

Radiochemistry and FDG Production Areas

Montréal, Québec



The project consisted of upgrading the existing FDG production area to ensure that the operations, facility, and documentation are compliant to the latest cGMP guidelines and CNSC regulations. Following the completion of the project, the PET centre successfully passed an audit by Health Canada in April 2010.

The GMP aspects of the area were improved by creating new clean rooms for the automatic synthesis units, hotcells, and for Quality Assurance activities. Upgrades were also made to the sterile dispensing area, with a new automated dose dispenser integrated into the process.

The existing ventilation supply and distribution system as well as the associated controls system were re-configured and validated, and the required SOP's implemented. A program for the monitoring of critical parameters was implemented, and SOP's generated for calibration, maintenance and alarm generation/reporting.

Environmental monitoring programs were implemented including the generation of SOP's, equipment purchases, and arranging for off-site service contracts.

Validation documentation was prepared and executed to demonstrate that the environmental conditions within the areas meet cGMP requirements, and that the ventilation, BAS and support utilities are operated and maintained in a state of control.

CLIENT

Montreal Neurological Institute –
PET Centre

LOCATION

Montréal, Québec

YEARS

2009–2010

PHASE

- Area Renovation and Validation

COST

\$300,000 (CAD)

