

> MASTER VALIDATION PLANNING

Maetrics employs a versatile team of industry veterans possessing an average of more than 15 years of experience. Our team's backgrounds include functions as managers, directors and vice presidents from a variety of industries. The team's business and project management expertise covers every level of validation planning for Site Validation Master Plans (SVMP), Master Validation Plans (MVP) and Design Validation Master Plans (DVMP) related to facilities, utilities, processes, methods, computer systems, cleaning, cold-chain transfer and contract manufacture validations.

Maetrics recommends the ISPE GAMP 5 as a guideline for validation activities, but also tailors validation plans and activities to the individual client's system. A few examples include: the development and execution of MVP's and protocols for pharmaceutical manufacturing facilities, medical device packaging systems and DVMPs for several medical devices. Not only can our staff prepare the plans and protocols, but they can also coordinate the resources assigned to execute the activities. This is demonstrated by our capabilities exhibited in the management of SVMP activities, including scheduling and review of work performed by other contractors, in support of site validation requirements.

> EXAMPLE CASE STUDY #1

Initial State

A manufacturer needed to qualify an HVAC system as part of a new facility prior to a Pre-Approval Inspection.

Objective

The primary objective was to ensure a successful PAI for NDA/PLA/BLA submissions.

Maetrics Engagement

Led HVAC validation teams to ensure a favorable Pre-Approval Inspection (PAI) in accordance with the requirements outlined in the NDA/PLA/BLA submissions.

- Authored the Validation Master Project Plan for the Facility HVAC System and Building Management System (BMS).
- Developed required test methodologies to ensure that the HVAC system was compliant with the Validation Master Plan, cGMPs, GAMP and FDA regulations, including 21 CFR Part 11.

Results

The HVAC system was qualified and the facility passed the pre-approval inspection.

> EXAMPLE CASE STUDY #2

Initial State

A global manufacturer sought to recertify several devices for sale in Europe (CE Mark).

Objective

The primary objective was to ensure all Design, Quality and Regulatory documentation, including technical files and design dossiers, was adequate for recertification.

Maetrics Engagement

After successful recertification of initial scope of products (2 families), project was extended to include recertification of more than 15 families with multiple derivatives for some families.

- Audited technical files, design dossiers, drawings, specifications, risk documentation and validations. Prepared gap analyses to identify deficiencies.
- Developed Design Verification/Validation Master Plans (DVMP) and Traceability Matrices to ensure all requirements were met, and deficiencies were remediated.
- Led interdepartmental teams to generate or update risk documentation including clinical risk/benefit analyses and Failure Mode and Effect Analyses.
- Prepared and executed protocols for design, test method, packaging and shelf life testing.
- Activities performed over the course of the project included the following:
 - Project Definition (Scope/Product/Process/Team)
 - Technical File Assessment/Evaluation
 - Product Specification Historical Review
 - Product Specification Update
 - Market Specification Update
 - Use Flow Chart Generation
 - Gap Analysis (DV/ISO/TM/Nominal/Challenge/Shelf-Life)
 - DHF Review
 - BOM Review
 - DV Historical Report Generation
 - DVMP Generation/Update
 - Equipment Qualification/Validation
 - Test Method Generation
 - Test Method Validation
 - Pre-DV Product Testing

- DV/ISO Protocol/Report Generation and Execution
- Shelf-Life Protocol/Report Generation and Execution
- Technical Report Generation
- MVP Review
- Compilation of information for the Clinical Benefit/Risk Profile
- Complaint Analysis
- Risk Management (Use-FMEA/Design-FMEA/Process-FMEA)
- Failure Investigation
- Materials Matrix Generation
- Product Comparison
- Quality Plan Generation
- Essential Requirements Checklist Generation for MDD Compliance
- Packaging/Labeling Review
- Biocompatibility Review
- Sterilization Review

Results

All products submitted for recertification received CE Mark with no interruption to sales.

> EXAMPLE CASE STUDY #3

Initial State

A manufacturer in Puerto Rico needed to qualify several balances and printers.

Objective

The primary objective was to develop and implement a plan to qualify the equipment according to corporate and regulatory requirements.

Maetrics Engagement

The following items and tasks led to a successful engagement and qualification of equipment:

- Prepared the Master Validation Plan (MVP).
- Developed the user requirements specification and risk assessment for Mettler Toledo Balances and Printers.
- Authored IQ/OQ protocols and final reports for several Mettler Toledo Balances and Printers.
- Wrote the SOP (Standard Operating Procedure) for the Mettler Toledo Balances and Printers.



Results

The Maetrics team successfully managed the development of procedures, specifications and test documentation to successfully qualify the equipment.