Case Study

FDA Pre-Approval Inspection PAI Preparation

Problem Identification

Our client, a diversified multi-national Biopharmaceutical company, with over 18,000 employees and annual sales of more than 20 billion dollars in 2014, was preparing to file a New Drug Application (NDA) with the FDA and needed to prepare for a PAI inspection.

Nature and Scope of Challenge

The client contacted EG Life Sciences to source and secure a team of over fifty 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 helping the cGMP Manufacturing facility prepare for its FDA Pre-Approval Inspection (PAI).

When a drug is up for approval in the US, companies can be inspected by the FDA as part of the New Drug Application Process. The NDA on file with the FDA contains an enormous amount of information on how the drug is manufactured, how it tested in clinical trials, and how it is evaluated against acceptance criteria showing safety and efficacy. The goal of the PAI inspection is to see if the information in the drug application is a good representation of how things operate in real world scenarios such as a cGMP manufacturing plant. The FDA wants assurance that problems that arise during the drug manufacturing process are investigated properly and quality systems are in place to document and remediate these issues in a timely manner.

The PAI is a crucial step in bringing a drug to market so it is very important to assemble the correct team to handle all of the different aspects of these inspections. Without the correct strategy, a drug can be delayed, allowing competitors to make it to market first, leading to losses in market share, branding and recognition, and revenue and profit.

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 PAI readiness plan that was developed by the client. The team reviewed cGMP documentation used for Manufacturing, Validation, and Quality Assurance. Other activities included re-validating manufacturing equipment such as Autoclaves, Temperature Chambers, biowelders and biosealers, computer systems, and filter integrity testers by generating IQ/OQ/PQ protocols and authoring final reports. Our consultants were also tasked with resolving outstanding Deviation, CAPA, and Change Control reports in order to bring the facility into an acceptable state of compliance for the inspection process.

Weekly progress was tracked by EG Life Sciences and 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. The addition of the EG Life Sciences consultant team allowed the client to successfully pass the FDA PAI inspection and get a very positive vote from an FDA advisory panel in favor of approval of their Phase III drug. This panel provides advice to the FDA to assist them in making a final approval decision. The majority of positive panel votes secure final drug approval.

EG Life Sciences℠

Positively Impacting Lives

www.eglifesciences.com