



Clean Rooms
Designed for Custom
Processes and
Equipment

THE CENTRE FOR CELL AND VECTOR PRODUCTION (CCVP)

*A Transparent and Flexible Approach
to Manufacturing*

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

FACILITY AND LOCATION

World-class Good Manufacturing Practices (GMP) facility built in partnership with University Health Network (UHN), located at MaRS, 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 Phase I and II trials
- ▶ Designed for USFDA, Health Canada, EMA compliance
- ▶ Located a short distance from Toronto Pearson International Airport



Commercializing
Living Therapies



Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

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

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

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

QUALITY SYSTEMS

Robust and phase-appropriate:

- ▶ Compliant with U.S. and Canadian cGMPs, 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): GE Healthcare, Miltenyi, Eppendorf, Sartorius and more
- ▶ QC capacity: real-time PCR, multi-mode plate reader, Endosafe, flow cytometry
- ▶ Software: MasterControl® QMS, batch record and material management systems
- ▶ Cryo-storage for 25,000+ vials
- ▶ Gamma cell irradiator

EXPERIENCE & EXPERTISE

40+ staff with 100+ combined years of experience in cell and gene therapy manufacturing:

- ▶ Manufacturing for global clinical trials
- ▶ Small-scale autologous and large-scale (200 L) allogeneic batches as well as scalable workflows
- ▶ Complex and highly customized manufacturing runs (CAR-T, PSC, NK, MSC, LVV, AAV)

COLLABORATION, PROJECT MANAGEMENT, TRANSPARENCY AND FREQUENT INTERACTION WITH TECHNICAL LEADERSHIP ARE THE CORE OF OUR PHILOSOPHY.