

Implementation of a Robust Audit Trail Review Program for QC Laboratory Systems



The Canadian arm of a global vaccines company required an audit trail assessment of their QC laboratory systems to address findings cited during an internal inspection. Brevitas consultants were enlisted to perform audit trail reviews and determine areas of focus for the implementation of a robust audit trail review program.

AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF SERVICE

Regulatory Compliance

EXPERTISE DELIVERED

- Data Integrity
- Project Management
- SOP Writing

DURATION

6 months

IMPACT

To address findings cited during an internal inspection, an audit trail review program was successfully implemented for QC laboratory systems, without jeopardizing day-to-day quality operations.

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Business Challenge

The pharmaceutical industry demands thorough understanding and strict compliance to regulatory and data integrity requirements. After regulatory gaps were identified during an internal inspection that could potentially put operations at risk, the requirement to implement an audit trail review program was identified. Faced with a short turnaround time, our client enlisted Brevitas consultants to support implementation while minimizing the impact on current operations.

Our Scope

The Brevitas team assisted by providing data integrity compliance and project management expertise for the development of the audit trail review program. Execution included:

- Assessment of existing documentation covering multiple laboratory systems
- Assessment of auditable fields for multiple laboratory systems
- Implementation of an audit trail review program for each laboratory system

Value Added

Our consultants, well versed in the pharmaceutical industry, were able to work in parallel with day-to-day operations, during multiple phases of this project, to minimize impact and deliver the project on-schedule, within a 6-month timeframe. The following were achieved:

- Assessment of multiple laboratory systems for audit trail review
- Management of resources, timelines, and stakeholders
- Updating of Standard Operating Procedures (SOPs) to ensure compliance

Results Achieved

Leveraging our specialized data integrity compliance and project management expertise, our client was able to implement a new robust audit trail review program, to address compliance concerns, mitigate risks, and meet regulatory requirements within the set timeline.