Stem Cell Network | Réseau de Cellules Souches
Powering Regenerative Medicine | Propulsons la médecine régénératrice

Conseil national de recherches Canada | National Research Council Canada

Title of Event: Canadian Rare Disease Symposium: Preparing for Clinical Trials – International Regulatory Insights, and cGMP Gene Therapy Manufacturing capabilities in Canada

Date: Oct 1, 2025
Time: 1:00 PM ET
Location: Virtual (Zoom)

AGENDA

13:00–13:15 | Welcome & Opening Remarks

13:15 - 14:45 | Session 1 - Preparing for Clinical Trials – International Regulatory Insights for Canadian Developers

Moderated by Patrick Bedford, Founder & Managing Director, weCANreg Consulting Group, Inc

- This session will feature short talks and discussions from regulatory leaders, including Japan, Europe and Canada, offering international perspectives and insights on the regulatory requirements for rare disease therapies, including gene therapies. The panel will provide an overview of regulatory and health system pathways for introducing rare disease therapies into clinical use across jurisdictions, covering approval and reimbursement timelines, opportunities for collaboration, and jurisdiction-specific incentives or challenges that developers should be aware of.
- Building on these perspectives, a global regulatory strategist will highlight similarities and differences across jurisdictions and share practical insights on how companies and researchers can plan for diverse requirements.
- Together, the panel will highlight lessons learned, identify opportunities for alignment, and provide practical guidance for researchers and developers seeking to bring rare disease therapies into clinical use.

Time	Speaker	Organization
13:15 – 13:30	**Yoshiaki Maruyama**, Review Director, Office of Cellular and Tissue-based Products	Pharmaceuticals and Medical Devices Agency (PMDA)
13:30 – 13:45	**Omar Tounekti**, Manager, Gene Therapies and Radiopharmaceuticals Division	Health Canada
13:45 – 14:00	**Ilona Reischl,** Quality Assessor,	Austrian Medicines and Medical Devices Agency; Chair, European Medicines Agency Committee for Advanced Therapies
14:00 – 14:15	**Sam Sathiamoorthy,** President & Principal Consultant	AspireBio Consulting
14:15 – 14:45	**Panel discussion and Q&A**	

14:45 – 15:00 EST: Break (15 minutes)

15:00 – 15:45 EST: Session 2 - Overview of Canadian Manufacturing
Moderated by Kelley Parato, Program Director, Health Challenge Program, National Research Council Canada

- This session will spotlight companies and national laboratories involved in supplying cGMP vectors for gene therapy. It will offer an up-to-date overview of Canada's GMP manufacturing landscape, highlighting current capabilities, future growth potential, and the role of these facilities in supporting the development and commercialization of gene and cell therapies. By mapping available resources and expertise, the session will help stakeholders navigate manufacturing challenges, identify opportunities for collaboration, and better understand how Canadian infrastructure aligns with international quality and regulatory standards.

Time	Speaker	Organization
15:00 – 15:05	Overview – Kelley Parato, Program Director, Health Challenge Program	National Research Council Canada
15:05 - 15:10	Flash Talk 1 - Jessica Madigan, Director, Business Development	BIOVECTRA
15:10 – 15:15	Flash Talk 2 - Minh-Luan Tran, Director, Clinical Trial Material Facility, Human Health Therapeutics Research Centre	National Research Council Canada
15:15 – 15:20	Flash Talk 3 - Jennifer Quizi, Director, Biotherapeutics Manufacturing Centre- Virus Manufacturing Facility	Ottawa Hospital Research Institute
15:20 – 15:25	Flash Talk 4 - Lisa Dreolini, Research Assistant, BC Cancer & Jessica Wilson, Production Coordinator, Quality Management Systems	Canada's Michael Smith Genome Sciences Centre
15:25 – 15:30	Flash Talk 5 - Dennis-Claude Roy, Chief Scientific Officer	C3i
15:30 – 15:35	Flash Talk 6 - Jessica Tate, Vector Platform Technologies	CCRM
15:35 – 15:45	Q&A	

15:45 – 15:55 EST: **Reflection**

15:55 – 16:00 EST: **What's Next & Closing Remarks**