extraktLAB®

SERVICES

Equipment Process & Layout Design

DESCRIPTION

Process and layout design defines the basis of the process design along with the associated equipment and its interaction with the material and information flow of the facility. The process design specifies the supporting utilities, HVAC systems, sanitary locations, room specifications, special piping and instrument requirements, locations of utilities relative to the equipment and the actual process itself. The process design also specifies the expected capability of the process.

Typically companies design their facility to meet GMP requirements and to accommodate the equipment required by conducting a process and layout design. After the process is completed, the design is typically commissioned to ensure that it is built correctly and according to all the specifications that are in the process documentation.

Phase 1: Identification & Definition

Once stakeholders are identified, they will provide product definition and quality specifications for the desired products. This is also when the stakeholders define the desired current and future capability goals for the production facility.

Phase 2: Review Drawings & Utilities Identified

Existing site and as-built architectural drawings are reviewed and locations of existing walls, HVAC, sanitary and utilities identified. If drawings are not available, drawings will need to be made by the Customer and verified by United Science.

Phase 3: Virtual Inspection & Approval to Proceed

At this point, the customer will facilitate a virtual inspection of the facility with the stakeholders to verify utility locations. Based on the supplied drawings and the virtual inspection, approval is given to proceed for the initial process design options to begin.

Phase 4: Onsite Review & Risk Identification

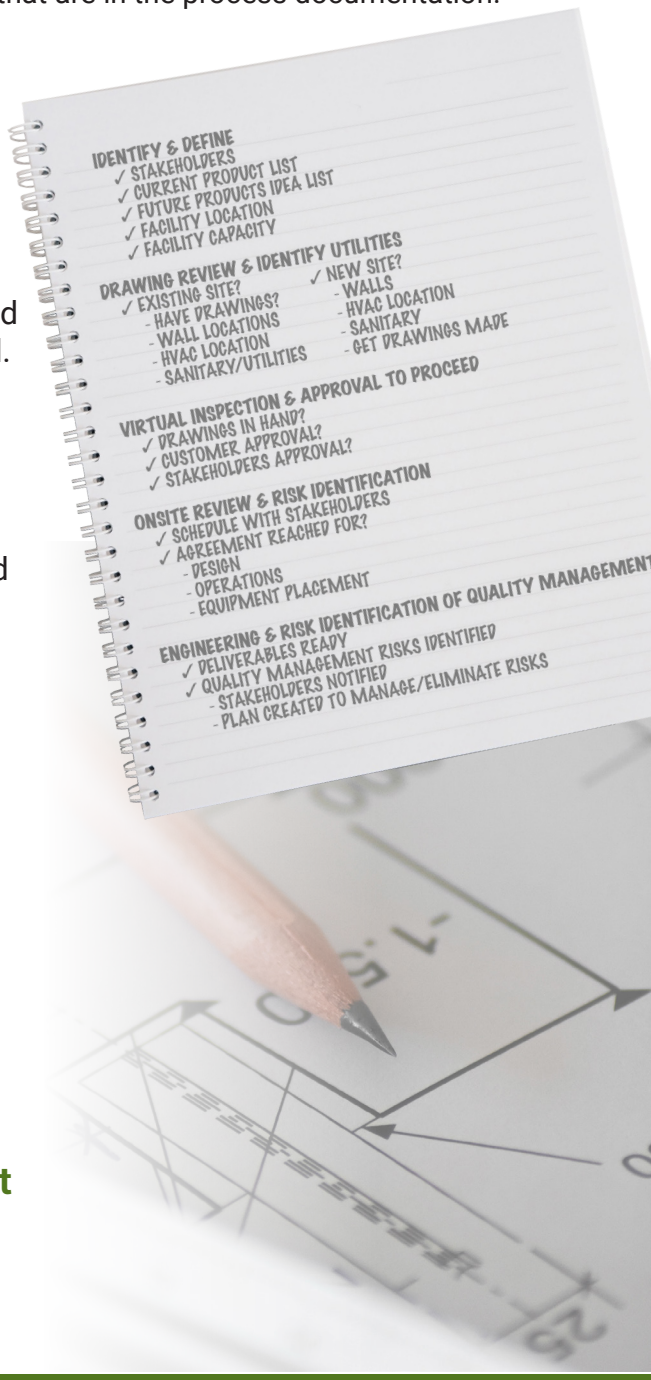
It is time for an on site design review with all stakeholders. The purpose of this review is agreement on the basis of design: the unit operations, identify risks, obtain approval for workflow and initial equipment placement, and to agree on process capability for the design. Once approvals incorporating all stakeholder inputs in addition to identifying risks for the design have been obtained, then the engineering phase can begin.

Phase 5: Engineering

Engineering the agreed upon processes for design and creation of the Deliverables.

Phase 6: Risk Identification of Quality Management

Stakeholders are informed of identified risks impacting the quality and specifications of the proposed products. These risks are managed and or eliminated by process or facility risk management.



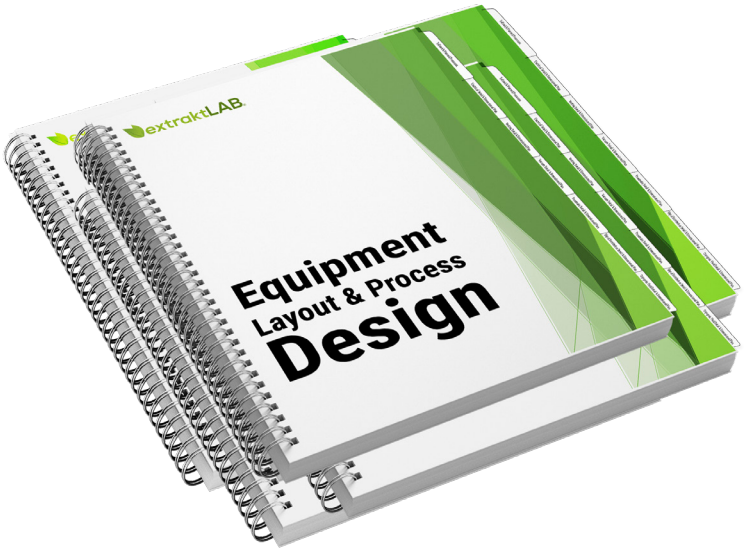
DELIVERABLES

Process Design Foundation

Identify & Define All Utilities Required for Each Process
Equipment Layout for Each Process
Material Flow Between Processes
Dimensioned Equipment Layout by Process Room
HVAC Details: Heat Loads, Positive Pressure Locations, Fugitive Emissions, and Minimum Air Exchanges
Chemical Inventory
Storage, Open Use, and Closed Use Defined by Process
Definition of Flammable Control Area

Process Design

Defined & Planned Processes for Raw Goods, Quarantine, Process, Hazardous, In-process, Waste and Finished Goods Areas
Electrical Detail & Dimensioned Plan for Equipment Placement by Process
Venting Detail & Dimensioned Plan for Equipment Placement by Process
Vacuum Detail & Dimensioned Plan for Equipment Placement by Process
Pneumatic Detail & Dimensioned Plan for Equipment Placement by Process
Glycol Distribution Detail & Dimensioned Plan for Equipment Placement by Process
Cryogenic Fluid Detail & Dimensioned Plan for Equipment Placement by Process



Please Note: Product is information & specialized knowledge.
We do not engineer your facility, we work with your engineers to implement a turn-key production facility.

ADDITIONAL NOTES:

- Design phase shall not exceed 3 months and includes one design. If the design phase takes more than three months, the contract shall be considered fulfilled even if the engineered drawings are not delivered.
- Additional designs will be charged $5,000 USD per design.
- Once there are engineering drawings, if the building changes there will be an additional 30% charge of the list price for additional engineering and to update the plan.
- The customer is responsible for approving and qualifying the process design.

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To Order: Part #80-9607

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