

## > QUALITY SYSTEM DEVELOPMENT

Maetrics has developed and audited compliance to a variety of quality system requirements including FDA requirements (21 CFR Parts 11, 58, 106, 107, 110, 111, 113, 120, 210, 211, 600, 820, 1270 and 1271), ISO requirements (including 9000, 13485 and 14969), MDD, EMEA, MHRA, TGA and HPFB to name a few. Maetrics projects have included the development of a Quality System Road Map to ensure that a client's quality system meets all of the requirements of FDA, ISO and ICH QS guidelines.

Maetrics consultants are experienced in FDA regulated industries. This experience specifically encompasses the pharmaceutical, medical device and biotechnology industries. The Maetrics team is familiar with the design and implementation of quality systems and quality assurance practices and procedures. Maetrics also utilizes Lean Six Sigma techniques to help minimize the effort required for compliance. Maetrics has extensive project experience with quality systems processes such as complaints, CAPA, MDR and recalls and our team of professionals has performed audits, inspections, assessments of quality systems and processes. The team has also set quality assurance testing models for analysis of raw materials, materials in process and finished products.

## > EXAMPLE CASE STUDY

### *Initial State*

A global manufacturer recently acquired several small companies which made similar products.

### *Objective*

The primary objective was to integrate four separate quality systems into one that was aligned with corporate goals.

### *Maetrics Engagement*

Maetrics experts were able to provide a roadmap of a new quality system that was tightly integrated to good business practices. Once the new roadmap was approved, over 1700 old documents were mapped into the new structure. This mapping helped assure that all previous requirements were considered as each new document was created.

### *Results*

The four separate quality systems were streamlined into a highly intuitive format containing approximately 250 documents.