



CELL & GENE THERAPY REVOLUTION

All hands on deck !

in partnership
with



CellCAN's Third
pan-Canadian Strategic Forum
on Cell & Gene Therapy

September 19 to 21, 2022
Ottawa

KNOWLEDGE – MOBILIZATION – ACTIONS
www.cellcan.com/forum2022

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**THANK YOU FOR MAKING
THIS EVENT A SUCCESS!**

WELCOME WORD FROM CELLCAN



Chers délégués,

Je suis fier de vous accueillir au troisième forum stratégique pancanadien de CellCAN sur la Révolution en thérapies cellulaires et géniques : Tous sur le pont! dans la capitale du Canada, Ottawa. Des personnes dévouées comme vous ont fait de cet événement un succès retentissant, comme en témoignent les retours extrêmement positifs des deux premières éditions. Avec plus de 35 conférenciers de renommée mondiale, le Forum est devenu un rendez-vous incontournable pour réseauter et s'informer sur les thérapies avancées au Canada et dans le monde.

La pandémie de COVID-19 a apporté son lot de défis et les thérapies avancées sont plus que jamais au premier plan des efforts de réponse thérapeutique. Nous devons continuer à unir les forces de tous les intervenants canadiens pour faire en sorte que le Canada prenne sa place parmi les leaders mondiaux en biofabrication de thérapies avancées. Chaque jour, nous nous rapprochons du sceau de qualité commun que nous envisageons pour la fabrication de thérapies cellulaires et géniques au Canada, ce qui augmentera la capacité de faire passer rapidement et efficacement les concepts de traitement novateurs dans la pratique clinique standard. La troisième édition de notre Forum stratégique, qui se penchera sur les solutions pour combler le manque de personnel qualifié, constitue une étape importante vers cet objectif et c'est un privilège de vous retrouver enfin en personne.

Le programme de la préconférence portera sur les biomarqueurs et l'analytique dans la nouvelle ère de la médecine personnalisée. L'accent a été mis sur les groupes à l'origine des efforts considérables et des essais cliniques axés sur la médecine régénérative et la thérapie cellulaire qui ont lieu au Canada. La conférence principale portera sur les nouvelles initiatives visant à accroître la capacité de biofabrication, les solutions clés pour surmonter la pénurie de talents, l'augmentation des investissements dans le secteur, la plasticité de la réglementation et des remboursements et les stratégies visant à éliminer les goulots d'étranglement dans la biofabrication pour répondre à la demande.

Au nom du conseil d'administration de CellCAN, de notre incroyable équipe de direction et de l'ensemble des comités scientifique et organisateur, je voudrais remercier nos conférenciers, nos précieux partenaires et commanditaires, et enfin et surtout, vous, qui participez à cette révolution. Je vous souhaite à tous un événement riche en enseignements, de nouveaux partenariats et d'excellentes discussions.

Cordialement,

Dear attendees,

I am proud to welcome you to CellCAN's third pan-Canadian Strategic Forum on the Cell & Gene Therapy Revolution: All hands on deck! in Canada's capital, Ottawa. Dedicated people like yourselves have turned this event into a tremendous success, as evidenced by the overwhelming positive feedback from the first two editions. With more than 35 world-renowned speakers, the Forum has become a key meeting to network and learn about advanced therapies in Canada and around the world.

The COVID-19 pandemic brought its many challenges and advanced therapies are more than ever at the forefront of therapeutic response efforts. We must continue to unite the strengths of all Canadian stakeholders to ensure that Canada takes its place among the global leaders in advanced therapies biomanufacturing. Every day, we are getting closer to the common seal of quality we envision for cell and gene therapy manufacturing in Canada, which will increase capacity to rapidly and effectively migrate innovative treatment concepts into standard clinical practice. With a focus on addressing the talent gap of skilled HQPs, the third edition of our Strategic Forum is an important step towards this goal and it is a privilege to finally see you in person.

The program of the preconference will cover biomarkers and analytics in the new era of personalized medicine. The spotlight has been placed on the groups behind the tremendous efforts and the regenerative medicine and cell therapy focused clinical trials taking place in Canada. The main conference will cover novel initiatives to increase biomanufacturing capacity, key solutions to overcome the talent shortage, increasing investments in the sector, regulatory and reimbursement plasticity and strategies to remove bottlenecks in biomanufacturing to meet demand.

On behalf of the CellCAN Board of directors, our incredible management team and the entire scientific and organizing committees, I would like to thank our speakers, our invaluable partners and sponsors, and last but not least, you, for being part of this revolution. I wish you all an insightful meeting, new partnerships and great discussions.

Sincerely,

Denis Claude Roy, M.D.
CEO

CellCAN AT A GLANCE



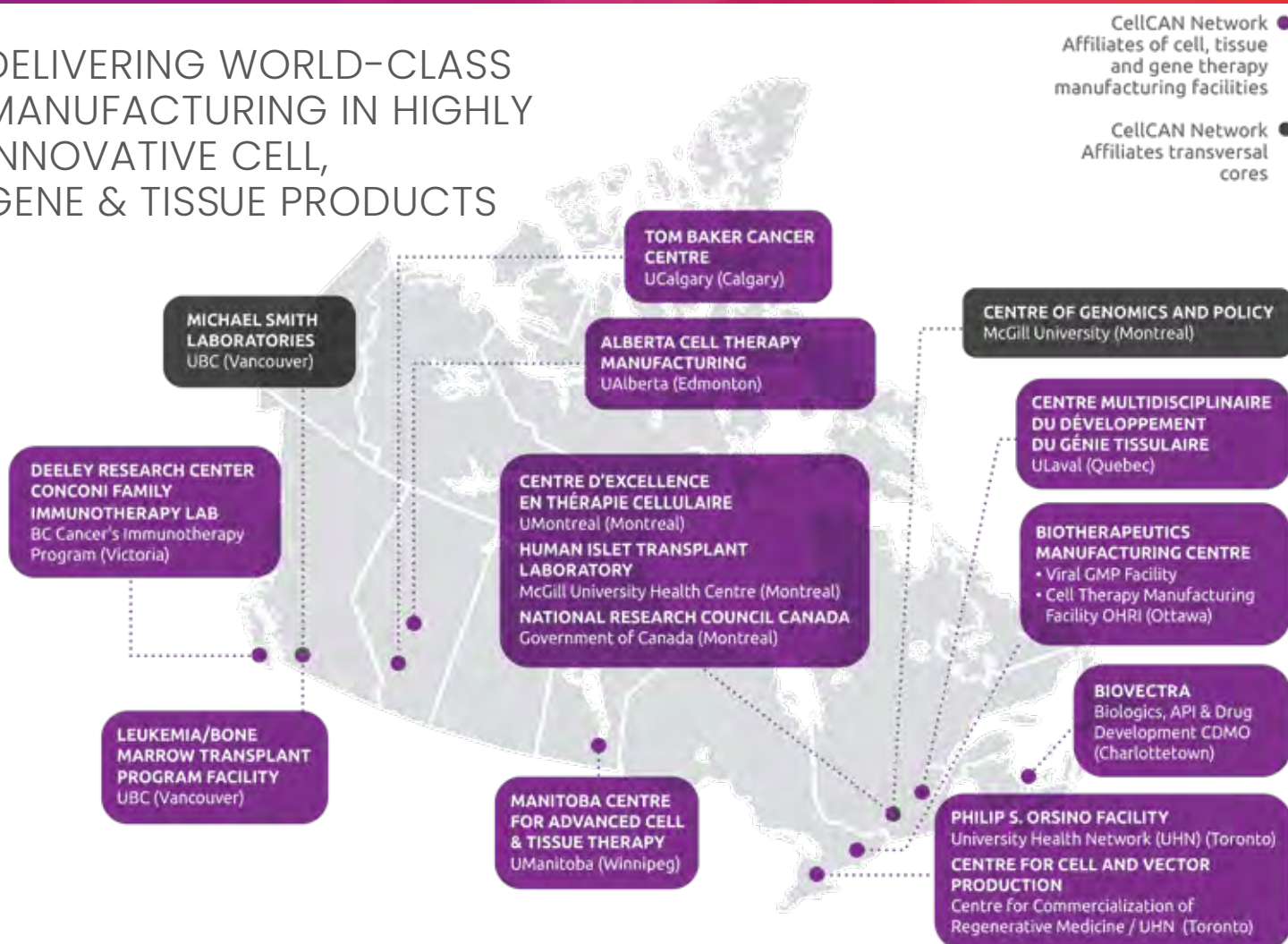
VISION

Our vision is that cell & gene therapy manufacturing in Canada must operate under a **common seal of quality** to increase capacity and rapidly and effectively migrate innovative treatment concepts into standard clinical practice.

MISSION

Our mission is to mobilize knowledge to improve the quality, safety and feasibility of cell & gene therapy in Canada through **optimal manufacturing practices**.

DELIVERING WORLD-CLASS MANUFACTURING IN HIGHLY INNOVATIVE CELL, GENE & TISSUE PRODUCTS



BUILD A STRONG CANADIAN NETWORK

We are translating and mobilizing knowledge to build a strong cell & gene manufacturing sector.



ADVANCE REGULATORY STANDARDS

We are channelling information from all Canadian CMF and providing input to Health Canada to advance regulatory standards and help establish adequate regulatory oversight. We take into account new technologies and deliver knowledge back to our stakeholders.



GENERATE EFFECTIVE OUTREACH

We are empowering information multipliers and Canadians to make informed decisions about their safety regarding cell & gene therapies.



POSITION CANADA AS A WORLD LEADER

We are helping to drive Canada's economy by creating business and networking opportunities with the cell & gene manufacturing community.

WELCOME WORD FROM C3I AND CCRM



CCRM, a leader in developing and commercializing regenerative medicine-based technologies, including cell and gene therapies, is delighted to welcome you to Ottawa and CellCAN's third pan-Canadian Strategic Forum on the Cell & Gene Therapy Revolution: All hands on deck!

Canada has a strong legacy of scientific excellence in stem cell research, bioengineering and regenerative medicine. This conference brings together experts in the field to discuss the challenges we face in bringing these discoveries to the marketplace so that people can benefit from them. CCRM believes that the pathway to Canadian leadership in the Life Sciences will build on our collaborative nature and our achievements in the science and industrialization of cell and gene therapies. We welcome opportunities, such as this event, to hear from industry, government, clinicians, researchers, and those knowledgeable in regulatory affairs and reimbursement, on how we can work together more productively to achieve this goal.

CCRM has invested heavily in personnel and infrastructure to boost Canada's capacity in advanced therapy manufacturing, and we're delighted to announce the launch of OmniaBio Inc. In case you missed the news in May (2022), OmniaBio, currently being built at McMaster Innovation Park in Hamilton, Ontario, will enable pivotal/Phase III and commercial-scale manufacturing for cell and gene therapies. As our subsidiary, it will complete CCRM's continuum of process development, and clinical and commercial manufacturing capabilities, building on the work that takes place at our cGMP-compliant facility for Phase I/II in-human clinical trials in Toronto.

At CellCAN's Strategic Forum, you will hear about the Canadian Advanced Therapies Training Institute (CATTI), a partnership between CellCAN and CCRM. We recognize how crucial it is to the industry to have a skilled GMP workforce. To this end, we have put the resources and infrastructure in place to ensure Canadian workers are trained and prepared to participate in an industry ushering in the future of medicine.

CCRM appreciates the opportunity to partner with CellCAN and C3i in developing a program that will be informative, thought-provoking, and even inspirational. We look forward to engaging with you over the next couple of days. Please stop by CCRM's booth.

Sincerely,
Michael H. May, PhD
President and CEO



Centre C3i would like to welcome all participants to CellCAN's third pan-Canadian Strategic Forum on the Cell & Gene Therapy Revolution: All hands on deck! We are on the cusp of a global revolution in medicine. Medical researchers and product developers are now poised to bring forward new gene, cell and tissue engineering therapies that hold great promise for profound and durable responses in patients exhibiting a diverse array of serious and costly conditions, many of which lack current treatments.

We, at C3i, are pleased to be a part of this partnership with CellCAN and CCRM as the objective of this innovative forum aligns with our mandate to accelerate discovery and commercialization, thereby providing access to lifesaving breakthroughs in cell and gene therapies. Indeed, future continuous growth of cellular and gene therapies will require the collaboration amongst experts from various disciplines, including clinical medicine, manufacturing, commercialization, regulatory and reimbursement, in an effort to maximize the success in bringing lifesaving therapies to patients.

We believe that you will find the topics and the program of this forum interesting, informative and inspirational. Our wish is for you to leave the conference enriched with ideas and plans for the future, with professional contacts and new friendships to support Canada's leadership in this important medical revolution.

Sincerely,
Louisa Petropoulos, PhD
CEO

PRECONFERENCE PROGRAM - SEPTEMBER 19, 2022

7:00 – 9:00	Registration Breakfast	Nunavut – 4th floor Confederation III
9:00 – 9:10	Welcome from CellCAN – Regenerative Medicine and Cell Therapy Network Denis Claude Roy, CEO, CellCAN	Confederation I & II
Theme 1	Biomarkers and analytics in the new era of personalized medicine Moderator: Renaud Manuguerra-Gagné, Journalist & Scientific Communicator Chair: Nicolas Montpas, Associate Director, Biomarker & Diagnostics Unit, C3i	Confederation I & II Sponsored by: 
Personalized medicine and quality control for CGT manufacturing under GMP rely on the identification, development and validation of biomarkers. This theme covers their utility in drug development and manufacturing and the generation of real-world evidence.		
9:10 – 10:30	Toolbox for quality control in cell & gene therapy Nicolas Montpas, Associate Director, Biomarker & Diagnostics Unit, C3i Accreditation for quality control testing in cell & gene therapy Stéphanie Peika, Founder & CEO, SLP Consult The role of digital PCR in discovery, safety and efficacy Claude Lachance, Senior Application Specialist, Bio-Rad Sponsored by: 	
10:30 – 10:50	Health break and exhibitors visit	
10:50 – 12:00	T-cell reconstitution after hematopoietic stem cell transplantation Jean-Sébastien Delisle, Physician-Scientist, Hôpital Maisonneuve-Rosemont, Medical Director, Centre d'excellence en thérapie cellulaire Novel technologies in CGT biomarker and analytics: Genome Canada's Precision Health Program Rob Annan, President & CEO, Genome Canada Regulatory challenges and possible approaches for microbiological testing of cell & gene therapy product Yves Vallières, Industry Business Development Manager – Rapid Microbiology Methods, bioMérieux	
12:00 – 13:30	Lunch, networking and exhibitors visit	Confederation III

PRECONFERENCE PROGRAM - SEPTEMBER 19, 2022

Theme 2

Clinical trials in advanced therapies

Confederation I & II

Moderator: Renaud Manuguerra-Gagné,
Journalist & Scientific Communicator

Chair: Denis Claude Roy, CEO, CellCAN

This preconference half-day overviews the structure of advanced therapy clinical trials under way and dives into the impact that these novel therapeutic trials have on patient access and growing the CGT ecosystem at large.

13:30 – 15:00

Early cell and tissue therapy trials in Québec; lessons learned and outlook on the future

Jean-Sébastien Delisle, Director, ThéCell - Réseau de thérapie cellulaire, tissulaire et génique du Québec

Advancing regenerative medicine clinical trials and clinical translation

Lauralyn McIntyre, Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute & Stem Cell Network-funded Investigator

Tailor-made for Canada: The BioCanRx cell and gene immunotherapy program

John Bell, Scientific Director, BioCanRx

15:00 – 15:20

Health break and exhibitors visit

15:20 – 16:55

Clinical trial design & launch for cell-based therapy targeting COVID

Duncan Stewart, Executive Vice-President, Research, The Ottawa Hospital, CEO & Scientific Director, Ottawa Hospital Research Institute, OIRM

Towards more efficient clinical trials in Canada

Annette Hay, Senior Investigator, Canadian Clinical Trials Group, Excellerate

Canadian Blood Services and Héma-Québec: Supporting Canada's cell therapy ecosystem

Jelena Holovati, Laboratory Director, Canadian Blood Services Stem Cell Manufacturing; Associate Professor, University of Alberta

Nancy Robitaille, Vice President, Transfusion Medicine, Héma-Québec; Professor, Pediatrics, Université de Montréal

16:55 – 17:00

Wrap-up of the preconference

17:30

Welcome Reception

Confederation foyer

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CCRM is expanding its CDMO offering. As a CCRM subsidiary, OmniaBio Inc. will extend CCRM's manufacturing capacity from Phase I/II clinical trials to Phase III and commercial-scale manufacturing. Benefitting from an ecosystem built over a decade, OmniaBio will be Canada's largest manufacturing facility for cell and gene therapies. This expansion will build on CCRM's training, infrastructure, manufacturing platforms, technologies and partnerships to deliver focused manufacturing for cell and gene therapies that includes viral vector, allogeneic and autologous manufacturing platforms. Reserve your space now.



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CCRM's GMP facility (operational)


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~80,000 sq ft


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15 clean rooms

OmniaBio phase II Opening 2025-6


~315,000 sq ft


45,000 sq ft lab


32 clean rooms

CONFERENCE PROGRAM - SEPTEMBER 20, 2022

7:30 – 8:50	Registration Breakfast	Nunavut – 4th floor Confederation III
8:50 – 9:00	Welcome from CellCAN – Regenerative Medicine and Cell Therapy Network Denis Claude Roy, CEO, CellCAN	Confederation I & II
9:00 – 9:20	Special announcement	
Theme 1	Pushing beyond the limits of CGT manufacturing Moderator: Renaud Manuguerra-Gagné Chair: David Courtman, Scientist, Director of Biotherapeutics, Ottawa Hospital Research Institute	Confederation I & II
Limited domestic biomanufacturing capacity has forced manufacturers to deploy novel strategies to increase production within existing and new facilities. Novel initiatives and innovative technologies will be detailed in effort to reduce bottlenecks and ramp up domestic biomanufacturing.		
9:20 – 10:20	Building momentum for now and the future: Canadian biomanufacturing strategy and investment Rodrigo Arancibia, Senior Director, Life Sciences and Biomanufacturing Branch, Innovation Science and Economic Development, Government of Canada Biomanufacturing and enabling capabilities at the NRC: vaccines and beyond Kelley Parato, Director, Cell and Gene Therapy Challenge Program, Human Health Therapeutics Research Centre, National Research Council of Canada	
10:20 – 10:40	Health break and exhibitors visit	
10:40 – 12:00	Challenges and answers to Cell Therapy Manufacturing – Issues and solutions to launching clinical trials – Cancer Immunotherapy production for clinical trials and the pathway to commercialization Louisa Petropoulos, CEO, C3i Biomanufacturing – Gatekeeper of success in cell & gene therapy Michael May, CEO, CCRM Panel discussion: Pushing beyond the limits of CGT Kasandra White, Director of Strategy, Life Sciences and Biomanufacturing Branch, Innovation Science and Economic Development, Government of Canada Kelley Parato, Director, Human Health Therapeutics, National Research Council of Canada Louisa Petropoulos, CEO, C3i Michael May, CEO, CCRM	
12:00 – 13:30	Lunch, networking and exhibitors visit	Confederation III

CONFERENCE PROGRAM - SEPTEMBER 20, 2022

Theme 2

Solving the talent development crisis for CGT manufacturing

Confederation I & II

Moderator: Renaud Manuguerra-Gagné

Chair: Gayle Piat, ACTM Manager, University of Alberta

Biomufacturing has been identified as the major bottleneck for the advancement of the gene therapy sector. This session will detail initiatives underway to attack the talent development crisis and ensure job creation for the production of advanced therapies.

13:30 – 15:00

Canadian Advanced Therapies Training Institute (CATTI): Solving the talent crisis through efficient, advanced training solutions

Craig Hasilo, CSO, CATTI

Mitacs: Internships for biomufacturing and biosciences

Fernanda Mendonça, Business Development Specialist, Mitacs

adMare Academy Executive Institute – Developing Canada's life sciences leaders in a COVID world and beyond

Kristy Lonergan, Senior Director, adMare Academy

Sponsored by:  adMare

Panel discussion on training

Craig Hasilo, CSO, CATTI

Paul-Xavier Etter, Director of Training, CASTL

Jennifer Quizi, Director, Biotherapeutics Manufacturing Operations, BioCanRx; Co-PI, CanPRIME

Fernanda Mendonça, Business Development Specialist, Mitacs

15:00 – 15:20

Health break and exhibitors visit

15:20 – 15:40

Impact of ALS and treatment options – A caregiver and patient advocacy vision

Moderator: Renaud Manuguerra-Gagné

Patient advocate: Jan Mattingly, ALS Action Canada, mother of ALS patient Wayne Mattingly

15:40 – 16:10

The next frontier of health: Canada's growing regenerative medicine sector

Cate Murray, President & CEO, Stem Cell Network

Sponsored by:  Stem Cell Network  Réseau de Cellules Souches

Theme 3

Sector investment: Doing business in Canada

Confederation I & II

Moderator: Renaud Manuguerra-Gagné

Chair: Cynthia Lavoie, President, CCRM Enterprises

Within the CGT sector, tremendous growth potential and investment opportunities have emerged. This session focuses on doing business in the Canadian CGT ecosystem, including the creation of new GMP facilities, government programs, and securing investment from venture capital and other sources.

16:10 – 16:50

Panel discussion: Investment in the advanced therapies sector

Louisa Petropoulos, CEO, C3i

Ella Korets-Smith, Chief Business Officer, Virica

Jonathan Yeh, Partner, Saisei Ventures

16:50 – 17:00

Wrap-up of Day 1

Armand Keating, Chair, CellCAN Strategic Advisory Committee; Senior Scientist, Krembil Research Institute and Clinician Scientist, Princess Margaret Cancer Centre

18:00 – 21:00

CATTI Launch Networking Event

Sponsored by:  catti

Venue Twenty-Two, Westin

CONFERENCE PROGRAM - SEPTEMBER 21, 2022

7:00 – 9:00	Registration Breakfast	Nunavut – 4th floor Confederation III
9:00 – 9:10	Introduction to day 2 activities Duncan J. Stewart, Executive Vice-President, Research, The Ottawa Hospital, CEO & Scientific Director, Ottawa Hospital Research Institute, OIRM	Confederation I & II
9:10 – 9:30	Hope for a cure – A T1D patient's view on CGT-based therapies David Morrison, Manager, BIO-PORTAL/COVID-19 Biobank, Jewish General Hospital	
Theme 4	Regulatory & reimbursement plasticity: lessons from key jurisdictions Moderator: Renaud Manuguerra-Gagné Chair: Patrick Bedford, President & Founder, WeCanReg	Confederation I & II
Advanced technology health products are regulated through various pathways by Health Canada to enable an adaptive and responsive framework. Participants will learn of the impacts of bringing these novel therapies to the healthcare system and the paradigms in reimbursement that impact patient care.		
9:30 – 10:20	Keynote Presentation: Setting a national pandemic response plan in action: lessons for future vaccine and therapeutics manufacturing Mark Lievonen, Co-chair, Canada's COVID-19 Vaccine Task Force	
10:20 – 10:40	Health break and exhibitors visit	
10:40 – 11:40	Regulatory reform to support innovation: Health Canada's agile and advance therapeutic product regulation efforts Michael Rosu-Myles, Executive Director, Centre for Oncology, Radiopharmaceuticals and Research, Biologics and Radiopharmaceutical Drugs Directorate, Health Canada Evaluation and reimbursement of advanced therapies Sylvie Bouchard, Director of Drug and Technology Evaluation for Reimbursement, Institut national d'excellence en santé et en services sociaux (INESSS) Panel discussion: Regulatory, reimbursement & patient access Michael Rosu-Myles, Executive Director, Centre for Oncology Radiopharmaceuticals & Research, Biologics and Radiopharmaceuticals Directorate, Health Canada Sylvie Bouchard, Directrice, INESSS	
11:40 – 13:30	Lunch, networking and exhibitors visit CellCAN Strategic Advisory Committee lunch workshop (invitation only)	Confederation III Provinces I & II

CONFERENCE PROGRAM - SEPTEMBER 21, 2022

Theme 5

Scaling up: strategies to overcome bottlenecks in biomanufacturing to meet demand

Confederation I & II

Moderator: Renaud Manuguerra-Gagné

Chair: Jason Dowd, Vice President, Science & Technology, CCRM

This theme details the creation of large scale biomanufacturing campuses that deploy process closure technologies for late phase clinical trials and commercial manufacturing. Upstream and downstream processes will be discussed to meet the demand for the Canadian and global CGT market.

13:30 – 15:00

Manufacturing of expanded hematopoietic stem cell-based therapies: Challenges on the path to commercialization

Sven Ansorge, Director of Manufacturing, ExCellThera

Towards standardized metrics to support manufacturing and regulatory approval of mesenchymal stromal cell therapies

Lorena Braid, Canada Chair in Mesenchymal Stromal Cell Research Tier 2, Assistant Professor, Simon Fraser University, CSO, Aurora Biosolutions Inc.

The next generation cell therapy clinical trials: pharmaco-optimization

Nicolas Noiseux, Cardiologist, ThéCell

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Developing a sanitisation program for cleanrooms and associated support spaces: importance & considerations

Aaron Bazal, Director of Business Development & Strategic Partnership, Vibraclean

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15:00 – 15:20

Health break and exhibitors visit

15:20 – 16:20

Panel discussion: Vision of the future to meet demand in Canada

Gene therapy manufacturing capacity building

Denis Claude Roy, Director, Hematology-Oncology & Cell Therapy University Institute, Medical Director, Centre d'excellence en thérapie cellulaire, Hôpital Maisonneuve-Rosemont, CSO, C3i

SmokePond Biologics: Offering a global 'D' to your 'R' for biologics

Rasmus Rajkjaer, CEO, SmokePond Biologics

OmniaBio: Launching commercial CGT-focused biomanufacturing in Canada

Jason Dowd, Vice President, Science & Technology, CCRM

16:20 – 16:30

Closing remarks

Denis Claude Roy, CEO, CellCAN



To learn more about our speakers,
visit www.cellcan.com/forum2022/speakers.



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The Canadian Advanced Therapies Training Institute (CATTI) and its predecessors have been leading the GMP biomanufacturing training space for the past six years.

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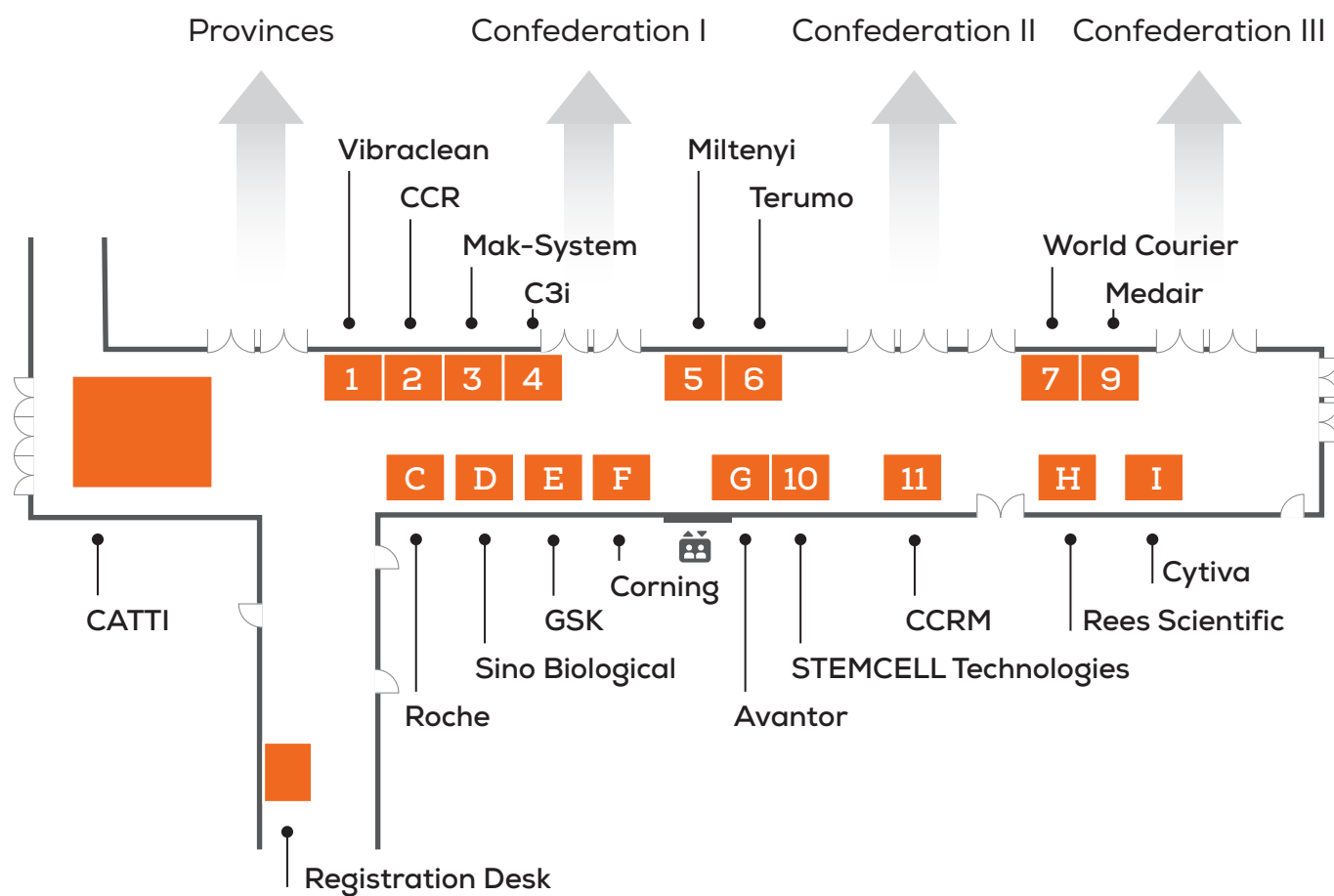
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THANK YOU FOR YOUR PARTICIPATION



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