility piping - Distribution piping - Clean utilities	- Distribution piping for clean utilities (i.e. clean steam, USP water, etc.) should be 316L stainless steel. All welds are ground flush to same finish as piping. Kynar & PVDF could also be considered when compatible with the service and allowed by local/Company guidelines.				
783	Materials of Construction - Piping - Utility piping - WFI	- WFI water piping should be 316L stainless steel (preferred) or polyvinylidene fluoride (PVDF)				
784	Materials of Construction - Piping - Utility piping - stainless - welded - utilities - core areas	- Stainless steel piping with welded fittings should be used for all utility piping that is run in the subdivision, manufacturing, and primary packaging modules				
785	Materials of Construction - valves - high purity water - WFI	- For high purity water and WFI, the material of construction for rupture discs, valves and sanitary parts should be 316L stainless. Internal component materials should be able to withstand steam sanitization.				
786	Materials of Construction - Vessels - finishes - WFI	- Hot WFI water storage tanks should be 316L stainless steel with surface finish of 20-30 rms or better. All welds should be ground smooth to same surface finish.				
787	Orifice Plates	- Orifice plates used in hygienic piping systems should be installed in a fully drainable position.				
788	Piping - circulating loop - connections - drains - sanitizing - WFI - SIP	- All use-points/take-offs in the WFI water loop should be fully drainable and have SIP connections from the Clean Steam header.				

789	Piping - Circulating loop - drains - sanitizing - WFI	- The WFI water loop should be continuous, fully drainable and capable of complete loop, high point sanitization.				
790	Piping - circulating loop - sub-loop - drains - WFI	- Cooled WFI sub-loop piping and use points should be fully drainable. If sub-loop water is returned to the hot loop, then proper pre-heating should be provided.				
791	Piping - Circulating loop - operating temperature - WFI	- A WFI water hot loop should be designed to circulate water at 80°C min. in order to be self-sanitizing. All loops, including cold and ambient, should be capable of full draining and SIP.				
792	Piping - cleaning - draining - dead legs - double block and bleed - CIP - Clean in Place	- Piping for CIP should be designed with no dead legs, be self-draining, and should be isolated from product when not in use (e.g. use double block & bleed assembly).				
793	Piping - double block and bleed - WFI - clean steam	- A double block and bleed arrangement should be used when clean steam is connected to a WFI water system.				
794	Piping - External finish	- Stainless piping, which is not insulated, in core areas should have an exterior polish of approximately 150 grit, or equivalent Ra				
795	Piping - Layout - Cleaning - core areas	- Pipe located in core areas are designed to minimize horizontal surfaces and to facilitate cleaning. Pipe shall be suitably spaced, and have insulation with sufficient strength, so that all exposed areas can be easily cleaned.				
796	Piping - purging - filters - Clean Utilities - compressed gases - CIP	- Compressed gases (nitrogen or air), which may be used to purge process systems, should use sanitary piping & should be provided with 0.2 micron filters) CIP systems should be designed to allow complete purging (with compressed gases) and maintenance.				
797	Piping - Sample connections - samples - sanitizing - WFI/Purified Water/ High Purity Water	- Sample valves should be provided on use points for WFI/Purified Water/High Purity Water Systems to allow for sampling during PQ and for ongoing monitoring. Sample valves should be located in an easily accessible location, and as close to the point of use as feasible.				

798	Piping - Utility piping - connections - walls	- End connections for utility piping should be terminated at a mounting plate that is level with the wall surface or 6 mm below (preferred) below the wall surface				
799	Piping - Utility piping - connections - walls - fascia plate	- 316L stainless fascia plate with beveled edges and no sharp corners should be provided level with the wall surface for utility pipe connections				
800	Piping - Utility piping - layout - routing - cleaning - subdivision - manufacturing - primary packaging	- If utility piping can't be avoided in subdivision, manufacturing or primary packaging module, it should be installed w/sufficient space between the wall to allow access for cleaning				
801	Piping - Utility piping - layout - routing - secondary packaging	- Utility piping may be concealed or run exposed in secondary packaging areas				
802	Piping - Utility piping - layout - routing conceal - subdivision - manufacturing - primary packaging	- Utility piping should be concealed and run in wall chases, service areas or service corridors for the subdivision, manufacturing and primary packaging modules				
803	Piping - Utility piping - welded	- Joints should not be used for welded pipe runs within walls				
804	Piping - Waste -Process Waste - Sanitary waste	- Dedicated pipe lines should be provided for sanitary waste and process waste lines that are routed to waste treatment to avoid cross-contamination. Consider air breaks for back flow prevention.				
805	Piping connections - Purified Water	- In stainless steel Purified Water systems, all connections should be sanitary and all parts should be sterilizable.				
806	Piping Connections - sanitary	- There should be no threaded connections in any sanitary systems. Connections should be welded with sanitary fittings.				

807	Piping- Drainability	Sanitary piping systems should be sloped to allow for free drainage. Lines should be pitched at the specified rate and direction. In no case should the pitch be less than 3 inches/50 feet. A minimum slope of 2% is generally recommended for short piping runs. Less of a pitch is acceptable for long runs.				
808	Piping Insulation - cold service	- Anti-sweat insulation should be used for pipe line services with temperatures below ambient				
809	Piping Insulation -sheathing - jackets - covers - cleaning	- Insulated piping in core areas should have a sealed cleanable outer covering to permit washdown. Generally, this covering is fused plastic sheathing or stainless steel.				
810	Piping Insulation -sheathing - jackets -covers - personnel protection	- Personnel protection insulation for intermittently steamed lines should be provided as necessary.				
811	Pumps - centrifugal pumps - Purified water - WFI - DI	- WFI and DI water pumps can have single or double mechanical seals, and should be sanitary centrifugal design.				
812	Pumps - Purified water - centrifugal - mechanical seals	- Purified Water pumps should be sanitary centrifugal design with single or double mechanical seals. Pump casings should have suitable drainage.				
813	Purified water - membrane filtration - distillation - still - hardness	- If incoming water has a high hardness or metal composition, membrane filtration or a multi-effect still should be used for purified water systems. If hardness of less than 2 ppm is required, softening system should be incorporated.				
814	Purified water - carbon beds - sanitization - drains	- If carbon beds are required for the purified water system, sanitization and drainage of the bed should be provided.				
815	Purified water - filtration - suspended solids - sanitization - drains	- If barrier filtration is used in the purified water system, adequate means for drainage and sanitization should be provided.				

816	Purified water - ion exchange - filtration - carbon beds - ozonator - ozonizer - organic impurities	- If incoming water has high organic impurities, suitable ozone, ion exchange or filtration, including carbon beds, should be used for purified water system.				
817	Purified water - membrane filtration - suspended solids	- If incoming water has low concentration of suspended solids, membrane filtration should be used for purified water systems. If SDI (Silt Density Index) of 3-5 is required, filtration should be incorporated.				
818	Purified water - softeners - sanitization - drains	- If softening is incorporated in the purified water system after chlorine removal, adequate means for drainage and sanitization should be provided.				
819	Purified water -ozonator - ozonizer	- When an ozonizer is used for the purified water system, residual ozone levels should be addressed from employee safety, product & system perspectives.				
820	Purified water -ozone residual - ozone analyzers	- If ozone residual is critical, an ozone analyzer should be installed to verify that all ozone has been destroyed.				
821	Seal Fluids	- Food Grade materials should be used. If seal fluid can potentially leak into the product, its impact on product quality must be assessed.				
822	Utility capacity	- Utility system capacities should be based on anticipated process operating extremes.				
823	Utility capacity - heating - cooling	Cooling and heating capacities should have a 30% a spare margin.				
824	Utility panels - aseptic	- Utility panels should not be provided in aseptic areas				
825	Utility panels - cleaning - manufacturing	- Utility panels should be provided with smoothly sloping surfaces that are easily cleanable for manufacturing areas				
826	Utility panels - drain connections	- Utility panels should be provided with trough and drain connections to catch spills and drips, if possible				

827	Utility panels - maintenance	- Utility panels should be demountable for repair/servicing in manufacturing areas				
828	Utility panels - manufacturing, primary packaging	- Utility panels w/front cover should be recessed in the wall to give a flush wall surface for manufacturing areas				
829	Utility panels - stainless	- Utility panels should be polished stainless steel				
830	Utility pressure - cooling	- Cooling fluid pressures should be lower than pressure of the process liquid being cooled.				
831	Vacuum lines - cleaning - chemically resistant - bio containment - BL3	- All vacuum lines for BL3 bio containment areas should be cleanable and chemically resistant to chemical biocides.				
832	Vacuum Lines	- Protection against backflow in case of a power outage is required.				
833	Vacuum Lines	- Vacuum systems not dedicated to one process system are a potential source of cross contamination. Multi-process vacuum systems need to be thoroughly reviewed during the design phase.				
834	Valves - block valves - diaphragm valves - tie-in points - Clean steam -	- Where Clean Steam is connected to a process line, a sanitary valve should be the main block valve.				
835	Valves - sanitary connections - utility valves - Subdivision - manufacturing, aseptic - primary packaging	- Valves with sanitary cGMP fittings/connections should be provided for utility connections in the manufacturing and primary packaging areas. Sanitary design valves should be provided for aseptic areas.				
836	Valves - Utility valves - secondary packaging	- Valves should be compatible with the service and comply with cGMP for utility connections in the secondary packaging areas				
837	Vessels - Spray balls - Purified Water	- Purified water storage tanks should be fed with spray ball(s) inside the tank. This permits all surfaces to be constantly washed for microbial/corrosion control				

838	Vessels - spray balls - WFI	- Hot WFI water storage tank should receive the circulated or fresh water through spray ball(s). Sterile vent filters, rupture disks and connections should be sanitary type.				
839	Vessels - vent filters - integrity testing - Purified water - WFI	- Vent filters on WFI and purified water storage tanks should allow for integrity testing (off line or in-situ)				
840	Vessels - vent filters - sterile - jacketing - heating - heat tracing - WFI	- In WFI water hot loop storage, vent filter should be jacketed and heated to prevent condensation, or electronically heat traced.				
841	Vessels - vent filters - sterile - WFI	- All WFI water storage vessels should be equipped with sterile vent filters with a pore size 0.20 micron. Design should be cartridge type and hydrophobic.				
842	WFI - Distillation - still	- Distillation should be used for producing WFI water.				
843	WFI - inerting - nitrogen blanketing - carbon dioxide absorption	- In WFI water hot loop storage, absorption of carbon dioxide and its effect on pH should be considered. If critical, an inert nitrogen blanketing system should be provided.				

A.3.10 PROCESS EQUIPMENT CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
1000	As-built P and I D drawing verification	The system P and I D drawings must be reviewed, verified and updated as required to reflect the "as-built" condition of the system.				
1001	Autoclaves - air intakes - air exhaust	For an autoclave, air intake should come from the clean area, and the air exhaust should be vented outside clean areas.				
1002	Barrier isolators - Transfer ports - interlocks - Alpha - Beta	All barrier isolator transfer ports (Ex: Alpha/Beta type) should be provided with interlocks and be interchangeable.				

1003	Barrier isolators - differential pressure	The barrier isolator should be at positive or negative pressure (dependent on process requirements) and relative to the operating room. Typically for toxic/potent it is negative pressure and for aseptic it is positive pressure.				
1004	Barrier isolators - materials of construction - chemical resistance - Cleaning	All materials of construction should be compatible with any solvents or cleaning/sanitizing materials to be used within the barrier isolators				
1005	Barrier isolators - openings - ports - breach velocity - toxic - potent - instrumentation - Safety	For toxic/potent processes, barrier isolator should be designed to maintain 98 FPM (0.5m/sec) breach velocity thru two fully open glove ports. Isolator should have audible/visual alarms to warn operators of breach conditions.				
1006	Barrier isolators - air changes	For conditions that require turbulent air flow, a barrier isolator should be designed such that there is a minimum of 20 air changes per hour.				
1007	Barrier isolators - Cleaning - aseptic	If the process requires aseptic conditions, the barrier isolator should be designed such that all product contact surfaces are capable of being sanitized/sterilized.				
1008	Barrier isolators - Connections - utility - sanitary - Cleaning	Sanitary fittings should be used for cleaning utility services within a barrier isolator				
1009	Barrier isolators - filters - environmental conditions - cleanliness level - air quality	All air should be filtered in and out of a barrier isolator in order to achieve the air cleanliness requirements for the process				
1010	Barrier isolators - filters - safe change - toxic - potent - safety	If the process being undertaken in the barrier isolator involves a toxic or potent product, all filters should be safe change type				
1011	Barrier isolators - laminar air flow - instrumentation	For conditions that require uni-directional laminar airflow, a barrier isolator should be fitted with airflow and pressure gauges/alarms to ensure the correct airflow conditions would be achieved.				

1012	Batch Loading - equipment	For pharmaceutical equipment designed to be loaded by batch (e.g. autoclave, lyophilizer, etc.), a typical load and loading pattern has been identified.				
1013	Centrifuge	The centrifuge manufacturer should identify all areas of primary and incidental product contact that require manual cleaning in addition to CIP.				
1014	Change Parts - Quantity - equipment	There should be sufficient change parts to accommodate all products to be filled.				
1015	CIP Devices	All CIP devices should be drainable and self-cleaning. The location and number of spray devices should be chosen to minimize shadowing at internal parts. Sparger and dip pipes should include an adequate number of drainage holes to ensure full drainage.				
1016	Cleaning - Equipment	All product contact surfaces should be capable of being sanitized and/or sterilized, where appropriate.				
1017	Document review and approval for direct impact systems	Ensure that Quality Operations reviews and approves the URS, the impact assessment, the commissioning plans, the protocols, and final reports for qualification				
1018	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
1019	Explosion proof - dust explosions -equipment - Safety	Whenever powders are being handled, appropriate precautions should be taken against dust explosion. The MSDS (with indication of the minimum ignition energy) of all the powders being handled should be available.				
1020	Exterior Design	Equipment located in clean areas will be periodically wiped down with cleaning solutions. The exterior design should be compatible with the area classification. All exterior components should be capable of being chemically cleaned, steam cleaned, or pressure washed. All burrs and weld marks should be removed. Hinges should be easily removed and/or cleaned.				

1021	Filling Equipment - Fillers - laminar air flow	For filling inside a Class 100 or better environment, the filling hardware should be designed so as not to disrupt laminar flow air patterns around: - Filling head during filling - Stoppering heads - Any areas where the product container is open				
1022	Filling equipment - fillers - Rejects	In the case of a filling machine, the filler should be able to reject units which are outside the filling acceptance criteria.				
1023	Pumps - sanitary design	All pumps handling the product should be of sanitary design.				
1024	Spares- Bioprocessing	The use of installed spares for in line equipment is not recommended for bioprocessing operations. The use of warehouse spares is preferred, with the system designed for ease of installation of the equipment.				
1025	Transfer - closed transfer - Containment	Closed containment and transfer methods should be used.				
1026	Vent Filters	Vent filters for hot process services should be steam jacketed or heat traced to prevent bacterial contamination.				
1027	Vessels/Hot Fluids/Design/ Vacuum	Where SIP, Hot WFI, or CIP processes where hot cleaning solutions (176 F, 80C) are used, vessels should be designed for full vacuum service.				
1028	Vessel Nozzles	All nozzles being cleaned by a spray device located inside the vessel should be designed to minimize the L/D ratio, with a target L/D design value of 2:1 for nonflow-through nozzles.				
1029	Vessel Nozzles	Nozzle connections less than 1 inch are not recommended for process vessels.				
1030	Weigh stations - weigh rooms - manual - automated	Weigh stations should allow for manual, as well as automated operation.				

A.3.11 PROCESS CONTROL/INSTRUMENTATION CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
1250	As-built P and I D drawing verification	The system P and I D drawings must be reviewed, verified and updated as required to reflect the "as-built" condition of the system.				
1251	Control Panels – finish	Exposed front portion of control panels should be polished to 30 – 40 Micro inches RA.				
1252	Calibration requirements	Instrumentation calibration requirements should be reviewed. Calibration frequency, type of calibration required (factory, bench, on-line) and a review process for new or one of a kind instrumentation. New calibration instrumentation/devices may be required to support a new instrument type.				

1253	Control Panels – location – Door swing - Panel swing	Control panels should be located for easy access. Control panel door swing radius should not interfere with the surroundings.				
1254	Control panels – manual back-up	Local manual back-ups panels should be provided in accordance with the project control philosophy.				
1255	Control Panels – UL rating	The control panels should be UL rated.				
1256	Control Panels – wall mounted – cleaning – drain	Wall-mounted control panels should be mounted flush with the wall surface or the exposed top portion slope should be at 45 degree to facilitate wipe down cleaning and draining.				
1257	Control Valves – sanitary diaphragm	For aseptic and sterile processes, process control valves in contact with product should be sanitary diaphragm valves.				
1258	Critical instruments – Bypasses/Drain lines Maintenance	Temporary bypasses around critical in-line instrumentation, and drain lines should be considered in the design.				
1259	Critical Instruments – definitions	Critical Instruments, which are defined as hardware where malfunction could affect the quality of the product, or that come in contact with the product, should be identified.				
1260	Critical Instruments – Instrument ranges – Calibration settings - QO – validation	QO should review and approve all instrument ranges and calibration settings for critical instruments during detail design				
1261	Critical Instruments – isolation seals – isolation valves Calibration – Maintenance	Critical instruments should be provided with isolation components (i.e. diaphragm seals, valves, etc.) so that hardware can be removed during their calibration/maintenance without exposing the process environment to the room environment. Consider methods of emptying/isolating lines to prevent/limit personnel exposure to process and/or piping contents.				
1262	Documentation requirements	Documentation requirements should be reviewed and understood prior to issuing a specification for instrumentation.				

1263	Document review and approval for direct impact systems	Ensure that Quality Operations reviews and approves the URS, the impact assessment, the commissioning plans, the protocols, and final reports for qualification				
1264	Drawing approval	Ensure that engineering drawings are reviewed by a second person at the engineering design firm				
1265	Electrical Enclosure Ratings – Instruments – NEMA – NEC	The NEMA/NEC rating of unenclosed instruments and enclosures must meet or exceed the area classification. If purge panels are required, area classification alarm and purge requirements and capabilities should be reviewed.				
1266	Factory Calibration	If instruments are factory calibrated, determine the number of calibration certificates required and the acceptable results.				
1267	Instrument sensors – non-intrusive – metal diaphragm seals	Primary instrument sensors should preferably be non-intrusive type. Pressure instruments should be metal diaphragm type.				
1268	Instruments – Diaphragm seals – FDA	When necessary, in-line instruments should be provided with diaphragm seals with FDA acceptable liquid (valves are not acceptable).				
1269	Instruments – Electrical Protection – Electromagnetic – Radio Frequency – Electric Static	Electrical instruments should be mounted away from sources of electromagnetic, radio-frequency, and static sources, wherever possible.				
1270	Instruments – Local Displays – local readouts	Wherever possible, instruments should have or be capable of a local display (if signal is transmitted remotely).				
1271	Instruments – pneumatic – instrument air – sterile air – core areas	Instrument air in classified core areas should be supplied from sterile filtered air.				

1272	Instruments – Utilities – connections – challenge points – recorders -	Instrumentation and ports for clean utilities (i.e. clean steam, USP water, etc.) should be provided at challenge points. Recording capability should be adequate for the utility service.				
1273	Instruments – Utilities – cooling – heating – Battery limits -	Cooling and heating systems should be instrumented at system battery limits to measure temperature, pressure and flow, as required.				
1274	Instruments – Vessels – Mounting Pads – flush mounted – CIP – SIP	Instruments mounted on vessels that require CIP/SIP should be flush mounted on pads to eliminate nozzle extension dead legs.				
1275	Instruments –Connections – fittings – Sanitary	Sanitary fittings should be provided for all instrumentation for the process and clean utilities.				
1276	Instruments-Documentation requirements	Documentation requirements should be reviewed and understood prior to issuing instrumentation specifications				
1277	Materials of Construction – Instruments	Materials of construction of process instrumentation in contact with the product is 316L stainless, or compatible with product and cleaning agents.				
1278	Passivation/Cleaning Requirements	Determine if there are any cleaning or passivation requirements for the specified instruments.				
1279	Pressure relief – rupture disks – sizing – SIP	Rupture disks, relief valves, etc. should be sized to accommodate SIP operations that may be required.				
1280	Transmitters – Control Panels – Aseptic – Core Areas	Transmitters should be located outside of classified core areas. Transmitters and remote mounted devices, which would need to be located in core areas due to any hardware transmission limitations, should be inside panels or interstitial spaces.				

A.3.12 SECURITY CHECKLIST

ID No.	Key Words	cGMP/GEP Requirements (Current Good Mfg./Engineering Practices)	Part of Design Basis (Y/N/NA or On Hold)	Design Documents and Sect. Nos.	Action Required, if not Addressed	Completion Initials / Date
1500	Airlocks - Door interlocks - controlled access - security	- Airlock doors should be electrically interlocked. Wall mounted push plates open the doors. Emergency panic bars on the door allow manual override in case of loss of electrical power.				
1501	Security - CCTV - closed circuit TV - warehouses	- CCTV (closed circuit TV) should be provided for the exterior building and interior loading docks. Avoid layouts that prevent monitoring exterior areas				

1502	Security - control systems - controlled access - core areas	- Controlled access, security systems for core areas should have: 1) Ease of programming for making changes 2) Multiple levels of security 3) Protection against vandalism/sabotage 4) Capabilities for future expansions/retrofits				
1503	Security - controlled access - visitors - warehouses	- Provide for entry of visitors to warehouse thru warehouse office area				
1504	Security - controlled access - warehouses	- Provide restricted or controlled access doors for external entry points (i.e. truck docks, rest rooms, offices, etc.) to warehouses				
1505	Security - controlled access - warehouses	- Provided controlled access door between warehouse and loading & unloading areas				
1506	Security - controlled access - warehouses	- Identify any special warehouse access control requirements based on: 1) Cost/type of materials 2) Local code requirements				
1507	Security - corporate security - site security - warehouses	- For warehouse security systems, consult with Corporate/local security to address their requirements				
1508	Security - doors - windows - monitoring - warehouses	- All exterior doors and windows in the warehouse should have suitable detection/monitoring equipment				
1509	Security - exterior lighting - warehouses	- Exterior warehouse lighting should be provided to prevent shadows that conceal intruders. Address allowance for parked trucks/trailers overnight				
1510	Security - staging area - loading unloading - warehouses	- Provide segregated staging area for materials to be loaded/unloaded				
1511	Security - truck drivers - warehouses	- Provide segregated area (accessible from outside) for drivers to prepare any paper work				

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