Successfully Remediating Major FDA-Compliance Citations

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The Challenge

In response to a product recall suggesting significant quality problems, a $500-million dollar global medical device company was subjected to a "for-cause" FDA inspection. The result of the inspection was a robust list of FDA-citations, bringing the company to the verge of an FDA Warning Letter. Among the citations were violations against the Complaint Handling and Corrective and Preventive Action (CAPA) clauses of Title 21 of the Code of Federal Regulations (21 CFR) part 820. These clauses are among those deemed by FDA to be the most indicative of the overall suitability and effectiveness of a company's quality system. Prior to partnering with ComplianceAcuity, the client utilized consultants who were unsuccessful in genuinely engaging company culture/business objectives and who used tactics that didn't fully address FDA's latest enforcement practices. As a result, the previous outsourced remediation efforts were unsuccessful.

The Solution

As described above, the U.S.-based device manufacturer partnered with ComplianceAcuity, Inc., to remediate the client's Complaint Handling and CAPA systems after prior outsourced efforts were unsuccessful. Consistent with ComplianceAcuity' mission statement, an authentic connection was first achieved with the client's culture and business objectives in order to regain the cross-functional trust and commitment that were lost during previous outsourced remediation efforts. Because of the global size of the client, and because of the corresponding complexity of its business processes, and because Complaint Handling & CAPA inherently touch multiple departments, it was necessary to map the client's business processes and their interrelationships to clearly identify the contact-points relevant to remediating the Complaint Handling and CAPA systems. Not only did the process-mapping clarify complex business processes for client and ComplianceAcuity personnel alike, but the mapping also incidentally led to the discovery of opportunities to eliminate redundancy and cumbersome practices.

Once the business processes were mapped and clear, ComplianceAcuity delivered the following customized, best-practices Complaint Handling & CAPA solutions for roll out by the client's corporate headquarters:

Complaint Handling:

- **Seamless integration** of day-to-day complaint handling, adverse-event reporting, CAPA, and modern-day risk assessment/management;
- **Complaint handling based on risk** management principles such as ISO 14971;
- **Practical procedures** delineating between complaint evaluation, complaint investigation, and failure investigation;
- **Clear trigger-criteria for failure investigations** to know when formal investigations are or aren't necessary;
- **Failure investigation identifying true root cause** of problems;
- **Standardized CAPA decision-trees** to decide when formal CAPA is or isn't required;
- **Sustainable monitoring/trending of complaint data** interfaced with management review;
- **Corporate policies and procedures** to facilitate corporate-wide launch;
- **Department by department work instructions** with cross-functional interfaces clearly defined; and
- **Department-specific training presentations** to facilitate implementation.

CAPA:

- **Proactive identification of various CAPA sources** to make it clear to everyone what data sources to monitor;
- **Systematic analysis (statistical where required) of CAPA source-data** to identify when CAPA is required;
- **Standardized risk assessment (i.e., ISO 14971) of nonconformities** to determine the appropriate degree of investigation and corrective action;
- **Failure investigation identifying the true root cause** of problems;
- **Genuine elimination of the root cause to prevent ongoing repetition** of observed problems;
- **Compliant verification/validation** of CAPA effectiveness; and
- **Sustainable monitoring/trending of CAPA data** interfaced with management review.

The Results

The results of an FDA follow-up audit make it official: The client received a *"Voluntary Action Indicated"* designation from the FDA, rather than an *"Official Action Indicated"* (Warning Letter) designation. ComplianceAcuity, continues to stand out by successfully remediating the ailing Complaint Handling and Corrective/Preventive Action (CAPA) systems at a $500-million dollar global medical device company. With an effective system now defined, documented, and delivered, the client is free to focus on resource and organizational phase-in to support their corporate implementation efforts.