Case Study

FDA Corporate Warning Letter Remediation Post Market Surveillance

Problem Identification

Our client, a diversified multi-national medical technology company, with nearly 14,000 employees and annual sales of more than 4.6 billion dollars in 2014, received a corporate warning letter from the U.S. Food & Drug Administration (FDA) citing significant violations with their operations and Quality Management System. One of the areas of most concern cited in the agency's report was a significant number of complaints received by the company that had not been processed appropriately. In addition, similar failures were cited in the CAPA system and in many legacy Design History Files (DHFs).

Nature and Scope of Challenge

The Client engaged EG Life Sciences to provide a team of senior level Quality consultants to be part of a remediation team tasked with addressing the issues noted in the FDA warning letter. The client requested a team of ten Post Market Surveillance specialists to review and remediate records and files associated with complaints and Medical Device Reports (MDRs). This team of consultants were tasked with reviewing approximately 8000 complaints that were in various stages of closure within the clients Trackwise and SAP electronic complaint systems. The reviews consisted of re-assessing reportability decisions, completing MDR decision trees, and where applicable, filing new or supplemental MDRs. In addition to the Post Market Specialist team, two Quality Engineers were engaged to assess and revise legacy product Design History Files (DHFs), as well as a CAPA Specialist to bring overdue CAPAs to completion.

The client committed to completing the remediation activities within a timeframe of four months.

Problem Resolution

EG Life Sciences' recruiting team immediately began a nationwide search of their extensive network of consultants to identify the talent and skill sets required to meet the client's timeline and budget for the project. Within 48 hours, a roster of consultants was established, matching exactly the type of remediation skills requested by the client. Based on the industry expertise of EG Life Science's internal staff of seasoned practice leaders, a team of thirteen consultants were screened, extended offers, and hired within two weeks following the contract award. All consultants started as planned at the client's respective facilities.

The team of Quality professionals and Post Market Surveillance Specialists were initially deployed in three phases; five of the ten Post Market individuals started on site in the first phase, followed a week later by the Quality and CAPA specialists, and finally the second five complaint/MDR experts. During their first week on-site at the client, the consultant groups received an intense but thorough training on the processes and products that they would be exposed to as part of the remediation. Once the training was completed, the remediation efforts commenced in earnest.

Weekly progress was monitored by EG Life Sciences and tracked by the client against agreed upon metrics for each team member. In addition, the EG Life Sciences Project Team held weekly conference calls with the consultants to check on their progress and to resolve any issues that potentially could contribute to delays in the schedule. The EG Life Sciences Account Executive and Subject Matter Expert held weekly update meetings with the client Program Managers to discuss deliverables against milestones and to address any challenges that could affect the progress and impact of the teams. These reviews proved to be an effective method of pro-actively getting ahead of problems before they had a negative impact on the project.

Value Proposition

EG Life Sciences' deep subject matter expertise allows us to quickly grasp client issues, resulting in the timely sourcing and placement of talent capable of assessing and resolving complex issues. In this case, the addition of the EG Life Sciences consultant teams allowed the client to demonstrate their commitment to resolving the compliance issues noted by the agency, and to successfully remediate the FDA warning letter in a timely and satisfactory manner.

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