

SOP Consolidation across Multiple Global Sites Promotes Move towards Lean Operations



AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF EXPERTISE

Regulatory Compliance

SERVICES PROVIDED

- Project Management
- Technical Documentation
- Organizational Change Management

DURATION

7 months

IMPACT

SOP consolidation helped the R&D department of a leading Canadian pharmaceutical company achieve lean operations by reducing the number of redundant SOPs and creating global policies for standard use.

Brevitas consultants provided technical and compliance expertise to a leading Canadian pharmaceutical company for the revision and creation of global GMP, GLP and GCP Standard Operating Procedures (SOPs). Within 5 months, the number of global R&D SOPs was reduced from 100 to 50, to help achieve lean operations.

Business Challenge

Our client was faced with a tight timeline to complete a lean documentation initiative across multiple global sites, including Canada, the United States, India, and Europe. The goal was to reduce the number of redundant R&D SOPs and create new global policies & SOPs, incorporating current regulatory expectations (FDA, EU, Canada). The completion of the project was crucial to achieve lean operations across all global sites.

Our Scope

Brevitas consultants were engaged to provide support services and expertise in GMP, GLP, and GCP compliance, and to expedite the reduction and revision of Standard Operating Procedures in 5 short months.

Value Added

- Enhanced efficiency of R&D documentation control by consolidating duplicate procedures and reducing the number of redundant documents
- Developed process maps to identify gaps and make improvements to procedures and policies
- Identified and addressed gaps within SOPs, across multiple global sites

Results Achieved

- Created new global GMP, GLP, and GCP policies and SOPs to improve compliance across all sites
- Harmonized R&D SOPs, reducing the document quantity from 100 to 50 across global sites within a 5-month timespan
- Developed 80 global GMP, GLP, & GCP SOPs and policies to streamline the processes across all global sites

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