



Clean Rooms  
Designed for Custom  
Processes and  
Equipment

# THE CENTRE FOR CELL AND VECTOR PRODUCTION (CCVP)

*A Transparent and Flexible Approach  
to Manufacturing*

## FACILITY AND LOCATION

World-class Good Manufacturing Practices (GMP)-compliant 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 ft<sup>2</sup> 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

## MANUFACTURING SERVICES

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

## MANUFACTURING SUPPORT

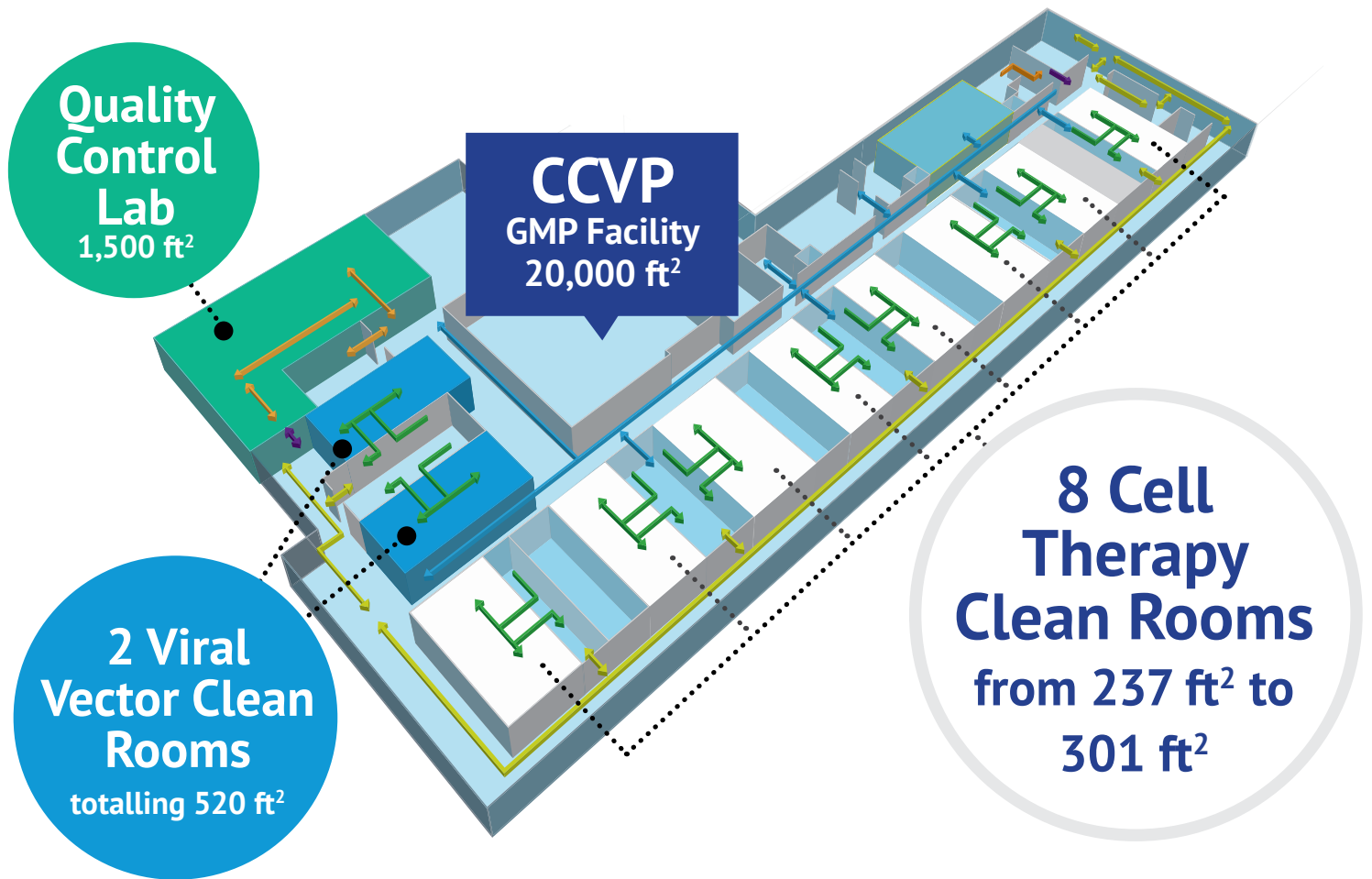
- ▶ On-site QC Testing Capabilities
- ▶ On-site QA/Audit Support
- ▶ Expert Regulatory Guidance
- ▶ Cryogenic Distribution using Validated Logistics
- ▶ Extensive Process Development Capabilities



Commercializing  
Living Therapies



Toronto General  
Toronto Western  
Princess Margaret  
Toronto Rehab  
Michener Institute



## QUALITY SYSTEMS

### Robust and phase-appropriate:

- ▶ Compliant with U.S. and Canadian GMPs, and 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, 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.**