Case Study

Remediation Plan to Address FDA Consent Decree

Problem Identification

A global multi-billion-dollar device company found themselves dead in the water until they could satisfy an FDA consent decree which prohibited the sale of their devices, as well as the development of upgraded products. EG Life Sciences brought in a team of industry-leading project managers and SMEs to swiftly identify the pain points, propose a resolution, communicate those actions to the FDA and see the job through to successful completion.

HIGHLIGHTED RESULTS

- EG Life Sciences consultants executed a successful remediation plan that ultimately saved the client an estimated $200 million.

Nature and Scope of Challenge

Medical device development is a challenging environment filled with complex manufacturing, life-cycle management and regulatory remediation to comply with Food and Drug Administration (FDA) standards.

Even the most comprehensive plans can fall short of meeting the FDA's Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) standards. The world's largest and most successful device companies depend on EG Life Sciences' experienced consultants to assist with a full range of development, manufacturing and regulatory matters. Organizations that partner with EG Life Sciences obtain access to consultants who are highly familiar with the FDA and have handled every type of case imaginable.

Year after year, EG Life Sciences has deep involvement with the most important projects at the world's largest life science companies, making the firm uniquely qualified to address a broad range of issues.

Problem Resolution

Within five months, the team closed 1,906 compliance gaps in the supplier management database and over 159 supplier audits, as well as implementing new corporate supplier procedures. As part of the project, the EG Life Sciences team unearthed six additional compliance gaps and offered solutions before they emerged as further trouble spots.

Value Proposition

The remediation plan and subsequent FDA clearance allowed the company to get back to business in a timely manner, which saved an estimated $200 million in product recalls and other expenses. The plan also yielded a pathway for the company to resume its efforts to introduce new products to the marketplace.

In a similar case, EG Life Sciences provided a team of a half-dozen project managers and experts to execute a quality improvement plan that resolved a 483 Warning Letter regarding an electronic infusion device. The multi-work stream leaders quickly examined and documented the gaps, proposed a comprehensive remediation plan and took corrective and preventative actions that addressed the FDA's concerns.

Medical Device companies turn to us for advanced strategy and hands-on knowledge. Our network of regulatory experts will complement your internal team to overcome complex challenges and resolve quality and compliance issues.