

Effective Project Execution with Minimal Disruption to Plant Operations

Brevitas' dedicated professionals oversaw the commissioning of three strategic projects within the engineering portfolio for a leading pharmaceutical company. With our expertise in project management and technical assurance, we successfully addressed compliance gaps, improved system redundancy, increased raw material testing capacity and reduced raw material testing cycle times.

AT A GLANCE**INDUSTRY**

Pharmaceuticals

AREA OF EXPERTISE

Engineering and Capital Projects

SERVICES PROVIDED

- Program/Project Management
- Commissioning & Qualification
- Training Solutions

BUDGET

\$3.5 Million (CAD)

DURATION

1 year

IMPACT

Client operations were at risk due to citations during a regulatory inspection. Project management and the commissioning of new equipment and facilities was pivotal in addressing compliance concerns, without jeopardizing day-to-day manufacturing operations.

Business Challenge

The pharmaceutical industry is one that demands a great deal of understanding of regulatory requirements and compliance. After identifying regulatory gaps that were putting operations at risk, our client was in need of upgrades at its Canadian facility. Faced with a short turnaround time, Brevitas supported our client in project management and commissioning with minimal impact on the current operations.

Our Scope

Brevitas team brought on board project management and technical assurance expertise for this portfolio of projects that included the commissioning of key components for the pharmaceutical operations including:

- A new QC raw material sampling area
- A new stability chamber to meet increased capacity
- The replacement of an old compressed air generation system with a new system in order to maintain reliability

Value Added

Because of the sensitive nature of our client's work, our consultants - well versed in the pharmaceutical industry - worked simultaneously during multiple phases of these projects. We achieved the following:

- Coordinated and supervised multiple contractors to ensure regulations and building codes were met during construction
- Led the development and execution of commissioning protocols according to vendor and client specifications
- Maintained a stringent verification process and took immediate corrective actions when required during equipment commissioning
- Developed Standard Operating Procedures (SOP), conducted technical documentation reviews and ensured preventative maintenance programs were in place

Results Achieved

Leveraging our unique project management and commissioning expertise, our client was able to implement new equipment and facilities to address compliance concerns and meet regulatory requirements. Our key accomplishments include:

- Upgraded a Class E area into a Class C and D 400 ft² fully functioning sampling suite and its associated utility systems, that met Good Manufacturing Practice (GMP) requirements
- Delivered a new stability chamber that met increased capacity
- Collaborated with the vendor of the new compressed air generation system to assure all specifications were met and smooth transitioning of operations including start-up training for multiple user groups

For more information, contact us at:

Phone: 289-819-1339

Website: www.brevitasconsulting.com

Email: info@brevitasconsulting.com