Prof. Rosanna Peeling, LSHTM, UK

Rosanna W. Peeling, PhD
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Dr. Peeling is currently Professor and Chair of Diagnostics Research at the London School of Hygiene and Tropical Medicine (LSHTM). Trained as a medical microbiologist, Dr. Peeling had been the Research Coordinator and Head of Diagnostics Research at the UNICEF/UNDP/World Bank/WHO Special Programme on Research and Training in Tropical Diseases (WHO/TDR) in Geneva, Switzerland, and the Chief of the Canadian National Laboratory for Sexually Transmitted Diseases before assuming her current position. Her work in WHO/TDR focused on the evaluation of diagnostics to inform policy and procurement decisions. Her concern for the lack of international standards for diagnostic evaluations led to a series of publications in Nature Microbiology Reviews on the design and conduct of diagnostic evaluations for malaria, sexually transmitted infections, visceral leishmaniasis, dengue and CD4 assays. Dr Peeling's work at LSHTM spans from facilitating test development and evaluation to the translation of evidence to policy and appropriate placement of new diagnostic technologies into different health care settings to ensure maximum impact. She has a strong interest in ethical issues associated with conducting research in developing countries and was appointed Chair of the WHO Research Ethics Review Committee while at WHO.

Dr. Peeling is a member of many international scientific and technical advisory panels and editorial boards. She was the recipient of a YM-YWCA Women of Distinction Award and a 5NR Award for Canadian Leaders of Sustainable Development. Her research was featured in a Discovery Channel documentary on Chlamydia Infection and Infertility, and in Fighting Syphilis, a documentary in the highly acclaimed BBC Kill or Cure series.

Dr. Peter Staehr,
Abbott Vascular, USA

Dr. Peter Staehr is Senior Director leading the worldwide Clinical Science group at Abbott Vascular. He was trained as internist and cardiologist at Johannes-Gutenberg University in Mainz in Germany. Dr. Staehr performed his postdoctoral training at Stanford University/USA at the Center for Research in Cardiovascular Interventions. His research was focused on the testing of various thrombolytic catheter devices and characterizing atherosclerotic plaque morphologies with intravascular ultrasound and radiofrequency analysis. Among other responsibilities at Abbott Vascular, Dr. Staehr oversees the clinical science development activities of the Absorb Bioresorbable Vascular Scaffold System. Dr. Staehr has had a decade of experience in Clinical Development with increasing responsibilities from early “First-in Human” to “late” stage (phase 1-4) at various Pharmaceutical companies, including ALZA/Johnson & Johnson, CV Therapeutics/Gilead, and Theravance. He was also supporting the clinical efforts to obtain US-FDA and EMA drug approval of regadenoson (Lexiscan®, Rapiscan), indicated for the detection of myocardial ischemia with radionuclide perfusion imaging. He joined Abbott Vascular in Santa Clara/California/USA in 2012.

Mr. Rainer Voelksen,
Edwards Lifesciences, USA

Rainer has accumulated an outstanding experience in medical technology regulations since 1991 in different companies and Government offices in different regions of the world.

He started his career in regulatory affairs in a French veterinarian pharmaceutical company near Nice/France. Two major osteosynthesis/joint prosthesis manufacturers in Switzerland followed.
For two years Rainer was the Director of Regulatory Affairs Europe for US biotech company Genzyme, based in the Netherlands. He worked closely in EUCOMED and other structures to lobby for new human tissue regulations.

In 1998 he joined the Swiss Government regulator for Medical Devices, which became Swissmedic, the Competent Authority for all therapeutic products, in 2002.
In the beginning of 2005 he joined the Australian Therapeutic Goods Administration TGA for a one-year delegation from Swissmedic.

After that year, he build up the Asia Pacific regulatory network for Synthes, a world leader in trauma products, being based in Sydney/Australia.

In 2008 Rainer joined GE Healthcare in Paris as the Executive for Regulatory & Quality Affairs, being responsible for harmonizing the RA strategies and post-market activities in Europe, Middle East and Asia Pacific, including related QA matters.

Since end of 2011 Rainer is now the Vice-President of International Regulatory Affairs with Edwards Lifesciences. Based in Paris, he coordinates the RA activities throughout the expanding network of Edwards in all regions outside the USA.

Being a member of the Regulatory Affairs Professional Society since more than 20 years, Rainer is now one of the Directors on the Board of RAPS and since September 2008 one of the first RAPS Fellows. He serves also as the Co-Chair of the European Advisory Committee of RAPS.

Recently Rainer had been nominated President-Elect for the year 2013.

By training, Rainer is a marine biologist, having studied in Oldenburg/Germany and Brest/France, added by a research project in Villefranche-sur-mer (Nice) /France.

Curriculum Vitae

Grant Ramaley

Co Chairman
Regulatory Affairs and Standards Committee
Dental Trade Alliance
www.dentaltradealliance.com

International Accreditation Forum (IAF) Since 2007

Grant Ramaley has been an active industry representative to the International Accreditation Forum (IAF) since 2007. His primary assignment has been to lead the development of the new IAF accreditation initiative for the medical device Quality Management System Standard ISO 13485. He is also an active member of other IAF Committees and Task Force groups, including Vice Chair of the User Advisory Committee, member of the Multilateral Recognition Arrangement and their Management Committee. Grant has also been an active member of the IAF Task Force Group for improving Assessor Competencies. Grant is a lead trainer that the IAF on medical device regulations and standards.

Representing the Dental Trade Alliance (DTA) 2001 to Present

Grant represents more than 200 manufacturers and distributors as Chairman of the Regulatory Affairs and Standards Committee for the Dental Trade Alliance (DTA). His volunteer work at the DTA has enhanced his ability to understand and communicate the needs of small and medium size medical device industry. Grant's primary responsibility at the DTA is to research the impact of new standards and regulations and help its members and regulators understand each other's needs.

Director of Regulatory Affairs at Aseptico Inc. from 1998 to present

Since 1998, Grant continues to work as Director of Regulatory Affairs for Aseptico Inc. The company manufactures and distributes medical equipment worldwide. Grant's experience preparing regulatory submissions and managing quality system compliance at Aseptico has helped him to speak clearly about the current and specific challenges related to the practical application of new standards and regulations.

Emergency Medical Technician

Before entering the regulated medical device industry, Grant worked for more than 10 years as an emergency medical technician, while volunteering on a highly specialized mountain rescue team. These experiences have deeply influenced Grant's interests in meeting the critical needs of patients that depend on healthcare, even where it is least accessible.

Mr. Jeffrey Gren,
Department of Commerce, USA

Jeffrey L. Gren is Director of the Office of Health and Consumer Goods (OHCG) within the U.S. Department of Commerce.

OHCG's mission is to help U.S. health and consumer goods firms to compete in world markets by fostering export opportunities, providing support for trade negotiations, performing industry analysis, working with foreign governments to reduce regulatory and other trade barriers, and developing industry-led joint government/industry initiatives.

Examples of major accomplishments as Director of OHCG include leading global activities to stop the spread of spurious medicines, serving as U.S. Co-chair of the Pharmaceuticals Task Force of the China - U.S. Pharmaceuticals and Medical Devices Subgroup, leading APEC drug safety and security workshops and organizing numerous health regulatory training programs for regulators and firms from countries with developing revised regulatory regimes, such as China, Russia, Ukraine, Asia and Latin America.

Mr. Gren has been with the U.S. Department of Commerce since 1976 and has held several past positions as well. Mr. Gren has a Masters of Arts in Economics from Northeastern University, Boston, Massachusetts in 1972, and a Bachelor of Science in Business Administration from Northeastern University in 1971.

In 2007, 2003, 1999, and 1997 Mr. Gren received the International Trade Administration Bronze Awards and in 2010, 2009, 2000 and 1996 he received the Department of Commerce Silver Awards.

Mr. Laurent Selles,
DG SANCO, European Commission, EU

Laurent SELLES is in charge of international relations for the Health Technology and Cosmetics Unit of the Directorate General 'Health and Consumers' of the European Commission.

With a background of Physics, he started in the automotive industry, before joining the European Commission.

Laurent SELLES is in charge of the international cooperation with bilateral dialogues and in multilateral frameworks. He represents the European position at the steering committees of GHTF, IMDRF (medical devices) and ICCR (cosmetics). He chairs the GHTF/IMDRF working group on Unique Device Identification (UDI) with the aim of permitting traceability at an international level.