



Your Vision
Our Purpose
Healthier Lives

THE CENTRE FOR CELL AND VECTOR PRODUCTION (CCVP)

*Deep Expertise in Manufacturing
Across the Development Life Cycle*

FACILITY AND LOCATION

World-class Good Manufacturing Practices (GMP) facility built in partnership with University Health Network (UHN), located in downtown Toronto, adjacent to some of Canada's leading hospitals and research institutes. CCVP includes:

- ▶ 10 suites, two dedicated to viral vectors, in 20,000 ft² facility
- ▶ ISO Class 7/Grade B clean rooms for clinical trial manufacturing
- ▶ Designed for USFDA, Health Canada, EMA compliance
- ▶ Located near both of Toronto's international airports

MANUFACTURING SERVICES

- ▶ Cell Manufacturing
- ▶ Viral Vector Manufacturing
- ▶ Cell Banking
- ▶ Fill & Finish
- ▶ Cryopreservation

MANUFACTURING SUPPORT

- ▶ On-site QC Testing Capabilities
- ▶ On-site QA/Audit Support
- ▶ Expert Regulatory Guidance
- ▶ Cryogenic Distribution Using Validated Logistics
- ▶ Extensive Process Development Capabilities
- ▶ Seamless Technology Transfer Process



Commercializing
Living Therapies



UHN Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

cdmo@ccrm.ca | www.ccrm.ca

GMP MANUFACTURING

CENTRE FOR ADVANCED THERAPEUTIC CELL TECHNOLOGIES (CATCT)

- ▶ Process Closure, Automation
- ▶ Cost Analysis, Risk Reduction
- ▶ Work Flow Simplification
- ▶ Media Development
- ▶ Culture Intensification

CATCT
Process Development Facility
10,000 ft²



Funded by the
Government
of Canada



**Quality
Control
Lab**
1,500 ft²

CCVP
cGMP Facility
20,000 ft²

**2 Viral
Vector Clean
Rooms**
totalling 520 ft²

**8 Cell
Therapy
Clean Rooms**
from 237 ft² to
301 ft²

QUALITY SYSTEMS

Robust and phase-appropriate:

- ▶ Compliant with U.S. and Canadian GMP, and the new EU ATMP Guidelines
- ▶ Supports CTA/IND acceptance by global regulators, minimizes variability, accelerates timelines, reduces costs
- ▶ Independent quality department including QC and QA
- ▶ Robust document management, change control and CAPA systems

CUTTING-EDGE TECHNOLOGIES

CCVP equipment capabilities include:

- ▶ Hardware (USP/DSP): Cytiva, Miltenyi, Sartorius, AsepticTech and more
- ▶ QC capacity: real-time PCR, multi-mode plate reader, Endosafe, flow cytometry
- ▶ Software: MasterControl® QMS, batch record and material management systems
- ▶ Cryostorage for 25,000+ vials
- ▶ Gamma cell irradiator

EXPERIENCE & EXPERTISE

100+ staff with deep experience in cell and gene therapy manufacturing:

- ▶ Manufacturing for global clinical trials
- ▶ Small-scale autologous and clinical-scale allogeneic manufacturing workflows
- ▶ Complex and highly customized manufacturing runs (CAR-T, PSC, NK, MSC, LVV, AAV)
- ▶ Significant growth of GMP operations, planning for commercial manufacturing facility

We solve the big challenges in cell and gene therapy through seamless integration of extensive expertise, enabling technologies, collaborative processes, and specialized infrastructure