

Regulatory Inspection Preparation Addresses Key Compliance and Production Issues



After a few years of compliance issues, our Global Pharmaceutical client retained the services of the Brevitas team to provide strong leadership and project management support in preparing their staff for a regulatory inspection.

AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF SERVICE

Compliance & Operational Effectiveness

EXPERTISE PROVIDED

- Program/Project Management
- Technical Documentation
- Organizational Change Management

DURATION

5 months

IMPACT

Immediate actions not only prevented further compliance issues but also addressed production issues to enable our client to continue supplying products to global markets.

Business Challenge

As a leading Global Pharmaceutical Company, our client was committed to having a strategic and holistic view of all the compliance challenges affecting their operations. Inspection preparations are often challenging because of the need to conduct a thorough review of previous citations and observations, to develop and track key performance metrics, and to ensure that Subject Matter Experts (SMEs) are adequately prepared for their meetings with inspectors.

Our Scope

Brevitas consultants played an instrumental role in implementing project management and change management tools and methodologies at our client's site to enable preparation for a major regulatory inspection. This involved a complete lifecycle management of the project and associated change management activities through communication and stakeholder management.

Value Added

The Regulatory Inspection Preparation project helped our client undergo an inspection with a successful outcome. Some of the key benefits that Brevitas brought to this project included:

- Providing a well-defined scope;
- Prioritizing critical resources;
- Facilitating meetings with both internal and external stakeholders;
- Working with coaches and leaders to gain their buy-in;
- Managing SME workload and conflicting schedules;
- Tracking and reporting metrics for Steering Committee members;
- Developing a process to address training gaps, providing an implementation plan and resources required;
- Creating weekly communications for leadership to help build employee momentum.

Results Achieved

From inception to completion, the Brevitas team contributed to the success of the project by:

- Organizing and tracking the status on approximately 100 pre-requests from inspectors;
- Managing of over 80 position papers and presentations around critical topics and issues;
- Supporting logistics of inspection;
- Developed an implementation approach for addressing training gaps;
- Providing an exhaustive "lessons learned" report to key managers and directors, and recommendations on how to improve performance for future regulatory inspections.

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