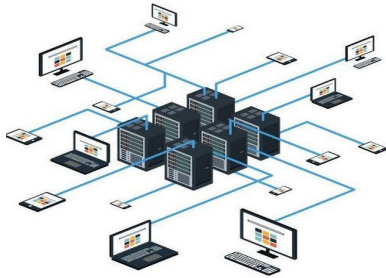


### Network IT Infrastructure Qualification and Process Controls



The Canadian arm of a global healthcare company required qualification of their network IT infrastructure, to prepare to host critical GxP applications. Brevitas consultants were enlisted to deliver an effective qualification and to implement policies & processes to ensure the network remains in a qualified state for the duration of its lifetime.

### AT A GLANCE

#### INDUSTRY

Pharmaceuticals

#### AREA OF EXPERTISE

Regulatory Compliance  
Information Technology

#### SERVICES PROVIDED

- Project Management
- Network Qualification
- IT Services
- Technical Writing
- SOP Writing

#### DURATION

1 year

#### IMPACT

The entire Canadian network IT infrastructure was qualified to host GxP applications. Policies were developed & implemented to ensure that the network remains in a qualified state.

For more information, contact us at:

Phone: 289-819-1339

Website: [www.brevitas.us](http://www.brevitas.us)

Email: [info@brevitas.us](mailto:info@brevitas.us)

Follow us on LinkedIn

[www.linkedin.com/company/brevitas](http://www.linkedin.com/company/brevitas)

### Business Challenge

A new manufacturing facility was being built; to be completed by summer of 2018. A building automation system was planned to go live after completion of the new facility. A requirement arose that the network needed to be qualified, before the building automation system was to go live. The challenge was the short timeline imposed by the need to get the network qualified before the building automation system went live.

### Our Scope

The organization required the support of external expertise and Brevitas was selected to qualify the network IT infrastructure. The network needed to be qualified in accordance with regulatory requirements. Also, policies did not exist for management and control of the network. The first stage of the project was to implement a framework for governing the qualification, and subsequently using this framework to qualify the network components at the main data center, main administrative site and the new manufacturing facility. The second stage of the project was to qualify the network components at the satellite offices across Canada.

### Value Added

- Raised awareness on the importance of data integrity, FDA 21 CFR Part 11 and EudraLex Annex 11
- Introduced a robust framework for qualification and control of the network over the company's lifetime
- Fully qualified the network IT infrastructure in Canada
- Implemented policies and procedures for ensuring that the network remains in a qualified state

### Results Achieved

- Full qualification of the network IT infrastructure including all required deliverables
- Implementation of a framework for asset lifecycle and continuity management
- Implementation of a framework for routine IT operations and client management
- Development & implementation of procedures to maintain regulatory compliance
- Implementation of network specific procedures for security, backup and recovery, inventory management, and event exception reporting