LIFE SCIENCES

Project Profile

Tour Andover Controls Helps Héma-Québec Ensure Safe and Sufficient Blood Supplies

Montréal Headquarters & Laboratory

Québec City Laboratory

"The Continuum system with CFR Compliance Pack plays a critical role in ensuring regulatory compliance for our facilities."

Luc Pelletier
Facility Director

HÉMA-QUÉBEC

Blood processing establishments require strict compliance with internationally recognized safety standards pertaining to the collection, screening, preparation, and delivery of blood components. A key element of regulatory compliance is having a quality facility management system in place to control and monitor the environment in which blood is processed and stored.

Héma-Québec, a leading Canadian blood supplier, must comply with standards established by Health Canada, the country's federally funded healthcare agency. In particular, Héma-Québec is subject to GMP *(Good Manufacturing Practices)*, GLP *(Good Laboratory Practices)*, and GTHP *(Good Tissue Handling Practices)* regulations. To meet this challenge, they turned to *ACS Montréal Inc.* to install an Andover *Continuum*® Facility Management System with CFR Compliance Pack™. *Continuum* provides Héma-Québec with facility-wide accountability and traceability of the environmental conditions in their labs and donor centers.

Héma-Québec Background

Héma-Québec was created in 1998 as part of the reorganization of Canada's blood management system. The organization is headquartered in Montréal, where one of their two laboratories is also located. A second lab is located in Québec City. In addition, Héma-Québec has two *Globule* blood donor centers located inside shopping malls in Montréal and Québec City. Another is located on the ground floor of their Montréal headquarters building. Last year, Héma-Québec collected more than 256,000 units of blood and provided blood products for more than 80,000 hospital patients.

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System Validation

Health Canada required that Héma-Québec's facility management system be thoroughly *validated* before the agency would allow blood processing operations to begin. In addition to designing and installing the Andover *Continuum* system, *ACS Montréal* partnered with Héma-Québec for the lengthy validation process.

***Continuum* workstation operator monitors cold room parameters**

Validation is an extremely extensive commissioning and qualification process, requiring a multitude of documented steps to assure a regulatory agency that a system both meets the predetermined design and installation specifications *and* conforms to the standard operating procedures (SOPs) of the facility using the system. To ensure a smooth validation process, *ACS Montréal* worked closely with Héma-Québec to adhere to and fully integrate the practices and principles outlined by the pharmaceutical industry's GAMP 4 *(Good Automated Manufacturing Practice)* guidelines. Along with subjecting their own business practices to a Héma-Québec *critical vendor audit*, *ACS Montréal* had to test and certify for Health Canada all hardware devices, all software programs and graphics, proper network operation, and the training levels of all its service technicians and programmers involved with the project.

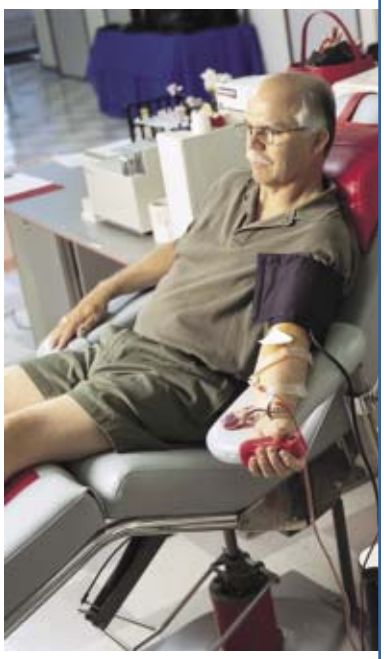
CONTINUUM®
CFR COMPLIANCE PACK™
Authorized Integrator

One Integrated System for Control, Monitoring, and Data Collection

Complying with Health Canada's standards did not end with initial system validation. Héma-Québec's facilities are audited at least once a year by Health Canada. Health Canada requires extensive data regarding the environmental parameters that blood collection and processing facilities operate within daily. As a result, SCADA (Supervisory Control and Data Acquisition) is a critical component of Héma-Québec's overall compliance program. The fact that the *Continuum* system integrates SCADA capabilities with control and monitoring particularly appealed to Héma-Québec. They could eliminate the need for a separate stand-alone data acquisition system, not to mention the numerous chart recorders installed throughout their labs and the stacks of paper they produce.

Redundant *Continuum* controllers for cold room control

"We were impressed not only by the amount of valuable experience *ACS Montréal* had in laboratory environmental controls and system validation," comments Luc Pelletier, Héma-Québec Facility Director, "but also that *Continuum* could provide us with a *single integrated system* for HVAC control, cold room control and monitoring, *and* data acquisition."



The *Continuum* Facility Management system plays a comprehensive role in the proper handling of blood at all Héma-Québec locations. These locations are connected over a Wide Area Network (WAN):

Security guards monitor CyberStation alarms 24/7/365

In the Montréal Labs and Headquarters offices:

- Complete HVAC control of labs and 10 cold rooms
- Monitoring of the donor center
- SCADA and fault alarms for lab equipment (testing equipment, incubators, platelet agitators, etc.)

In Québec City Labs and Offices:

- Complete HVAC controls of labs, 12 cold rooms, and office areas
- SCADA and fault alarms for lab equipment (testing equipment, incubators, platelet agitators, etc.)

In the Remote Donor Centers:

- SCADA for lab equipment and room temperature monitoring
- HVAC control

CyberStation workstation cold room monitoring screens

Units of blood stored in one of several walk-in freezers

Continuum's front-end graphical operator interface, CyberStation®, is used in both locations by facilities staff to control and monitor all HVAC and refrigeration conditions and alarms. Héma-Québec security guards also use a CyberStation workstation in the Command Center to monitor equipment alarms and critical temperatures.

Blood Processing and Storage

When units of blood arrive either by trucks from the remote blood donor centers or directly from their in-house donor center, as in the case in the Montréal headquarters, the accompanying sample vials are sent immediately to a testing area to be checked for viruses, bacteria, etc.

The blood units are processed and refrigerated until testing is completed and then placed into a centrifuge, where the blood is separated into plasma, platelets, and packed red blood cells. The platelets are then transferred to agitators to prevent aggregation. Depending on the blood product, it will either be stored in a walk-in refrigerator or in a freezer until it is transferred to a medical facility for patient use.

Héma-Québec also freezes and stores umbilical cord blood, bone marrow, stem cells, rare blood types, and human tissues for transplant purposes. These products are deep frozen in special cryogenic freezers.

Blood Products	Storage Periods and Temperatures
Red Blood Cells	42 days in the refrigerator (2-6°C.) and up to 10 years in the freezer for rare blood types
Platelets	5 days at room temperature (20-24°C.), with continuous agitation
Plasma Products	1 year in the freezer (-22° C.)

Redundant compressors for one of Héma-Québec's cold rooms

High-Availability, Redundant Cooling Systems Provides Peace-of-Mind

Because proper blood storage temperature is of paramount importance, both Héma-Québec locations have *redundant* cooling systems. Each system is controlled and monitored by a separate *Continuum* controller. If one system fails, the second is started by its *Continuum* controller. In addition, the evaporator defrost cycle is adjustable by the operator to meet each cool room's particular requirements.

"The cooling redundancy looked at first to present a programming challenge," says David Allen, Vice President of *ACS Montréal Inc*. "But with Andover's flexible *Plain English*® programming language, we were able to program a custom sequence of operations that enables the cooling systems to switch every 6-8 hours (depending on how often the walk-in doors have been opened), with a 10 minute overlap period built into the control sequence."

An Infistat®, *Continuum*'s programmable operator interface with built-in thermistor, is installed in every critical department. The unit features a 2-line LCD display and a 12-button keypad, which allows lab workers to view the environmental parameters, scroll and view alarm messages, and silence alarms.

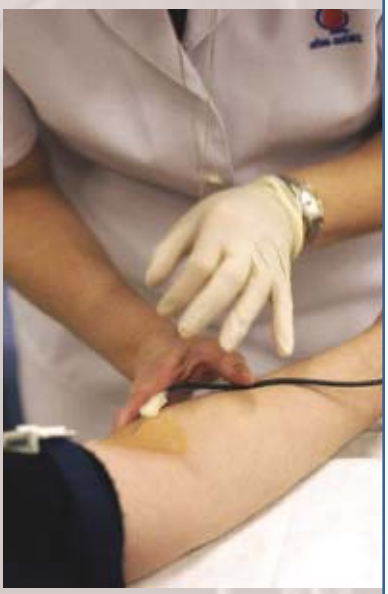
21 CFR Part 11 Compliance

The United States Food and Drug Administration (FDA) has a strong influence over global regulatory affairs. Recognizing this, alongside their desire to migrate to electronic recordkeeping, Héma-Québec specified a system capable of meeting the requirements of **21 CFR Part 11**.

In place since 1997, 21 CFR Part 11 was developed by the FDA to promote and regulate the use of electronic signatures, record keeping, and reporting practices for all business disciplines under its control. To enable compliance, all operational and environmental conditions that affect product safety, efficacy, or quality must be recorded along with details of confirmed operator identity and explanation of actions taken. These records must be securely stored, and be readily retrievable in both electronic and human readable form; and in the case of blood products, kept *forever*.

Paperless Proof of Regulatory Compliance

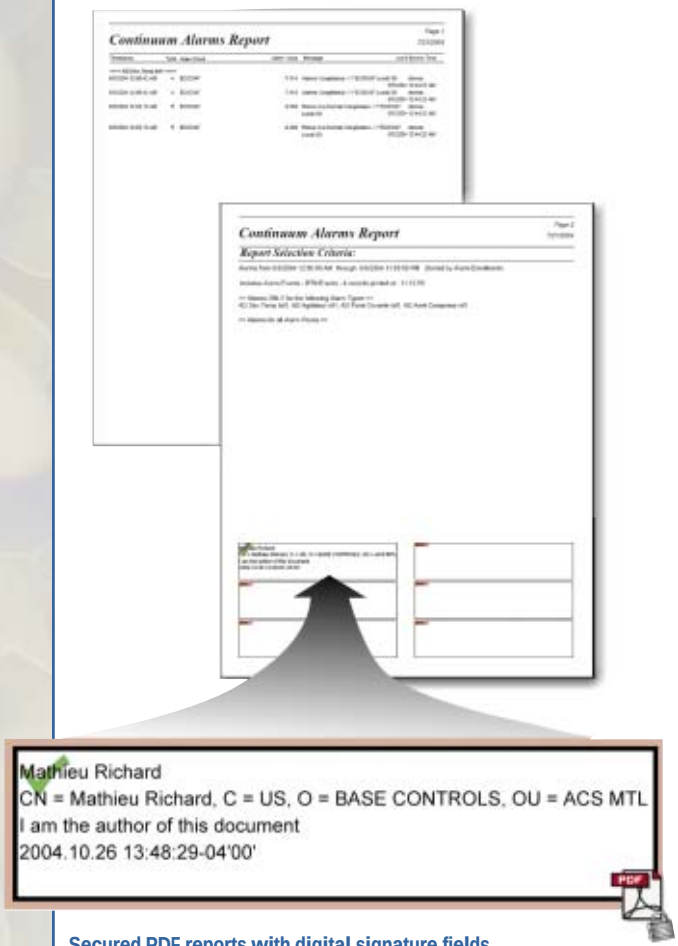
In order to facilitate 21 CFR Part 11 compliance, *ACS Montréal* installed Andover's CFR Compliance Pack software on Héma-Québec's CyberStation workstations. CFR Compliance Pack is an enhancement to the *Continuum* system. It provides regulated businesses with the ability to generate paperless proof of regulatory compliance. How? The software includes comprehensive tracking, record-keeping, archiving, and report generation capabilities, along with rigorous password management and operator prompting features for all system changes and alarm acknowledgments. Together, these features deliver facility-wide accountability and traceability of the environmental conditions at Héma-Québec 24/7/365.



Blood platelet agitators are monitored for alarms

A temperature set point change or out-of-range alarm; a sudden change in pressure or relative humidity; an equipment failure; or unauthorized access to a computer system in the lab area — the CFR Compliance Pack maintains a complete record of all such system events and parameters. In addition, trend logs, operator and alarm activity reports, and access events, when applicable, can be generated automatically from these electronic records and formatted as Adobe PDF files. After verifying a report's information, a department supervisor at Héma-Québec can sign off on it by applying their digital signature to the document.

Health Canada Santé Canada



Secured PDF reports with digital signature fields

"There is a phrase in the regulated industries our customers are familiar with," says Clive Smith, Tour Andover Controls' Life Sciences Industry Marketing Manager. " 'If it's not documented, it didn't happen.' Our CFR Compliance Pack allows Héma-Québec to document all critical system data *electronically*. Laboratory chart recorders, stored reams of paper records, and boxes of microfiche film archives are the physical manifestations of a now outdated paper-based legacy. The CFR Compliance Pack's feature set allows Héma-Québec to meet the FDA's 21 CFR Part 11 electronic records and signatures standards and derive all the advantages of electronic record keeping."

PROJECT AT A GLANCE:

Project Type:
Lab HVAC Controls and SCADA

Project Name:
Héma-Québec

Location:
Montréal & Québec City, Canada

Market Segment:
Life Sciences

Number of Buildings:
2 Laboratories, 3 Blood Donor Centers (on WAN)

Total Square Feet:
over 250,000+ (23,225 m^2)

***Continuum* Equipment Installed:**
6 – CyberStation Workstations
10 – NetControllers with I/O modules
13 – Infistat Display Modules
10 – SCX 920s & I2920s
9 – LCX 810s & i2810s
20 – i2814s
3 – i2608s
5 – i2624s
4 – i2800s
204 – TCXs and i2867s
1 – TCX 851

Network:
Ethernet TCP/IP network

Applications:
Temperature and humidity control
Room pressure control
Cold room controls and monitoring (with total redundancy)
Clean room control ISO5 (Class 100)
Incubator and agitator monitoring

Total System Points:
650 (Montréal); 760 (Quebec City)

Andover Controls Representative:
ACS Montréal Inc.

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