

> COMPLAINTS/ADVERSE EVENTS

The Maetrics team of experts has broad based experiences in FDA regulated industries. This experience refers specifically to the pharmaceutical, medical device and biotechnology industries. Maetrics is familiar with the processes and procedures related to compliance with US Food and Drug regulations, as well as Canadian, European, British, Australian, Japanese and ISO requirements.

Maetrics has been involved in all aspects of complaints and adverse event reporting from the development of quality systems for complaint handling to complaint investigations and drafting reports for applicable regulatory agencies. Project experiences have included: training client staff in formal problem solving techniques, root cause analysis, statistical modeling and systems integration for complaints, risk documentation, validation and CAPA programs.

> EXAMPLE CASE STUDY #1

Initial State

A global manufacturer was found by the FDA to have a deficient complaint handling system. The company also had potential tampering and counterfeiting issues.

Objective

The primary objective was to effectively respond to FDA imposed Consent Decree.

Maetrics Engagement

- Instrumental in the creation of a new quality group.
- Improved complaints processing by reducing turnaround time, and improving inter-departmental efficiencies for completion of complaints.
- Delivered new complaint processing procedures, new workflows and methods across different departments.
- Generated Annual Product Review Sub-Reports and weekly/monthly Metrics Trending Reports.
- Utilized problem solving, process analysis and cross-functional teams to find root causes.
- Issued and ensured implementation of manufacturing and packaging CAPAs.
- Reviewed site investigation reports and closed complaints.
- Worked intimately with the FDA regarding potential tampering and counterfeiting issues, and effectively determined resolutions.

Results

The complaint handling system was completely revised to a compliant state as part of the removal of the Consent Decree, and the tampering and counterfeiting issues were mitigated.

> EXAMPLE CASE STUDY #2

Initial State

A global manufacturer identified gaps in their complaint handling and Medical Device Reporting (MDR) systems.

Objective

The primary objective was to update the complaint handling and MDR systems to a more compliant and efficient state.

Maetrics Engagement

Developed a risk-based complaint handling system including the editing of local and corporate quality procedures.

- Managed group performing failure analysis on medical devices.
- Renovated failure analysis facility to comply with *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* requirements for a Biosafety Level 2 laboratory classification.
- Developed processes for identifying the root cause for complaints.
- Reviewed and approved complaint investigations including MDRs.
- Assembled customer complaint data to support CAPA remediation effort.
- Participated in a one-month crash project to analyze an extensive customer complaint database and CAPA records.
- Utilized complaint and MDR data trends during the development of Risk Analysis and Validation documentation.

Results

The complaint handling and MDR systems were updated to integrate efficiently as a feed to the CAPA, risk analysis, and validation systems. The increased efficiency and accuracy provided the compliance required for Biosafety Level 2 laboratory classification.