

> COMMISSIONING

Maetrics engineers have degrees in Engineering, Chemical, Mechanical, Industrial, Biomedical and related disciplines with experience in FDA regulated industries. This experience refers specifically to the pharmaceutical, medical device and biotech industries. They are experienced in identifying and defining processes and equipment for manufacturing of medical devices or drugs including experience in process validation, equipment qualification and equipment validation. Some specific applications of these capabilities include mixing equipment, filling equipment, vessels, autoclaves, freeze dryers, packaging equipment, cleaning equipment, HVAC, WFI and purified water systems.

Our engineers have developed and executed commissioning, qualification and validation project plans. These capabilities include past experiences performing review of vendor documentation and compilation of engineering turnover packages, equipment/system inspections, start-up and commissioning, factory and site acceptance testing and the development and execution of commissioning and qualification programs. They have authored all equipment protocols required for assigned capital projects including FAT, SAT, CSV, IQ, OQ and PQ, and have been responsible for reviewing progress vs. schedule vs. cost with appropriate teams.

> EXAMPLE CASE STUDY #1

Initial State

Manufacturing facility was designed and qualified as a Research & Development facility.

Objective

Primary objective was to transition the multi-product vaccine production start-up facility from a non-GMP/Process Development state to full GMP Compliance.

Maetrics Engagement

All applicable systems and equipment were successfully transitioned to a state of compliance through some of the following activities:

- Qualified process systems and equipment in a newly constructed manufacturing facility for the production of Phase II/III clinical material. Collaborated on pre-purchase specifications, design drawings and sketches, P&IDs, PFDs, vendor submittal and bid tabulation reviews, project coordination and scheduling. Participated in project functions from the design phase through production start-up and remained on-site for all stages of construction.
- Participated in cross-functional team meetings, quality audits, FATs, commissioning reviews, system troubleshooting and root-cause analysis.

- Developed and reviewed SOPs, equipment qualification protocols (IQ, OQ) and templates. Provided training on new SOPs and protocol formats.
- Coordinated and reviewed metrology and equipment certification efforts while maintaining and organizing records. Developed calibration matrix to easily and efficiently monitor dates, contractors and instrument identification numbers.
- Developed and executed equipment qualification protocols (IQ, OQ, PQ), SOPs and final reports for various process equipment including legacy equipment following recommissioning. Proposed and implemented procedural and equipment modifications in compliance with Quality System Regulations.
- Coordinated validation efforts with internal corporate departments such as Manufacturing, Engineering, Facilities Management and Quality Assurance for the development and execution of validation project planning.

Results

By utilizing the strengths of Maetrics' engineering experts, this Biologics facility efficiently and cost-effectively realized GMP compliance. They were able to begin production in their new capacity well on schedule, saving money, and most importantly, time.

> EXAMPLE CASE STUDY #2

Initial State

The Air Handling Units (AHUs) for a Global Manufacturer were being commissioned. The manufacturer regularly provides conditioned and often filtered air supply to the following areas:

- Manufacturing
- Packaging
- Fill
- Support Areas
- Amenities

The Building Management System (BMS) HVAC controls and monitors the supply of air to the above identified areas. AHU control is maintained through the controllers, and the BMS Human-Machine Interface (HMI) provides a window to the controllers for maintenance and troubleshooting. The HMI and AHUs interface with the Network Control Unit (NCU) to provide status verification of all field equipment. The NCU stores data for AHUs and related devices to perform controller programs for data upload and download. For BMS communication, interface between HMI and NCU IP addresses is provided through low level communication with Plant Automation Ethernet (information) system.

Objective

The primary objective is to verify that the BMS HVAC connects AHU controllers together and provides an interface to the controllers for maintenance and troubleshooting the AHU operation.

Maetrics Engagement

All of the activities and tasks within the scope of the Commissioning were satisfactorily completed. The activities appropriately challenged and demonstrated that the BMS HMI, BMS Network Controller and AHUs were correctly interfaced, and reflected the system's current operational status.

- There were four (4) commissioning test cases successfully reviewed and executed, and no deviations were recorded during the execution of the protocol.
- Documentation was generated for the installation requirements, and IP addresses of the BMS HMI and Network Control Module.
- A Disaster Recovery procedure was written to facilitate building and system compliance with the site IT Master Validation Plan in case recovery is needed from any scheduled and unscheduled power loss to the BMS.

Results

This manufacturer now has the assurance that their systems are working cohesively, and that there is a well-designed backup plan for disaster recovery.

> EXAMPLE CASE STUDY #3

Initial State

Global manufacturer sought to update their commissioning, validation and decommissioning procedures.

Objective

The primary objective was to revise the corporate procedures for commissioning, validation and decommissioning to ensure compliance and efficiency.

Maetrics Engagement

Utilizing guidance documents from the FDA, ISO, ICH, ISPE and other sources, procedures were developed for all stages of the Product Life Cycle and System Development Life Cycle, including the following:

- Validation Master Plans

- Risk Assessments
- Product Requirement Specifications
- Process Specifications
- System Specifications
- Validation Testing Procedures
- Validation Template Usage
- Commissioning
- Installation Qualifications
- Operational Qualifications
- Performance Qualifications
- Decommissioning
- Summary Reports
- Traceability Matrices
- Periodic Reviews
- Change Control Management
- Training

Results

By utilizing the collaborative backgrounds of Maetrics' engineers, a comprehensive quality infrastructure was developed. The combined expertise of Maetrics' personnel made this process swift, and provided this client's personnel with more allocated time to focus on other internal issues.