Hilton Lac-Leamy

Nov 14, 2024 7:30 AM - Nov 15, 2024 4:10 PM

3 Boulevard du Casino, Gatineau, QC J8Y 6X4, Canada

Canada Annual Meeting

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Print Agenda

Day 1 Nov 14, 2024

7:30 AM — 8:30 AM

Networking Breakfast

7:30 AM — 6:30 PM

Registration

8:30 AM — 8:45 AM

Welcome and Opening Remarks

8:45 AM — 10:00 AM

Session 1 Plenary: Understanding Health Canada’s Precision Regulating Initiatives

Session 1 Plenary: Understanding Health Canada’s Precision Regulating Initiatives

Track: General Session

Session Chair(s)

Katalin Bertenyi

Manager, Centre for Blood, Blood Products and Biotherapeutics
Health Canada, Canada

Katalin Bertenyi is the manager of the Clinical Evaluation Division - Endocrine and Metabolic Diseases, situated in CBBB in the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada. Her team is responsible for the evaluation of biologics for endocrine and metabolic diseases, including rare diseases. She has over 20 years of experience with Health Canada, in the clinical evaluation of biologic and pharmaceutical drugs in the areas of reproduction, urology, oncology, endocrinology and metabolism, as well as experience in regulatory affairs, and clinical trials for medical devices and pharmaceutical drugs. Katalin holds a B.Sc. (Honours) in Biotechnology/Biology and a M.SC in Biology, both from Carleton University in Ottawa.

My Dang, MBA

Director/Consultant, Regulatory Affairs
Cencora, Canada

My is a Senior Manager of Regulatory Affairs at Knight Therapeutics Inc. She started out her career in health care working at Sunnybrook and Women`s Health College in their laboratory and then transitioned into the pharmaceutical industry. With over 20 years experience, My has worked on regulatory submissions for human, animal and cannabis health products, covering a variety of therapeutic areas and overseeing both RA and QA responsibilities. She enjoys coaching and mentoring team members and shares a true passion for her work. My has been an active CAPRA member over the years and is currently on the Board of Directors. She had spearheaded the NOC and eNOC publications, assisted in CAPRA dinner coordination and presented CAPRA webinars.

10:00 AM — 10:45 AM

Refreshments, Exhibits, and Networking Break

10:45 AM — 12:00 PM

Session 2, Track A: Health Canada and International Collaboration Initiatives

Session 2, Track A: Health Canada and International Collaboration Initiatives

Track: Track A: Regulatory

Session Chair(s)

My Dang, MBA

Director/Consultant, Regulatory Affairs
Cencora, Canada

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10:45 AM — 12:00 PM

Session 2, Track B: Why Canada for Conducting Clinical Trials?

Session 2, Track B: Why Canada for conducting Clinical Trials?

Track: Track B: Clinical

Session Chair(s)

Marie-France Goyer, MSc

Director, Clinical Operations
Abcellera, Canada

As Director of Clinical Operations at AbCellera, I am passionate about and proud to be working on clinical trials because they help to improve and save the lives of patients in need. I have more than 20 years of experience in Clinical Research. Before joining AbCellera, I spent 5 years as a Director of Clinical Operations at Merck, working in Oncology and General Medicine portfolios. Before moving to Merck, I worked as a Clinical / Sr. Clinical Project manager on the Asthma/Allergy, Cardiovascular, and HIV portfolios at Schering Canada. I completed a master's degree in Drug Development from Université de Montréal.

Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

Rebecca began as a bench cancer researcher and over the past 15 years has worked in different leadership roles, all related to enhancing health research capacity through sustainable systems, processes and robust stakeholder engagement. Prior to joining N2 she was responsible for helping lead the Canadian Tissue Repository Network and overseeing research engagement for the Vancouver Island Health Authority by serving as lead of the CIHR Strategy for Patient Oriented Research (SPOR) initiative within the Vancouver Island region. Recently she worked as Director of the University of Victoria's Office of the Vice-President Research and Innovation. She holds a Bachelor of Science (Biology) and a Masters (Environmental Toxicology/Carcinogenesis).

10:45 AM — 12:00 PM

Session 2, Track C: Update on Health Canada's PV Guidances and Ongoing Initiatives

Session 2, Track C: Update on Health Canada's PV Guidances and Ongoing Initiatives

Track: Track C: Safety/Pharm

Session Chair(s)

Myriam Salem, MSc

Pharmacovigilance Manager
Health Canada, Canada

Myriam Salem is currently a pharmacovigilance manager in the Health Products and Food Branch (HPFB) at Health Canada. She previously led the Good Pharmacovigilance Practices inspection

Program within the Regulatory Operations and Enforcement Branch (ROEB) and worked within HPFB as a senior scientific evaluator for several years. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia at Merck Frosst Canada and McGill's Lady Davis Institute. She holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology from a consortium of European Universities under the EU2P program.

Nadiya Jirova, MSc

Manager, Bureau of Biologics, Radiopharmaceuticals and Self-Care Products
Health Canada, Canada

Nadiya Jirova is a manager for the Bureau of Biologics, Radiopharmaceuticals and Self-Care Products within the Marketed Health Products Directorate of Health Canada. Her section is responsible for post marketing surveillance of biotechnology products including blood, cells, tissues and organ products. She is also leading a team responsible for post market surveillance of Monoclonal Antibodies for COVID-19. She has over 15 years of experience in pharmacovigilance and risk management for biologic and pharmaceutical drugs working within Health Canada. Nadiya holds a Bachelor's degree in Biochemistry from McGill University and a Master's degree in Pharmaceutical Sciences with specialization in Drug Development from the University of Montreal.

12:00 PM — 1:00 PM

Luncheon, Exhibits, and Networking Break

1:00 PM — 2:15 PM

Session 3, Track A: HC/HTA Collaboration – Updates and Insights

Session 3, Track A: HC/HTA Collaboration – Updates and Insights

Track: Track A: Regulatory

Session Chair(s)

Louise Blythe, MSc

VP & Head, Regulatory Affairs
Bayer Inc. Canada, Canada

Louise Blythe has been with Bayer Canada Inc. since 2021 as the VP and Head of Regulatory Affairs for the pharmaceuticals division. With over 25 years of broad therapeutic experience in the

biopharmaceutical industry, Louise is dedicated to supporting access to innovative medicines for patients. Louise has a Master of Science degree in Pharmacology from the University of Toronto, and an Honours Bachelor of Science degree in Life Sciences from Queen's University.

Tharany Ganesh

Head, Regulatory Affairs
AstraZeneca Canada Inc., Canada

Tharany Ganesh has been with AstraZeneca since 2006, holding progressive roles in Regulatory Affairs, Quality Assurance and Patient Safety. She has worked in several different therapy areas including Oncology, Cardiovascular, Respiratory, Vaccines and Infectious Diseases, Gastrointestinal and Neuroscience during her career at AstraZeneca and is the current Head of Regulatory Affairs for the Canadian business. Tharany holds a Master of Biotechnology degree from the University of Toronto, and an Honours Bachelor of Science degree from the University of Waterloo.

Speaker(s)

The Role of the Regulatory Affairs Professional in the Reimbursement Process

Myriam Antoun, MBA

Global Head of Regulatory Affairs
IQV, Canada

1:00 PM — 2:15 PM

Session 3, Track B: Equity, Diversity, Inclusion and Accessibility (EDIA) in Trials

Session 3, Track B: Equity, Diversity, Inclusion and Accessibility (EDIA) in Trials

Track: Track B: Clinical

Session Chair(s)

Rebecca Barnes, MS

Executive Director
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1:00 PM — 2:15 PM

Session 3, Track C: Post-marketing Surveillance: Best Practices

Session 3, Track C: Post-marketing Surveillance: Best Practices

Track: Track C: Safety/Pharm

Session Chair(s)

Nadiya Jirova, MSc

Manager, Bureau of Biologics, Radiopharmaceuticals and Self-Care Products
Health Canada, Canada

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Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Labs Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine in 2006.

2:15 PM — 3:00 PM

Refreshments, Exhibits, and Networking Break

3:00 PM — 4:15 PM

Session 4, Track A: Current and Emerging Regulatory Uses of Real-World Evidence

Session 4, Track A: Current and Emerging Regulatory Uses of Real-World Evidence

Track: Track A: Regulatory

Session Chair(s)

Zohra Douida, MPharm, MS, MSc

Head, Regulatory Affairs Canada
Indivior Canada Inc., Canada

Zohra Douida is the Head of Regulatory Affairs for Indivior Canada Ltd.

Brenda Gryfe, MSc

Director, Regulatory Affairs
TPIreg, Innomar Strategies, Canada

Brenda Gryfe has been Director of Regulatory Affairs at TPIreg, a Division of Innomar Strategies since 2014. She is a pharmacist with over 25 years' experience in the pharmaceutical industry. Ms. Gryfe has a business-focused understanding of Regulatory Affairs, gained from experience across several companies. Ms. Gryfe has guided Regulatory teams through a variety of strategically complex regulatory processes. She also provides support to promotional material development teams with regulatory advice and review services for the Canadian drug advertising environment. Since her research at U of Toronto in seniors' understanding of prescription drug labels, Ms. Gryfe retains a particular interest in labeling and patient education materials.

3:00 PM — 4:15 PM

Session 4, Track B: Decentralized Clinical Trials – Canada's First Case Study and Next Steps

Session 4, Track B: Decentralized Clinical Trials – Canada's First Case Study and Next Steps

Track: Track B: Clinical

Session Chair(s)

Stephanie Anderson

Associate Director, Regulatory Affairs
Intrinsik Corp., Canada

3:00 PM — 4:15 PM

Session 4, Track C: Pharmacovigilance Unleashed: Unlocking PV Best Practices through KPIs and Data Mining

Session 4, Track C: Pharmacovigilance Unleashed: Unlocking PV Best Practices through KPIs and Data Mining

Track: Track C: Safety/Pharm

Session Chair(s)

Mei Lam, BSN, RN

Canada PV Manager/Safety Regional Country Contact
Haleon, Canada

Mei Lam is the Pharmacovigilance Manager for Haleon Canada. She has over 15 years in industry, primarily in Pharmacovigilance (PV). In addition to PV, Mei has experience in medical information, medical affairs, and global governance. Mei is a registered Nurse in Ontario who volunteers for the Region of Peel Public Health Unit.

Vanessa Zapata

Associate Director, Regional Pharmacovigilance Officer
Merck Canada Inc., Canada

Vanessa Zapata started her career in the pharmaceutical industry in 1998. For 12 years, she fulfilled different roles in the Clinical research field. In 2011, she moved to Pharmacovigilance where she has held various roles of increasing responsibility. She currently fulfills a position of Associate Director, Regional Pharmacovigilance at Merck Canada Inc. She also is the business owner of the company's Global Pharmacovigilance training that gets assigned annually to more that 115 000 employees and external partners around the world.

4:20 PM — 5:35 PM

Session 5, Track A: Latest Advancements in AI – A Regulatory Perspective

Session 5, Tracks A: Latest Advancements in AI – A Regulatory Perspective

Track: Track A: Regulatory

Session Chair(s)

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VP & Head, Regulatory Affairs
Bayer Inc. Canada, Canada

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Melanie Cote, MS

Senior Manager, Regulatory Affairs
Otsuka, Canada

Melanie Cote, Senior Manager in Regulatory Affairs, has been with Otsuka Canada Pharmaceutical for 7 years working on regulatory filings in Canada. She studied biochemistry and worked for a few years in analytical development after graduating. She later completed a DESS (diplôme d'études supérieures spécialisées) in drug development, focusing on CMC, and has a Master of Pharmaceutical Sciences from the Université de Montréal. In 2010, Melanie fell in love with Regulatory Affairs and worked in European regulatory for 2 years at Mylan and AstraZeneca in the United Kingdom. Since 2013, Melanie has focused on Canadian regulatory. She is thrilled to be a committee member of the DIA Canada Annual Meeting for the first time this year.

4:20 PM — 5:35 PM

Session 5, Track B: Harnessing the Potential of AI in Clinical Development and Operations

Session 5, B: Harnessing the Potential of AI in Clinical Development and Operations

Track: Track B: Clinical

Session Chair(s)

Stephanie Anderson

Associate Director, Regulatory Affairs
Intrinsik Corp., Canada

4:20 PM — 5:35 PM

Session 5, Track C: AI-Enhanced Pharmacovigilance: Shaping the Future of Drug Safety

Session 5, Track C: AI-Enhanced Pharmacovigilance: Shaping the Future of Drug Safety

Track: Track C: Safety/Pharm

Session Chair(s)

Daniel Greco, PharmD, RPh

Associate Director of Patient Safety
Bristol-Myers Squibb Company, Canada

Daniel Greco is the Associate Director of Patient Safety at Bristol Myers Squibb, with a specialization in Risk Management. In this capacity, Daniel has led substantial changes to the risk management program responsible for overseeing the risks associated with thalidomide and its derivatives in Canada. He earned his H.BSc. and PharmD from the University of Toronto, and is presently pursuing a Masters in Pharmacovigilance and Pharmacoepidemiology through the Eu2P program. Moreover, Daniel is practicing as a licensed Pharmacist in the province of Ontario, where he has gained invaluable firsthand experience in direct patient care.

Nadia Mian, MS

Pharmacovigilance Manager
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Mian is currently working as local pharmacovigilance lead for the affiliate office at Ipsen Biopharmaceuticals Canada. With over 20 years of successful experience in the Biotech/Pharmaceutical industry and expertise in Pharmacovigilance and Clinical research, she has a diverse range of experiences in different therapeutic areas: Neuroscience, Oncology, Hematology, Immunology, Renal disease and

Rare diseases. She holds a Master’s degree in Pharmaceutical Science, Biopharmacy from King's College, University of London, UK.

5:35 PM — 6:35 PM

Networking Reception

Day 2 Nov 15, 2024

7:30 AM — 8:30 AM

Networking Breakfast

7:30 AM — 4:30 PM

Registration

8:30 AM — 9:45 AM

Session 6, Track A and B: Insights into Rare Diseases: Pioneering Pathways for Patient Access and Drug Development

Session 6, Tracks A and B: Insights into Rare Diseases: Pioneering Pathways for Patient Access and Drug Development

Track: Track A & B

Session Chair(s)

Brenda Gryfe, MSc

Director, Regulatory Affairs
TPIreg, Innomar Strategies, Canada

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Amber McLeod, PhD

Immunology, Virology, and Specialty Head, Regulatory Affairs
Abbvie Corporation, Canada

Amber McLeod has held the role of Lead, Regulatory Affairs at AbbVie Canada since May 1, 2020. She leads a team of Regulatory Affairs professionals focused primarily on the filing and approval with Health Canada of biopharmaceutical drug submissions for clinical development and commercial products in the areas of Immunology, Oncology, Virology, Neuroscience, Hormone Replacement Therapy, and Specialty Care. Amber joined Abbott in January 1999. Over her 24-year career with Abbott/AbbVie, she held various roles of increasing responsibility where she led and managed countless regulatory filings, approvals and product launches in different therapeutic areas. Amber holds a Doctorate in Pharmacology and Therapeutics from McGill University.

8:30 AM — 9:45 AM

Session 6, Track C: Advancements in Patient Safety and Centricity

Session 6, Track C: Advancements in Patient Safety and Centricity

Track: Track C: Safety/Pharm

Session Chair(s)

Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Labs Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed

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9:45 AM — 10:30 AM

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM

Session 7, Track A: Opportunities and Challenges of Electronic Labelling Implementation

Session 7, Track A: Opportunities and Challenges of Electronic Labelling Implementation

Track: Track A: Regulatory

Session Chair(s)

Melanie Cote, MS

Senior Manager, Regulatory Affairs
Otsuka, Canada

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AstraZeneca Canada Inc., Canada

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10:30 AM — 11:45 AM

Session 7, Track B: The State of ICH GCP: Moving towards Innovative Approaches in Clinical Trial Operations

Session 7, Track B: The State of ICH GCP: Moving towards Innovative Approaches in Clinical Trial Operations

Track: Track B: Clinical

Session Chair(s)

Vatche Bartekian, MSc

President
Vantage BioTrials, Canada

Mr. Bartekian is President of Vantage BioTrials, an award-winning Canadian CRO specializing in clinical trial management services. He's contributed his drug development knowledge to the pharma & device industry for over 24 years and has gained vast experience handling complicated trials across an array of therapeutic areas. He has also contributed his knowledge as an Advisor to Global Affairs Canada's Life Science division, and Colorectal Cancer Canada's Scientific Advisory Board for the establishment of a Patient Group Pathway Model to Accessing Cancer Clinical Trials. Vatche was also honored in 2021 by his alma mater, Concordia University, as a "Top 50 under 50 Who are Shaping Tomorrow" for his work in combatting Covid-19.

10:30 AM — 11:45 AM

Session 7, Track C: Signal or Noise? Decoding the Pharmacovigilance Symphony

Session 7, Track C: Signal or Noise? Decoding the Pharmacovigilance Symphony

Track: Track C: Safety/Pharm

Session Chair(s)

Mei Lam, BSN, RN

Canada PV Manager/Safety Regional Country Contact
Haleon, Canada

Mei Lam is the Pharmacovigilance Manager for Haleon Canada. She has over 15 years in industry, primarily in Pharmacovigilance (PV). In addition to PV, Mei has experience in medical information, medical affairs, and global governance. Mei is a registered Nurse in Ontario who volunteers for the Region of Peel Public Health Unit.

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Bristol-Myers Squibb Company, Canada

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Speaker(s)

Aspects to Consider in Causality Assessment of Safety Signals: Broadening the Thought Process

Salman Afsar, MD, MHA

Senior Director and Signal Management Team Chair
Bristol-Myers Squibb Company, United States

Dr. Salman Afsar, Senior Director and Signal Management Team Chair at Bristol Myer Squibb, is a distinguished physician specializing in Medical Safety Assessment. With a strong background in the pharmaceutical industry including notable positions at Sanofi and Astellas, Dr. Afsar brings extensive expertise to his role. Before transitioning to industry he made significant contributions in academia and clinical practice, earning him prestigious awards for his exceptional work.

11:45 AM — 12:45 PM

Luncheon, Exhibits, and Networking Break

12:45 PM — 2:00 PM

Session 8, Track A: Fostering Transparency: Health Canada, Industry, and Patient Perspectives on PRCI's Role

Session 8, Track A: Fostering Transparency: Health Canada, Industry, and Patient Perspectives on PRCI's Role

Track: Track A: Regulatory

Session Chair(s)

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Immunology, Virology, and Specialty Head, Regulatory Affairs
Abbvie Corporation, Canada

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Marcia Sam

Regulatory Affairs Strategy and Policy Manager
Hoffmann-La Roche Canada Limited, Canada

Marcia Sam is enjoying her role as a Regulatory Affairs Strategy and Policy Manager at Roche Canada. With over 16 years of experience in the Biotech/Pharmaceutical industry, she has a diverse range of experiences with exposure to different areas of drug development, regulatory submissions in therapeutic areas as Hematology, Neuroscience, Oncology, Virology, Rare Diseases, etc., volunteered on the regulatory affairs committees of IMC, was a past guest speaker and instructor for regulatory courses at Seneca College of Applied Arts and Technology. She holds a BSc (Honours) degree in Neuroscience/Biology from the University of Toronto and a Post-graduate diploma in Pharmaceutical Regulatory Affairs and Quality Operations from Seneca College.

12:45 PM — 2:00 PM

Session 8, Track B: Statistical, Modeling and Dose Optimization Considerations for Trial Design

Session 8, Track B: Statistical, Modeling and Dose Optimization Considerations for Trial Design

Track: Track B: Clinical

Session Chair(s)

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

Oxana Iliach, PhD is a Sr. Director, Regulatory Strategy and Policy at Certara/Synchrogenix. She has more than 15 years of experience in the healthcare industry including the last 10+ years in regulatory affairs. Her specialty is developing and executing regulatory strategies for drugs for rare diseases, pediatrics, advanced therapy products and biosimilars, with a focus on Chemistry, Manufacturing and Control (CMC). Oxana has experience with the FDA, EMA, Health Canada, and other smaller agencies. She is also a part-time lecturer at Northeastern University, Toronto campus and professor at Seneca College of Applied Arts and Technology. Oxana is a member of CAPRA, RAPS, CORD and IRDiRC.

Katalin Bertenyi

Manager, Centre for Blood, Blood Products and Biotherapeutics
Health Canada, Canada

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12:45 PM — 2:00 PM

Session 8, Track C: Unveiling the Power and Value of Pharmacovigilance Teams: Pioneering Safety Guardians of

the Pharmaceutical World

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Track: Track C: Safety/Pharm

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Associate Director, Regional Pharmacovigilance Officer
Merck Canada Inc., Canada

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2:00 PM — 2:30 PM

Refreshments, Exhibits, and Networking Break

2:30 PM — 3:45 PM

Session 9 Plenary: AI: Investments and Future Outcomes

Session 9 Plenary: AI: Investments and Future Outcomes

Track: General Session

Session Chair(s)

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

Oxana Iliach, PhD is a Sr. Director, Regulatory Strategy and Policy at Certara/Synchrogenix. She has more than 15 years of experience in the healthcare industry including the last 10+ years in regulatory affairs. Her specialty is developing and executing regulatory strategies for drugs for rare diseases, pediatrics, advanced therapy products and biosimilars, with a focus on Chemistry, Manufacturing and Control (CMC). Oxana has experience with the FDA, EMA, Health Canada, and other smaller agencies. She is also a part-time lecturer at Northeastern University, Toronto campus and professor at Seneca College of Applied Arts and Technology. Oxana is a member of CAPRA, RAPS, CORD and IRDiRC.

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Regulatory Affairs Strategy and Policy Manager
Hoffmann-La Roche Canada Limited, Canada

Marcia Sam is enjoying her role as a Regulatory Affairs Strategy and Policy Manager at Roche Canada. With over 16 years of experience in the Biotech/Pharmaceutical industry, she has a diverse range of experiences with exposure to different areas of drug development, regulatory submissions in therapeutic areas as Hematology, Neuroscience, Oncology, Virology, Rare Diseases, etc., volunteered on the regulatory affairs committees of IMC, was a past guest speaker and instructor for regulatory courses at Seneca College of Applied Arts and Technology. She holds a BSc (Honours) degree in Neuroscience/Biology from the University of Toronto and a Post-graduate diploma in Pharmaceutical Regulatory Affairs and Quality Operations from Seneca College.

3:45 PM — 4:00 PM

Closing Remarks