

## > WARNING LETTER REMEDIATION

Maetrics auditors and consultants have a broad base of experiences in FDA regulated industries; specifically, the pharmaceutical, medical device and biotechnology industries. They are familiar with the processes and procedures related to the 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. Our auditors are capable of providing pre-inspection audits as well as 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 consultants and engineers 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 consultants, at all levels of expertise, to the remediation effort. The following items and tasks led to a successful remediation:

- 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**

The Warning Letter status was removed by the FDA, and several products were approved once the status was lifted.

## **> EXAMPLE CASE STUDY #2**

### **Initial State**

The US FDA applied the Application Integrity Policy (AIP) to a life science manufacturer.

### **Objective**

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

### **Maetrics Engagement**

The following items and tasks led to a successful project that eliminated falsification and increased integrity of data:

- Maetrics developed documentation, validation, material handling, OOS, and purchasing control systems to increase compliance and reliability.
- Developed 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 material, in-process, and finished product testing to ensure all required data was captured in a compliant and reliable manner. Consulted 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.