

> VALIDATION REMEDIATION

Maetrics employs consultants and engineers with an average of more than 15 years of experience including managers, directors and vice presidents from a variety of industries. Their business and project management expertise includes every level of validation covering facilities, utilities, processes, methods, computer systems, cleaning, cold-chain transfer and contract manufacture validations. In all cases, risk management plays a key role in the level and content of a Maetrics validation project.

Maetrics recommends the ISPE GAMP 5 as a guideline for validation activities, but also tailors validation plans and activities to the individual client system. FDA and GHTF guidance documents are also used in the Maetrics method of validation. A few examples include the development and execution of Master Validation Plans and protocols for manufacturing facilities, packaging systems and Design Validation Master Plans. Not only can our staff prepare the plans and protocols, but they can also coordinate the resources assigned to execute the activities. This capability has been demonstrated by the management of Site Validation Master Plan activities in support of site validation requirements for engagements including scheduling and review of work performed by other contractors.

For a leader in the life sciences industry, Maetrics led HVAC Validation Teams to ensure a favorable Pre-Approval Inspection (PAI) in accordance to the requirements outlined in the NDA/PLA/BLA submissions. Maetrics has also authored the Validation Master Project Plan for the facility's HVAC System and Building Management System (BMS). This entailed the development of the 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.

> EXAMPLE CASE STUDY

Initial State

A global industry leader was challenged with significant validation issues in a warning letter from the FDA. Findings included deficiencies in process and design validations involving more than 400 product codes. Most processes had no formal documentation of validation. Findings also included deficiencies in traceability of label claims to design validation activities.

Objective

The primary objective was to ensure all label claims were supported through proper design validations and that design history files were complete.

Maetrics Engagement

- Maetrics provided several team leaders and subject matter experts to augment a team of more than 200 workers over a 14 month engagement.

- Team leaders developed project plans and provided status updates.
- Maetrics developed a sorting scheme to divide the products into families, and establish worst case criteria for each group.
- Maetrics used reverse engineering to establish proposed specifications where none existed at the product level.
- Maetrics consultants developed and validated more than 100 test methods for design validation activities.
- Maetrics worked with clinicians to document failure modes and effects related to the use of the products.
- Maetrics facilitated design reviews, and created design FMEAs.
- Maetrics consultants managed teams ranging from 5 to 30 members.
- Maetrics developed standards for the format and content of the design history files and led efforts to remove any and all gaps.
- Maetrics analyzed and reported more than 300,000 test results.

Results

Ultimately, this client was able to efficiently and cost effectively achieve compliance. This has resulted in leaner, compliant operations, and the FDA Warning Letter status was removed.