

## > TRAINING

FDA regulated firms face a unique set of challenges today. First and foremost, they must operate in a state of compliance with relevant FDA regulations. This is not an inexpensive or simple endeavor to undertake. Once compliance is achieved, efforts to maintain a state of compliance are subject to constant pressures of cost reduction. Maetrics understands the challenges that you are up against, and has developed an approach that is tailored to FDA regulated industries. If you are looking for ways to make your organization more efficient and effective while maintaining your FDA compliance, Maetrics is here to help.

### *Our Team*

Our team has diverse and extensive experience in FDA regulated industries from the most basic medical devices and biotechnology products to the most intricate. Additionally, our team is experienced in developing and implementing practical and sustainable plans. Our experience includes:

- Domestic and international firms
- Start-ups to multi-national corporations
- Individual processes at a single site to full system optimization at multiple sites
- Participating on teams as a partner to leading and staffing entire teams

We have a team of experienced professionals who not only know the industry and regulatory requirements, but who are also experienced in the development and implementation of superior training programs for FDA regulated industries.

## > EXAMPLE CASE STUDY 1

### *Initial State*

A contract manufacturer was in jeopardy of losing its number one customer due to the lack of a good training process. Several audits cited the same problem even after internal attempts failed to address the findings.

### *Objective*

The primary objective was to continue the relationship with their number one customer. Creating a sound training process was the number one criteria identified to reach this goal.

### *Maetrics Engagement*

Our experts have years of industry experience and proven track records of success. The following items and tasks led to a successful audit for our client, and continued business with their number one customer:

- The current training program, including the current and any relevant procedures, was reviewed for adequacy.
- The work process was defined within each functional area based upon information gathered from individuals in specific functional areas (compounding, packaging, receiving, test & inspect, etc). This included identifying Key Skill Areas (KSA), additional training needs and On the Job Training (OJT) processes and separate shifts.
- Maetrics created a priority list based on areas that needed to be addressed first (i.e. the problem areas - most nonconformities or highest risk of nonconformities.)
- Process measurements/metrics (M&Ms) were identified and developed.
- Maetrics documented the interactions between training processes and QS processes.
- Job descriptions were identified within each functional area, and Key Skill Areas (KSAs) were defined for each job description, including:
  - Laboratory KSAs
  - Shop floor KSAs
  - Management KSAs
- Maetrics prepared a training needs analysis spreadsheet, including management positions, and a list of all current job descriptions.
- The training process was defined in a process flow diagram (PFD):
  - Identified process inputs, outputs, owners, boundaries and metrics.
  - Delineated the primary path, alternative path and parallel processes.
- Modified and/or developed new SOP and Work Instruction(s).

## **Results**

The next audit by the major customer went very smoothly and this contract manufacturer was able to successfully maintain their number one client.

## > EXAMPLE CASE STUDY 2

### *Initial State*

A leader in the industry was using the traditional toll gate inspection for release of parts. The manufacturing process had several key parameters that caused drift in the outputs such as tool wear. Delays in the inspection increased the number of parts that were suspect after an out-of-tolerance result. All suspect parts were inspected in order to release the good parts.

### *Objective*

The primary objective was to reduce the amount of rework and additional inspection caused by the delays.

### *Maetrics Engagement*

Our experts have years of industry experiences and proven track records of success. The following items and tasks led to a reduction in costs and improved systems:

- The work process was defined within each functional area based upon information gathered from individuals in specific functional areas (molding, machining, packaging, test & inspect, etc). This included identifying Key Skill Areas (KSA), additional training needs and On the Job Training (OJT) processes and separate shifts.
- Maetrics documented the interactions between training processes and QS processes.
- Maetrics prepared a training needs analysis spreadsheet including management positions and a list of all current job descriptions.
- Training processes were defined in a process flow diagram (PFD).
  - Identified process inputs, outputs, owners, boundaries and metrics.
  - Maetrics provided the required training and assessments for the initial roll out.
- Maetrics defined the certification levels, initial requirements and recertification requirements.
- The monitoring program was established including the training requirements for these auditors.



## *Results*

The project resulted in a 5% reduction in the standard cost of the components under the new system. Each machine operator became certified to perform the required inspections in the final state. These operators also received enough training to perform minimal trending of their own results, and make adjustments before any rejects were produced.