

Effective Project Management for Facility Renovation Helps Address Compliance Concerns



AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF EXPERTISE

Engineering and Capital Projects

SERVICES PROVIDED

- Program/Project Management
- Engineering Design Support
- Commissioning
- Technical Documentation

DURATION

1.5 years

IMPACT

A client's production was temporarily shut down due to regulatory citations. Brevitas' services in project management, project engineering, and design support during the facility renovation were pivotal in addressing the compliance concerns and improving future manufacturing capacity.

Brevitas consultants managed and coordinated the design, construction, and commissioning of an engineering capital project for a global pharmaceutical company. Brevitas consultants successfully addressed compliance issues, remediate potential risks, and improve production capacity by applying their expertise in project management and technical assurance.

Business Challenge

Following an inspection, the regulatory agency cited our client's production facility with several compliance concerns. It was crucial to remediate these issues within an aggressive timeline to prevent product stockout.

Our Scope

Brevitas consultants were brought onboard to provide project management, engineering & design support, and technical assurance expertise to complete this portfolio of projects, including:

- Remediation & upgrades to clean rooms
- Upgrades to walk-in refrigerators and incubators
- Installation of a new HVAC system

Due to the sensitive nature of our client's project, our consultants were required to attend to multiple remediation activities simultaneously during the project phase.

Value Added

- Managed and coordinated project activities with cross-functional teams
- Developed engineering project documents including project charter, construction plan, and preventative maintenance task plans
- Supported clean room design and environmental chamber upgrades (walk-in refrigerators and incubators) with design consultants during the detailed engineering and review phase
- Provided construction supervision to track project progress, resolve problems, protect client assets, and ensure worker safety
- Performed commissioning activities for HVAC and compressed air systems
- Developed a list of critical project equipment/instruments for maintenance registration and calibration
- Led decommissioning activities for old systems

Results Achieved

- Successfully delivered project on schedule and within budget
- Qualified and handed over the newly renovated production facility, along with upgraded equipment and systems, to production for use
- Updated all relevant SOPs for proper operator training

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