CMBEC45 Device Innovation and Development Program

Session	Session Name	Date	Time
B1	How Much Does It Cost to Develop a Medical Device?	May 16	10:45 AM – 11:45 AM
B2	Regulatory Pathways In Medical Device Development: How to Cross the Unknown Valley	May 16	1:30 PM – 2:50 PM
B3	The Future of Medical Device Development (With an Eye to the Past)	May 17	10:45 AM – 12:05 PM
A/B/C 4	Combined Session: Innovative Medical Technologies and the Challenges They Pose	May 17	1:40 PM – 3:00 PM
B5	Machine Learning is Changing Medical Devices: What to Expect and How to Prepare	May 17	3:45 PM – 5:05 PM
A/B/C 6	Combined Session – Indigenous Reconciliation	May 18	8:40 AM – 10:00 AM
B7	Local Medical Technology Showcase: Life 360 Innovations Inc. and Clarius Mobile Health	May 18	10:45 AM – 12:05 PM
B8	Local Medical Technology Showcase: Arbutus Medical and Aspect Biosystems	May 18	1:40 PM – 3:00 PM

Session Descriptions on Following Pages

B1: How Much Does It Cost to Develop a Medical Device?

Speaker(s): Mark Drlik

Chair: Garrett Kryt

Date and Time: May 16, 10:45 AM – 11:45 AM

Description: The journey to a marketable product is fraught with pitfalls, traps and challenges. Here is your opportunity to get a grasp on these hurdles from an industry expert. This exciting session will feature Mark Drlik, Director of Program Design at Starfish Medical as he provides direct experience of the true costs and challenges of medical device development.

Speaker Bio

Mark Drlik

Director of Program Design

For over 20 years, Mark has been contributing his design and engineering expertise to product development activities. Mark works closely with clients to transition medical devices from initial product architecture definition to final product delivery to ensure client success. His 13 years with StarFish Medical have proven instrumental in the design and commercialization of innovative medical devices employing ultrasound, stereotactic positioning systems, therapeutic delivery systems, novel ingestible devices, and high frequency oscillation technologies, to name a few. Before joining StarFish Medical, Mark managed prototype and manufacturing design projects related to liquefied natural gas pumps, gas purification/separation systems and solar powered lighting products. Mark's collaboration, leadership and mentorship inputs continually provide value to StarFish Medical, its clients, and the medical device community.

B2: Regulatory Pathways in Medical Device Development: How to Cross the Unknown Valley

Speaker(s): Jean Smart, Helen Simons

Chair: Garrett Kryt

Date and Time: May 16, 1:30 PM – 2:50 PM

Description: So, you have an exciting new medical technology that will change the world, but what next? The answer is regulatory. In this joint session Helen Simons, Senior Quality Assurance Manager at Starfish Medical and Jean Smart, Regulatory Affairs and Quality Officer at Clinical Trials BC will speak on regulatory pathways, program development and some of the interesting initiatives in the Canadian Regulatory environment.

Speaker Bios

Helen Simons

Sr. Qty Assurance Manager • Quality Assurance / Regulatory Affairs

With a background in engineering, Helen has over 15 years experienced in product development, mainly focused on Medical Devices and IVD. Helen has worked on a wide range of Medical Device and IVD products, from inhalers and injection devices to phototherapy devices and ventilators. She has experience in project managing product developments and providing quality and regulatory guidance to both internal teams and clients. Helen has supported clients worldwide in developing products for the US, EU and Canadian markets, providing detailed insight into the regulatory requirements for those markets. Helen is also an expert in business improvements; working with internal teams and clients to build effective and efficient quality systems.

Jean Smart

Regulatory Affairs and Quality Officer (Clinical Trials BC) and Privacy Officer with Michael Smith Health Research BC.

Jean Smart has participated in numerous provincial and global regulatory initiatives and is currently active on national and international project committees, teams and boards. Her education and specializations are in global health (research), and development studies in research policy and governance. She has an interest in research program development, training and growing a research culture in advancing regions.

B3: The Future of Medical Device Development (With an Eye to the Past)

Speaker(s): Marianne Black, Dr. Nancy Paris, PEng

Chair: Garrett Kryt

Date and Time: May 17, 10:45 AM – 12:05 PM

Description: This joint session will feature Marianne Black, Canada Research Chair at UVIC, and Dr. Nancy Paris, P.Eng. Marianne Black will provide a unique talk on her experience in Silicon Valley and the resources available there for innovative medical device startups, as well as how we can implement these lessons locally. Dr. Nancy Paris will discuss lessons learned in her experience as a medical device innovator for the past 30 years in the lower mainland.

Speaker Bios

Dr. Marianne Black

Dr. Marianne Black is a Canada Research Chair in Assistive Technologies and Assistant Professor of Mechanical Engineering at the University of Victoria (UVic). Dr. Black completed her BASc in Engineering Physics at the University of British Columbia (UBC), where she became fascinated with orthopaedic biomechanics during her co-op research placements with Dr. David Wilson at UBC. Dr. Black then completed a MASc in Biomedical Engineering as a continuation of her co-op research studying orthopaedic biomechanics and simultaneously co-founded Arbutus Medical, which was spun out of UBC's Engineers in Scrubs program. In 2015, Dr. Black was named by BC Business Magazine as a '30 under 30'. She then went on to complete her PhD in Mechanical Engineering at Stanford University under Drs. Marc Levenston, Brian Hargreaves, and Garry Gold using quantitative MRI and CT to assess early changes occurring in pre-osteoarthritic knees. During a Postdoctoral Fellowship under Dr. Brian Hargreaves in the Stanford School of Medicine, Dr. Black started developing Augmented Reality tools for applications in surgical procedures and was named a Rising Star in Mechanical Engineering by the University of California, Berkeley. Now, as director of the HATlab (Health-Assistive Technologies lab) at UVic. Dr. Black was an Accel Innovation Scholar while at Stanford University, providing her entry and understanding to the inner workings of Silicon Valley, and access to Venture Capitalists, stealth start-ups, and large technology companies.

Dr. Nancy Paris, P.Eng.

I have been involved in designing products for my entire career. I am a professional biomedical engineer with a doctorate in social sciences with a research focus on design and diaspora groups. Since 1989, I have been involved in the development of medical and assistive devices and helping to build the health technology community in BC. I am the co-inventor of the PROSTALAC total hip replacement system that was licensed to Depuy of Johnson and Johnson and has been commercially available since 1999. I became the Director of BCIT's Health Technology Research Group (HTRG) in September of 1996. I led a diverse team of professionals in research, development, evaluation and commercialization of a wide range of health technology products. I retired from BCIT in 2021 to form PK Partners with my husband Ryan Kanigan.

A/B/C 4: Combined Session: Innovative Medical Technologies and the Challenges They Pose
Speaker(s): Marc Saab, Emil-Peter Sosnowski, Jon Bracken, Carol Park

Chair: Garrett Kryt

Date and Time: May 17, 1:40 PM – 3:00 PM

Description: While the demand for emerging technology in healthcare applications continues to grow at an exponential rate, the supply seems to be stalled by familiar factors. The requirements to ensure patient safety and to show compelling clinical validation have always been imposed by regulatory agencies like Health Canada and the FDA. When new technology is introduced into the clinical environment, and even directly into the hands of the patients at times, issues around inter-operability, usability, data integrity, cybersecurity, and data privacy arise.

The amazing possibilities offered by medical wearables, artificial intelligence, and remote patient monitoring applications are exciting. This presentation will address some of the considerations for tech companies and clinical organizations alike to overcome new challenges, such that real-world medical applications based on these exciting new technologies can be integrated into existing clinical frameworks and used reliably.

This session will feature a presentation by Marc Saab followed by a panel discussion with experts in cybersecurity, clinical engineering, regulatory and medical device development.

Speaker Bios

Marc Saab, Meng

Founder and Managing Director, BML Technology
linkedin: https://www.linkedin.com/in/marc-saab-6048263/

Marc is a passionate business leader with 20 years' experience in Medical Device, Digital Health and Consumer Wearables. His expertise is in all aspects of medical device and wearable product development from conception R&D to launch, clinical validation, and commercialization for international markets, including regulatory compliance and strategic business development. Marc is an expert in biometrics and a thought leader on the technical aspects of Digital Health. He is a speaker on a variety of digital health topics, including product development, clinical application development and technology adoption. He also serves on the Strategic Advisory board of Henri&Wolf, a boutique data governance and cyber security law firm, the Medical Advisory Board of Alto Design, an award-winning industrial design firm, and the Science Advisory Board of ABI Wellness, a unique brain injury recovery provider. Marc holds a Bachelor of Applied Science from the University of Waterloo, with a major in Electrical Engineering and a minor in Biology, and a Master of Biomedical Engineering from McGill University and the Montreal Neurological Institute. He currently lives in Montreal, Canada with his two daughters and their two dogs.

B5: Machine Learning is Changing Medical Devices: What to Expect and How to Prepare

Speaker(s): Natalia Grane, Jaspreet Oberoi

Chair: Garrett Kryt

Date and Time: May 17, 3:45 PM – 5:05 PM

Description: Machine learning and AI are beginning to change everything we do. From chatbots to medical devices, we are still learning exactly what the impact of machine learning is on society and how to use this technology. In this exciting session Jaspreet Oberoi and Natalia Grane from Synthesis Health will present on all aspects of Machine Learning and health-related technology. The session will start with an overview of machine learning, discuss applications and Synthesis Health's own technology as well as discuss experiences and challenges in developing robust processes to ensure compliance when using machine learning in product development.

A/B/C 6: Combined Session: Advancing Reconciliation: The Role of the Biomedical Community

Speaker(s): Gary Housty (First Nations Health Authority), Lauren Brown (First Nations Health Authority), Karen Mooder (First Nations Health Authority), Miguel Antonio (Interior Health Authority), Brendan Gribbons (Lower Mainland Biomedical Engineering), Murray Rice (Mount Sinai Hospital and University Health Network), Sarah Kelso (Winnipeg Regional Health Authority

Chair: Sundeep Bath (Lower Mainland Biomedical Engineering)

Date and Time: May 18, 8:40 AM – 10:00 AM

Description: This conference session is a valuable opportunity to learn about the negative impacts of colonialism on Indigenous peoples' health outcomes and the role that the biomedical community can play in supporting reconciliation efforts. By promoting collaboration and action-oriented approaches based on respect, humility, and honesty, the biomedical community can help to improve Indigenous health outcomes and contribute to the ongoing process of reconciliation. The session will begin with dialogue on factual information about the negative impacts of colonialism on Indigenous peoples' health outcomes. Disparities in Indigenous health outcomes and the root causes of these disparities will be discussed, such as the ongoing effects of colonial healthcare policies. Next, the panelists will explore some key principles related to reconciliation, such as respect, humility, and collaboration. They will discuss how these principles can be applied in the context of the biomedical community to support reconciliation efforts and improve Indigenous health outcomes. The panelists will then provide an example of action-oriented work within the biomedical community towards reconciliation. They will discuss a collaborative initiative between FNHA and B.C. biomedical engineering departments to

improve support for medical technologies in Indigenous communities, demonstrating the principles of reconciliation in action. The CMBES President and Vice President will share the society's perspectives on reconciliation, and the session will conclude with Q&A with the panelists. Attendees will have the opportunity to ask questions and engage in a dialogue about reconciliation efforts within the biomedical community

B7: Local Medical Technology Showcase: Life 360 Innovations Inc. and Clarius Mobile Health

Speaker(s): Robert Orr, Kris Dickie

Chair: Garrett Kryt

Date and Time: May 18, 10:45 AM – 12:05 PM

Description: This session will feature speakers Robert Orr, the CEO of Life 360 Innovations Inc. and Kris Dickie, VP Research and Development from Clarius Mobile Health. The speakers will delve into the technology behind their companies, as well as share stories of the challenges faced in developing medical technology.

Speaker Bios

Robert Orr

President & CEO of Life360 Innovations

Robert is a seasoned corporate development strategist with 30+ years of executive and public practice experience. His academic background includes a BSc in applied mathematics in economics from the University of Victoria. He has professional designations as a Chartered Professional Accountant (CPA) and Chartered Business Valuators (CBV) and a few others, He co-founded Life360 to commercialize the Contino urethral insert a Health Canada Licensed first of its kind Class 2 medical device for men with urinary incontinence. He is a board member and advisor to a number of Canadian and US technology companies and a trustee of a not-for-profit foundation.

Kris Dickie

Kris graduated from the British Columbia Institute of Technology with a B.Tech in Computer Systems. Currently he is the Vice President of Research and Development at Clarius Mobile Health. Kris has over 20 years experience in the ultrasound industry as a software developer, engineering leader, and product ambassador.

B8: Local Medical Technology Showcase: Arbutus Medical and Aspect Biosystems

Speaker(s): Erin Bedford, Radu Postole

Chair: Garrett Kryt

Date and Time: May 18, 1:40 PM – 3:00 PM

Description: This session will feature speakers Erin Bedford, head of academic partnerships at Aspect Biosystems and a speaker from Arbutus Medical. The speakers will delve into the technology behind their companies, as well as share stories from the challenges of the challenges faced in developing medical technology.

Speaker Bios

Erin Bedford

Dr. Erin Bedford currently leads the Bioprinting Innovation team at Aspect Biosystems, working to expand the potential applications of Aspect's microfluidic 3D bioprinting platform through internal R&D activities and external partnerships with academic researchers. Erin holds a BASc in Nanotechnology Engineering from the University of Waterloo and a PhD in Nanotechnology Engineering/Chemistry from the University of Waterloo and the Université Pierre et Marie Curie.

Radu Postole

Radu Postole is the Lead Design Engineer at Arbutus Medical. His past work has focused on product development and R&D in a variety of industries - solar lighting for commercial office buildings, assistive devices for people with disabilities, and medical devices for use in orthopedic surgery. He is an avid tinkerer and maker, passionate about designing and building products that have positive social impact.