

## > CORRECTIVE ACTION / PREVENTIVE ACTION

Maetrics has developed and audited compliance to a variety of quality systems requirements including FDA requirements (21CFR 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. CAPA is one area where this type of roadmap is invaluable.

Maetrics also utilizes Lean Six Sigma techniques to help minimize the efforts required for compliance. These techniques, combined with our roadmap, allow us to remove all duplicated efforts across the system, saving our clients time while providing the assurance of a successful quality system infrastructure. Maetrics has extensive project experience in designing the CAPA sub-systems as well as the core problem solving methods.

## > EXAMPLE CASE STUDY

### *Initial State*

A global manufacturer had recently received a warning letter specifically citing gaps in their CAPA system.

### *Objective*

The primary objective was to build a robust system to facilitate rapid identification and closure of CAPA projects.

### *Maetrics Engagement*

CAPA is one system that interacts with nearly every other part of a quality system. Maetrics experts were able to provide a roadmap of a new quality system that is tightly integrated to good business practices.

- Mapped the outputs of each sub-system as it related to CAPA.
- Revised each sub-system so that lower level non-conformances could be handled within each system.
- Established monitoring and trending metrics within each sub-system.
- Established risk based escalation procedures.
- Established minimum guidelines for investigations.
- Provided training and mentoring to project teams.



## *Results*

The client was left with a streamlined two-tier system for CAPA. A backlog of 100 old projects was closed within 6 months with the help of Maetrics mentors. The lower-level systems are monitored directly via reports in the management review process. With the confidence gained through an effective CAPA system, and the reduction of backlogged projects, this client has now expanded their capabilities at this facility and has effectively resolved their CAPA citations from the FDA.