

## > REGULATORY SUPPORT SERVICES

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 US Food and Drug regulations, as well as Canadian, European, British, Australian, Japanese and ISO requirements.

Maetrics has been involved in all aspects of the approval process from the development of quality systems for complaint handling to complaint investigations and drafting reports and submissions for applicable regulatory agencies. Project experience has included pre-approval documentation such as PMAs, 510(k)s, IDEs, HDEs, Design Dossiers, Technical Files and Correspondence Files. Post-market surveillance activities have included the review and implementation of systems for complaints, Adverse Event Reports, MDRs, MDVs and Canadian Mandatory Reports. Maetrics has also overseen the recertification of products in Europe (CE Mark) and in Japan.

## > EXAMPLE CASE STUDY

### *Initial State*

Global life science manufacturer was introducing a new drug.

### *Objective*

The primary objective was to accelerate the preparation of the NDA package.

### *Maetrics Engagement*

The following items and tasks led to additional revenue for the manufacturer:

- Maetrics played an integral part in preparing the data required for the CMC section.
- Maetrics helped define the required tests, and supervised the execution of the testing.
- Maetrics also generated Annual Product Review Sub-Reports and weekly/monthly Metrics Trending Reports.
- Maetrics has also helped prepare PMA and 510 (k) submission packages.

### *Results*

Maetrics consultants were able to assist the organization by shortening the cycle more than 3 months, thus generating millions of dollars in additional sales revenue.