Brevitas
People, Process and Program Excellence

CASE STUDY

On-Site Evaluation (OSE) Preparation Facilitates Early Licensure of New Biological Drug

An international client required support to address recent findings from an FDA inspection and prepare for an On-Site Evaluation (OSE) by the Biologics & Genetic Therapies Directorate (BGTD). Brevitas provided GMP advice and coaching which facilitated the successful execution of the OSE, with no observations.

AT A GLANCE

INDUSTRY
Biologics

AREA OF EXPERTISE
Regulatory Compliance

SERVICES PROVIDED
- Project Management
- Inspection Readiness
- Technical Documentation

DURATION
1 month

IMPACT
Due to Brevitas' GMP advice and coaching, covering facilities and operations, an international client was able to successfully prepare for and successfully complete an On-Site Evaluation, in preparation for the licensure of their new biological drug.

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Business Challenge

Our client requested assistance in preparing their manufacturing site for an On-Site Evaluation (OSE) by the Biologics and Genetic Therapies Directorate (BGTD) for the Pre-License Inspection of a new biological drug. The client is part of a complex inter-site arrangement, with locations in several geographical regions. The manufacturing site had recently been inspected by the FDA, which resulted in a number of findings that were of some concern and a potential risk for the OSE, as there were several issues still outstanding that could potentially impact the approval for licensure of the new product.

Our Scope

Brevitas worked with the client and sister sites to assess the findings and proposed remediation plans for the FDA 483, as well as the performance and compliance status of key quality systems (including change management and regulatory reporting, CAPA, and non-conformance handling). Several risk areas were identified, along with avenues that the inspection would likely follow. Brevitas provided GMP advice and coaching to the client, including on-site support during the inspection.

Value Added

- Performed an assessment against regulatory compliance requirements and provided recommendations for further improvement covering quality systems, facilities, aseptic processes, and operations prior to the BGTD On-Site Evaluation; Areas covered during the visit included:
  - Warehouse
  - Bulk Manufacturing
  - Pharmaceutical Production – Aseptic Filling Operations
  - Review of Deviation List
  - Review of Change Control List
  - Overview of Environmental Monitoring Data
  - Overview of Utilities monitoring Data
- Provided coaching and GMP advice during the OSE to ensure adequate supporting data and appropriate responses to inspection enquiries

Results Achieved

As a result of Brevitas' extensive efforts, the OSE was successfully executed, with no inspectional observations being raised by the BGTD. This outcome helped facilitate the early licensure of their new biological drug.