

> INSPECTION REMEDIATION

Maetrics auditors and consultants have a broad base of experiences in FDA regulated industries. These experiences refer specifically to the pharmaceutical, medical device and biotechnology industries. The Maetrics team is familiar with the implementation of regulatory strategies, processes, and procedures related to compliance with US Food and Drug regulations as well as Canadian, European, British, Australian, Japanese and ISO requirements.

Maetrics employs several types of auditors including Ex-FDA, certified BSI and IRCA auditors. These experts are capable of providing pre-inspection audits and assisting with remediation of formal inspection findings such as FDA 483, Warning Letter, Consent Decree, Application Integrity Policy (AIP) and Notified Body Review reports. Additionally, Maetrics team members have developed or updated Quality System policies and procedures, and have executed all levels of remediation testing.

> EXAMPLE CASE STUDY #1

Initial State

A global life sciences industry leader was under a corporate level warning letter from the FDA. This warning letter was preventing any new approvals.

Objective

The primary objective was to expedite clearing of the warning letter.

Maetrics Engagement

Maetrics provided more than 70 relevant team members to the effort at all levels of expertise.

- Helped draft action plans, and provided key monitoring tools to track progress.
- Managed cross-functional teams from 5 to 30 people each at several client locations across the country.
- Developed process and design validations including IQ/OQ/PQ/PV/Risk Assessments.
- Validated test methods for process and design testing.
- Reviewed and updated complaint handling systems.
- Coordinated client staff for system remediation.

- Developed on-going processes to integrate post-market surveillance into risk assessments and clinical benefit/risk profiles.
- Managed CAPA systems for correction of deficiencies.

Results

Utilizing the combined efforts of multiple Maetrics personnel, possessing varying levels of expertise, this client was able to swiftly lift the warning letter status while minimizing outsourced costs.

> EXAMPLE CASE STUDY #2

Initial State

A manufacturer was issued a Consent Decree by the FDA.

Objective

The primary objective was to assist with the remediation of the quality system issues and the removal of the Consent Decree injunction.

Maetrics Engagement

Maetrics was an integral contributor in remediation efforts to regain cGMP and FDA regulatory compliance based on the signed issuance of a “Consent Decree of Permanent Injunction”. The following tasks led to a successful engagement:

- Managed project closure activity associated with CAPA: Corrective and preventive actions, complaint handling, control of non-conformances, investigation, implementation, adverse event reporting, field actions reporting and Quality Data Analysis Reporting (QDAR).
- Responsible for authoring, performing and/or approving qualification and validation documentation such as System Design Requirement Specifications (SDRS), Change Control, Document Change Notice (DCN), Non Conformance Reporting (NCR), GAP Analyses, CAPA, Process Failure Mode and Effect Analyses (PFMEAs), Engineering Studies (ES), Process Verification and Qualification, Design History Records (DHR), Protocols, SOPs, Test Methods and Drawings with BOM definition.
- Starting with System Design Requirement Specifications (SDRS), systematically performed documentation review providing GAP analyses that identified deficiencies in objective evidence that were critically required to support existing processes and products.

- As Core Validation Team Member, created retrospective and remediation documentation required for Process Development, Engineering Studies, DOE Analyses, Protocols and Protocol Summary Reports which all became part of the Master File for submittal to the FDA audit function.
- Authored Tool Qualification (TQ), Installation (IQ), Operational (OQ), Process (PQ) and Test and Inspection Method Validation (TIMV) protocols and applicable Protocol Summary Reports inclusive of design transfer between medical device manufacturing sites.

Results

Upon completion of initial contractual agreement, and with recognition of individual accountability and accomplishment, an additional 6-month extension was offered and accepted.

> EXAMPLE CASE STUDY #3

Initial State

The US FDA had applied the Application Integrity Policy (AIP) to a Pharmaceutical manufacturer in Minnesota.

Objective

The primary objective was to develop systems for the organization that reduced or eliminated the possibility of falsification, and increased the focus on the integrity of data and information in applications submitted for Agency review and approval.

Maetrics Engagement

Maetrics systematically developed documentation, validation, material handling, OOS and purchasing control systems to increase compliance and reliability. The Maetrics team also managed the development of testing documentation to reduce or eliminate the possibility of falsification.

- Developed and validated analytical testing methods.
- Prepared and performed IQ/OQ/PQ of new equipment and applications.
- Developed and delivered employee training in Good Manufacturing Practices and OSHA laboratory safety procedures including blood-borne pathogen training.
- Developed electronic data systems and testing documentation (canned data sheets) for all raw materials, in-process products and finished products testing protocols to ensure all required data was captured in a compliant and reliable manner.



- Provided expert advice on revision of investigation procedures to ensure root-cause analysis was accurately determined.
- Created controlled database of purchasing and inventory systems for all laboratory supplies and primary standards. Drafted SOPs for primary and secondary standard material handling as well as safety procedures for hormone product handling.

Results

The manufacturer successfully emerged from AIP upon completion of project involvement.