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Remediation of Major Quality System Deficiencies

By
Kevin Randall, ASQ CQA, RAC (US, EU, CAN)

The Challenge

A manufacturer of nuclear cardiology medical devices received robust lists of citations and a Warning Letter from the U.S. Food and Drug Administration (FDA) due to significant quality system deficiencies noted by FDA during multiple inspections. Among the citations were the following:

- Failure to implement and maintain an adequate and effective quality system;
- Failure to establish a Quality Policy;
- Failure to establish a Quality Plan;
- Failure to establish a Management Review process;
- Failure to establish purchasing specifications;
- Failure to establish a training system for personnel;
- Failure to establish Device Master Records (DMR);
- Failure to establish a Design Control process to control device design;
- Failure to establish a Document Control system;
- Failure to establish a Corrective and Preventive Action system;
- Failure to establish Finished Device Acceptance procedures;
- Failure to establish a Quality Audit system;
- Failure to establish Complaint handling procedures;
- Failure to establish adverse event reporting procedures;
- And others.

These quality system areas are among those deemed by FDA to be the most indicative of the overall suitability and effectiveness of a company's quality system. Prior remediation attempts by the device manufacturer were insufficient to resolve these serious quality system deficiencies in a manner acceptable to the FDA.

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The Solution

The nuclear cardiology medical device partnered with ComplianceAcuity, Inc., for expertise and intervention to resolve this serious compliance and business crisis. ComplianceAcuity delivered the following customized, best-practices quality system remediation solutions:

- **A seasoned and expert remediation team**;
- **Accurate interpretation of FDA 483 and Warning Letter** citations;
- **Translation of citations into plain-language** meaningful to the company;
- **Professional, effective liaison with FDA** District Office and Compliance Officer;
- **A tactical remediation strategy** based on a proven understanding of "behind-the-scenes" FDA activities;
- **Development of a master corrective action plan** to resolve quality system deficiencies;
- **Preparation of formal written response to FDA** as required to convey the plan to FDA;
- **Itemization of tangible tasks** needed to resolve all deficiencies;
- **Preparation of a master project plan** clearly arranging hundreds of tasks so as to organize, track, and manage the remediation effort and clarify roles and responsibilities;
- **Timely progress reports** to company and FDA officials throughout the remediation effort;
- **Development of company quality policy**;
- **Authentic connection with company culture and business** objectives;
- **Customized, "best-practices" quality subsystems** for:
    - Document Controls;
    - Management Controls / Review;
    - Purchasing Controls;
    - Design Controls;
    - Production / Process Controls;
    - Device Master Records;
    - Validation;
    - Device fabrication and quality control;
    - Device handling, storage, and distribution;
    - Corrective and Preventive Action;
    - Quality Auditing.
- **Lean operating documentation**
- **User-friendly controlled forms** to document quality system activities where required by FDA;
- **Continuous interaction with all stakeholders** to assure company-wide "buy-in" and participation during design and implementation of the quality system;
- **Change-management strategies** to facilitate the transition process;
- **One-on-one and group training sessions** to ensure effective implementation and to empower quality subsystem owners.

The Results

The nuclear cardiology device manufacturer struggled for years and was unsuccessful meeting FDA's quality system requirements prior to partnering with ComplianceAcuity. **After just a few months of help from ComplianceAcuity, the company received written notification from FDA confirming that the ComplianceAcuity solutions were addressing FDA's concerns.**

With a compliant and functional quality system now defined, documented, and delivered, the company is finally free to turn its attention back to its growth in the nuclear cardiology medical device marketplace.