

## CASE STUDY | GxP QUALITY AND VALIDATION SOLUTIONS

### *Quality Systems Remediation: Assessment, Program Management, Engagement Oversight and Execution*

## Business Challenge

A Fortune 500 company and leading medical device manufacturer received a 483 warning letter, inclusive of 14 observations, as a result of an FDA inspection. Key areas noted by the agency included failures to establish validated procedures within quality systems, process validations, design control, CAPA process, NCR's, complaints process, document control, equipment, and packaging. The company was seeking a firm to assess their current internal procedures, evaluate the received observations, and develop work streams based on the findings of the agency.

The client requested Advanced to provide program managerial oversight and the execution-level consultants to complete the required activities.

## Goals

### Project

- Formulate work streams with client steering committee oversight
- Use engagement oversight approach, ensuring deliverable execution, and cost control
- Achieve aggressive deadlines established by top management

### Delivery Team

- Identify, assemble, and on-board 50+ project team members within one month from contract award
- Team members were required to have the following experience:
  - Quality Systems
    - CAPA
    - NCR's
    - Complaints
    - MDR
  - Packaging Validation
  - Equipment: IQ, OQ, PQ
  - Project Management
  - Medical Device background
  - Lean Manufacturing

## Approach

Advanced deployed a highly effective, managed and scalable team of 50+ Quality Systems, Packaging, and Validation Engineers.

**Strategy:** Develop, manage and execute strategic work stream remediation activities and train project team on client's SOP's.

### Execution:

- Create traceability matrices for CAPA and Complaints process
- Install and manage program to ensure defensible process is maintained per FDA standards
- Conduct weekly status meetings on progress, findings, and next steps
- Monthly meeting to ensure project team is on track for completion

**Continuous Improvement:** Continue to provide engagement oversight and execution resource support.



## Results

Program oversight, project team selection, retention and full-time on-site leadership resulted in timely and effective responses to the Agency.

Generated and supported the work streams with internal expertise and resource support, maintaining deliverable integrity and cost control.

Utilized Advanced's internal delivery methodologies, stringent screening process, and on-site project management to ensure delivery and project completion.

The project team continues to provide program management and execution level resource support within the identified work streams.