Mr. Mike Ward,
Chair of APEC RHSC / Health Canada, Canada

Mike Ward joined Health Canada in 1986 following nine years industrial experience in the QA/QC area.

Since that time he has held a variety of regulatory positions including GMP specialist, premarket Quality reviewer and manager, and senior policy analyst. Mike is Manager of the International Programs Division of the Therapeutic Products Directorate of Health Canada.

He served as the Canadian Observer to the ICH Steering Committee and a former regulatory co-chair of the Global Cooperation Group.

He chairs the Regulatory Harmonization Steering Committee of the APEC Life Sciences Innovation Forum and is an alternate representative for NAFTA on the PanAmerican Regulatory Harmonization Steering Committee.

Mr. John (Barr) Weiner, FDA, USA

John Barlow Weiner is the Associate Director for Policy in the Food and Drug Administration's Office of Combination Products, which is tasked with the classification and assignment for regulation of therapeutic products (drugs, devices, biological products, and combination products), and with ensuring the sound and consistent regulation of combination products.

Prior to joining OCP, Mr. Weiner was an Associate Chief Counsel in FDA's Office of Chief Counsel, advising the agency on various issues including regulation of drugs, associated intellectual property issues, and cross-cutting topics including the regulation of products that use nanotechnology.

Before coming to FDA, Mr. Weiner was in private practice in the areas of food and drug, environmental, and related aspects of public international and trade law.

He has published and lectured on topics in all three areas. Mr. Weiner received a BA from Princeton University and a JD with honors from the Columbia University School of Law.

Dr. Yoichi Onodera,
PMDA, Japan

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[Experience]

2012.7 – Present	Principal Reviewer, Office of Medical Devices II, PMDA
2010.4 – 2012.6	Principal Researcher, National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries
2004.4 – 2010.3	Reviewer, Office of Medical Devices, Pharmaceuticals and Medical Devices Agency (PMDA)
2002.3 – 2004.3	Technical Staff, Brain Science Institute, RIKEN
1999.4 – 2002.2	Researcher, National Institute of Advanced Science and Technology (AIST)
1998.4 – 1999.3	Post doctoral fellow, Japan Society for the Promotion of Science

[Education]

1998.3	Doctor of Engineering, Hokkaido University

Ms. Elizabeth Baker,
MHRA, UK

Elizabeth Baker trained as a pharmacist and began her career in pharmaceutical research and development with Pfizer in the UK.

She then joined the then UK medicines regulatory body as a pharmaceutical assessor and worked in a variety of roles on a wide range of products.

She is now a Group Manger in the medicines Licensing Division of MHRA and primarily concerned with the licensing of medicines .

However she spends a significant amount of time on Notified Body consultations and advising on the borderline between medicines and devices and has done since the introduction of the medical devices directive in 1993.

Mr. Scott Sardeson, 3M, USA

Scott S. Sardeson RAC US/EU
International Regulatory Affairs Manager
3M Health Care
St. Paul, MN U.S.A

Scott Sardeson has held various positions at start-up and multinational medical device companies in manufacturing, R&D, quality, regulatory, and auditing. His current position is at 3M as the International Regulatory Affairs Manager for 3M Health Care.

The 3M Health Care Business has sales globally > $4 billion and represents approximately 17% of 3M Company revenue. The primary goal is to provide clinical solutions in the areas of infection prevention, skin and wound care, dental, and orthodontics applications. Scott's role is to provide regulatory guidance and quality system leadership to over fifty 3M subsidiaries globally in support of this business. Prior to joining 3M, Scott was the Quality Systems and Regulatory Affairs Manager for Synovis Life Technologies, a mid-sized implantable medical device company in St. Paul, MN. He started his regulatory career with Closure Medical an Ethicon/J&J company after working in R&D on synthetic tissues adhesives.

Scott has two key activities outside of 3M focused to improve medical device regulation and allow better patient access to new products. He is the current Advamed representative for Global Harmonization Task Force (GHTF) Study Group 3 - Quality Systems and continues to participate in various international activities to drive harmonization of medical device regulations around the world. In addition, Scott is an adjunct professor at St. Cloud State University in St. Cloud, Minnesota U.S.A where he teaches the International Regulatory Affairs course in the Master of Science in Regulatory Affairs and Services Program. This unique Masters program is designed to bring more skilled regulatory professionals into the medical device industry.

Scott has a B.S. in Chemistry through the University of Minnesota's Institute of Technology, and is certified in European and U.S. Regulatory Affairs through the Regulatory Affairs Professional Society (RAPS). In his spare time, he enjoys his time in Minnesota gardening, fishing and relaxing with family.

Dr. Gert Bos,
BSI, UK

Dr. Gert W. Bos has 20 years of experience in lifesciences (devices and pharma), in university, industry as well as in four Notified Bodies. Dr. Bos holds a position as Head of Regulatory and Clinical Affairs at BSI Healthcare and is certification manager at EUROCAT. He is president of the Notified Body association TEAM-NB, vice-chair of the Medical Notified Body forum NB-Med in Brussels, and participates in the Notified Body Recommendation group (NBRG), the Clinical Investigation and Evaluation Group (CIE), Medical Device Expert Group (MDEG) and the MDEG workgroups on animal tissue, on MRA's, e-labeling, EUDAMED and on IVD's. He is a member of the RAPS advisory committee.

Ms. Gerardine Finn, Medtronic, USA

Gerardine Finn is Vice President of Regulatory Affairs for Medtronic CardioVascular in Santa Rosa, California.

Gerardine has over 25 years of experience in the healthcare industry. For the past 15 years she has held regulatory affairs leadership roles in Europe and the US.

She currently has global regulatory responsibility for Medtronic's Coronary and RDN products. Gerardine is a chemistry and biochemistry graduate from the National University of Ireland. Prior to joining Medtronic Gerardine held roles in R+D, Quality and Operations in a number of small in vitro diagnostic companies.

Ms. Janet Trunzo, AdvaMed, USA

Janet E. Trunzo is Senior Executive Vice President, Technology and Regulatory Affairs for the Advanced Medical Technology Association (AdvaMed) and leads a team of regulatory experts.

During her tenure at AdvaMed, she focused her efforts on the passage of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), its reauthorization in 2007 and most recently the negotiation for MDUFA III which was enacted into law as part of the 2012 FDA Safety and Innovation Act. She also concentrates on global regulatory harmonization and represents the U. S. device industry on the Global Harmonization Task Force. She currently chairs the international Board of Trustees for the Global Medical Device Nomenclature Agency.

Prior to joining AdvaMed, Trunzo held positions at Hybritech, Inc., a medical device and diagnostics manufacturer and Scripps Clinic and Research Foundation, a hospital, diagnostic clinic and research institute.

Trunzo received her M.S. in health physics from Rutgers University and her B.S. in Chemistry from California University of Pennsylvania.