Case Study

FDA Consent Decree

Problem Identification

Our client, a diversified multi-national Biopharmaceutical company, with over 100,000 employees and annual sales of more than 40 billion dollars in 2014, entered into a Consent Decree with the U.S. Food & Drug Administration (FDA) citing significant violations with their cGMP Manufacturing operations and Quality Management System. Areas of concern were widespread in the Manufacturing, Quality Assurance, Quality Control, and Validation departments.

Nature and Scope of Challenge

The client contacted EG Life Sciences to source and secure a team of over thirty seasoned cGMP consultants including technical writers, manufacturing associates, quality control technicians, validation engineers, and QA associates to supplement their internal resources, and tasked them with remediating the deficiencies that were cited in the Consent Decree in the Manufacturing, Quality Assurance, Quality Control, and Validation departments. Some of the deficient areas that were cited included but were not limited to CAPA, Deviations, Validation studies, Documentation, and Change Control.

After a drug is approved in the US and other markets, companies must maintain compliant systems and processes for the manufacturing of those products. This regulatory mandate, referred to collectively as current Good Manufacturing Practices (cGMPs), provides a set of guidelines for drug companies to follow in order to consistently produce safe and effective drugs. Drug manufacturers are required to keep detailed records of the processes that are used to produce these approved therapies. The US Food and Drug Administration (FDA) can periodically inspect these manufacturers to ensure that cGMPs are being followed. If observations are noted the FDA requires companies to respond to these observations. If the responses are unsatisfactory, the FDA may issue a warning letter as a next step. If warning letters are unsuccessfully answered, a consent decree may result. A Consent Decree will typically outline the steps a drug firm needs to take in order to bring itself back into compliance by meeting predetermined milestones. Hefty fines and multi-year supervision by the FDA and other 3rd party participants usually will result as part of this agreement.

Problem Resolution

EG Life Sciences supplied the team of specialists on a rolling basis after being awarded the contract, and on-boarded those individuals within the client's agreed to start date. The teams of cGMP Specialists were deployed in various areas depending on the milestones and needs of the Consent Decree remediation plan. During their first week on-site at the client, the consultant group 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 team members and group jumped in with both feet. The team remediated cGMP documentation used for Manufacturing, Validation, and Quality Assurance. Other activities included re-validating QC Laboratory equipment and Manufacturing equipment by generating IQ/OQ/PQ protocols and authoring final reports. Deviation, CAPA, and Change Control backlogs were also reduced as a result of this effort.

Weekly progress was tracked by the client against agreed upon milestones. Periodic adjustments were made to ensure completion of the project by the required completion milestone.

Value Proposition

An EG Life Sciences core competency and market differentiator is our ability to quickly assess problem attributes, allowing us to rapidly source and select the best team to be deployed to the client. In this case, the selection of the EG Life Sciences team allowed the client to successfully navigate and resolve the backlogged complaint files in a timely manner. The consultant group executed flawlessly on the project plan providing the client with the specific expertise and skills they needed, at a price that fit into their budget, and freed up their internal resources to focus on other areas of need.

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