ABHI

ABHI REGULATORY CONFERENCE

13th October, 08:30 – 16:45

Cavendish Conference Centre 22 Duchess Mews London W1G 9DT

AGENDA

Time	Topic	Speaker
08:30	**Registration & Coffee**	
09:30	Introductions & Welcome	**Steve Lee** Director, Diagnostics Regulation, ABHI
09:45	Post Brexit Opportunities	**Kim Trautman** Managing Director and Vice President, MEDIcept Inc & Former Associate Director International Affairs, FDA
10:15	The UK Opportunity	**Sharon Lamb** Partner, McDermott Will & Emery
10:45	**Coffee Break**	
11:00	Innovation Pathways / IDAP	**Johan Ordish** Head of Software and AI, Innovative Devices Division, MHRA
11:30	MDSAP / Global Quality Systems and UK Opportunities	**Graeme Tunbridge** SVP Global Regulatory and Quality, Medical Devices, BSI
12:00	Innovation Pathways and Predictability	**Dario Pirovano** Senior Regulatory Adviser - MedTech Europe
12:30	**Lunch**	
13:30	Afternoon Introduction	**Phil Brown** Director, Regulatory & Compliance, ABHI
13:40	Regulation as an Enabler	**Alex Mclaughlin** Deputy Director, Innovation and Growth, Office for Life Sciences
14:10	Integrated Regulatory Strategies; the Global Company	**John Brennan** VP Regulatory Affairs and Quality EMEA, Medtronic
14:40	Regulatory Science and the Role of Regulatory Affairs	**Prof Alastair Denniston** Director of INSIGHT - the Health Data Research Hub for Eye Health, Consultant Ophthalmologist, & Hon Prof, Uni of Birmingham
15:10	**Coffee Break**	
15:30	The Advantages of CA Marking; Beyond Unilateral Recognition	**Jane Wilson** Senior Manager RA QA, Intuitive **Darren Thain** Director, Global Regulatory Policy & Intelligence, Smith+Nephew
16:00	International Work Plans	**Ed Rozynski** Senior International Advisor, MDMA In conversation with **Erin Cutts** International Policy Analyst, FDA
16:30	Closing Remarks	**Phil Brown & Steve Lee**
16:45	**Event Close**	

MEET THE SPEAKERS

John Brennan

VP Regulatory Affairs and Quality EMEA, Medtronic

John joined Medtronic in September 2018 as Vice President, Regulatory Affairs & Quality EMEA. In May 2019 he took on additional responsibility in heading up Government Affairs EMEA.

John brings nearly 30 years' experience from the healthcare sector, most recently in European healthcare innovation and legislation policies in Brussels. John was Secretary General for the European biotech trade association, EuropaBio, as well as Director of Regulatory Affairs and Industrial policy for nearly ten years at the European health industry trade association MedTech Europe. He also spent five years in the Medical Devices Unit within the European Commission.

Prior to coming to Brussels John worked in, and managed, the Irish Notified Body, NSAI gaining extensive European and international experience in the design approval of high-risk devices and quality management systems. He sat on the working group which developed the international quality management systems standard for medical devices, ISO 13485. He began his career in the industry with five years' experience spanning the in vitro diagnostic, pharmaceutical and medical device industries.

John is a science graduate from Dublin, Ireland, with added post-graduate studies in quality control and environmental engineering.

Phil Brown

Director, Regulatory & Compliance, ABHI

Phil started his career at Smith and Nephew qualifying as a Graduate of the Royal Society of Chemistry in 1984, before joining the Company's Woundcare Regulatory Affairs team at the time when the Medical Device Directive was being enacted. Company moves to Genzyme Biosurgery, Quintiles, Wright Medical Technology and more latterly Kinetic Concepts Inc., (an Acelity company), included work with novel technologies, liaising with National Authorities, the European Commission, Trade Associations and standards bodies on issues related to regulation and ethics.

Phil extended his Trade Association work by joining the ABHI in June 2016 as the Director responsible for regulatory and compliance matters. Phil is a Fellow of TOPRA and lectures at the Sheffield Hallam University on medical device regulatory frameworks. He also chairs the UK BSI's CH/210 working group which has a mirror relationship to the ISO committee responsible for quality and risk standards.

Prof Alastair Denniston

Director of INSIGHT - the Health Data Research Hub for Eye Health, Consultant Ophthalmologist, University Hospitals Birmingham NHSFT & Hon Professor, University of Birmingham

Alastair Denniston is a consultant ophthalmologist (eye specialist) at University Hospitals Birmingham leading research into the use of health data research and artificial intelligence to improve patient care in the 'real world'. He is Professor at the University of Birmingham, and part of the Biomedical Research Centre for Ophthalmology at Moorfields Eye Hospital/UCL.

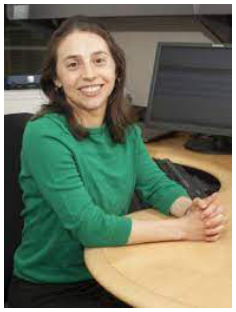
Alastair has particular interest in how we can ensure that the innovation within the broad field of 'artificial intelligence' is translated efficiently but safely to benefit patients. This includes improving the reporting standards of trials (CONSORT-AI and SPIRIT-AI), helping define the regulatory framework for AI in healthcare, and working with HDRUK and other relevant organisations to support the best of these innovations right through the implementation pathway.

He is Director of INSIGHT, the HDRUK Health Data Research Hub for Eye Health which is focused on eye disease and its application to wider health, including diabetes and dementia. It will use anonymised large-scale data and advanced analytics, including artificial intelligence, to develop new insights in disease detection, diagnosis, treatments and personalised healthcare.

Alastair's specialist interests within ophthalmology are ocular immunity, ocular imaging and outcome measurement in inflammatory eye disease. He was awarded an MRC Clinical Research Training Fellowship in 2006, and completed his PhD in Dendritic Cell Regulation in the Ocular Microenvironment in 2009. His laboratory work in immunology is directed towards understanding what causes intraocular inflammation (uveitis) and other forms of inflammatory eye disease. In the clinic with his collaborator Pearse Keane University College London, UK), he has demonstrated the potential for newer forms of imaging such as Optical Coherence Tomography (OCT) to provide much-needed objective markers for intraocular inflammation (uveitis). With Pearse Keane and colleagues across the UK and US, he has established EQUATOR an international collaboration of researchers working on 'Extended OCT-Quantification of Uveitis Activity for Trial Outcomes and Reporting'. He is a passionate advocate of the need to develop better measures for inflammatory eye diseases which are objective and quantifiable to improve the power of clinical trials and inform day-to-day treatment decisions. This work is balanced by a prioritisation of patient reported outcomes (PROs) for ocular inflammatory disease working with Professor Mel Calvert as part of CPROR).

He regularly publishes research papers in scientific journals as well as reviews and book chapters, but is best known for writing the Oxford Handbook of Ophthalmology with Professor Philip Murray (Professor of Ophthalmology and Head of the Academic Unit of Ophthalmology, University of Birmingham). Alastair is keen to promote awareness of ophthalmic research and has been actively involved with the MRC Max Perutz Science Writing Prize, the Big Bang and the British Science Festival.

Alastair's motivation, whether in research or in the clinic, is to improve the care of patients with potentially blinding disease.



Erin Cutts

International Policy Analyst, FDA

Erin Cutts is an international policy analyst at FDA's Center for Devices and Radiological Health (CDRH). While at FDA, she has led various projects related to trade and international harmonization efforts including development of FDA's position on medical device nomenclature. She has also managed a variety of Center-wide programs including the Accreditation Scheme for Conformity Assessment (ASCA), which leverages internationally harmonized standards and conformity assessment practices. Erin's career began as a Research and Development Engineer at a medical device start-up company after which she joined FDA as scientific reviewer and then branch chief in the cardiovascular space.

Erin holds a bachelor's degree in biomedical engineering from Georgia Tech.

Sharon Lamb

Partner, McDermott Will & Emery UK LLP

Sharon Lamb focuses her practice on transactional and regulatory advice in the health and life sciences sector.

Sharon advises on global transactional mandates, including mergers and acquisitions and joint ventures in health services, pharma and life sciences, digital health and health data technologies.

Sharon also provides strategic, regulatory and commercial support to UK and international clients on UK health and life sciences with a focus on health services, pharmaceuticals, medical devices, digital health and health data. Sharon is widely recognized for her expertise on NHS and public law regulatory and contracting matters, including payment and reimbursement and market access. She works closely with international technology and life sciences companies on regulatory issues relating to pharmaceuticals, medical devices, digital health and health data protection. She has particular experience advising strategic and private equity investors in transactions and investments in health and life sciences.

Sharon is also well-versed in health care services governance and regulatory matters, NHS public private partnerships, procurements, joint ventures and shared working arrangements, mergers, acquisitions, health data and competition issues.

Sharon has practiced health law in the UK since 2002 and is recognized in Chambers and Legal 500. Sharon has written and lectures widely on health and life sciences issues and has a wealth of experience with NHS law and policy, having worked on a 4-year part time secondment with the NHS and national health bodies in London. In 2019, Sharon gave oral evidence to the UK government's health and social care select committee on reforms to NHS legislation. Sharon is also an associate fellow of the Nuffield Trust.

Sharon is head of the UK health practice.

Steve Lee

Director, Diagnostics Regulation, ABHI

Steve joined ABHI as Director of Diagnostics Regulation in 2020.

After completing his degree in Biochemistry and Biology at Aston University, Steve trained as a Biomedical Scientist, working in hospital microbiology before moving to industry to work as company microbiologist. Steve joined MHRA in 1996 when it was still the Medical Devices Agency and when the IVD Directive had yet to be implemented.

While at MHRA, Steve worked with manufacturers, Notified Bodies, other Competent Authorities, Trade Associations, standards bodies and government departments. Steve was Chair of the European Commission's IVD working group when the IVD regulations where being developed.

In 2019, Steve was presented with the TOPRA award for regulatory excellence.

Dario Pirovano

Senior Regulatory Adviser - MedTech Europe

Dario Pirovano has been a consultant for regulatory affairs with Eucomed and subsequently for MedTech Europe since 2002. He worked in the European Commission for 4 years, where he contributed to the drafting and negotiating of the 90/385 /EEC and 93/42/EEC directives.

Dario has over 30 years experience in medical technology as designer and regulatory affairs expert. In 1995 he founded Pirovano Management SPRL, a consulting firm advising manufacturers, Notified Bodies and authorities in regulatory matters relating to medical technology.

Dario can be considered the historical memory of the development of medical devices regulation in Europe. He holds a Doctorate in Engineering from the Politecnico di Milano. An Italian national, Dario is fluent in French and English.

Johan Ordish

Head of Software and AI, Innovative Devices Division, MHRA

Johan leads Software Group within the Medicines and Healthcare products Regulatory Agency (MHRA). Software Group are responsible for most aspects of regulating software as a medical device (AI included) and work to ensure these devices are acceptably safe and deliver for patients. He was a co-author of Good Machine Learning Practice for Medical Device Development, has been involved in the development of various reporting standards for AI such as DECIDE-AI, and represents the UK in several international fora such as the AI Medical Device Working Group at the International Medical Device Regulators' Forum. Previously, Johan was a Senior Policy Analyst (Law and Regulation) with the PHG Foundation, specialising in the regulation of digital health and genomic technology and led work on how medical device and data protection regulation applies to AI. Johan has four degrees, the last being a BA in Law from Wolfson College, University of Cambridge.

Ed Rozynski

Senior International Advisor, MDMA

Ed has been a pioneer, an effective advocate and a well-known voice in the field of government affairs and market access in the worldwide medical device community. Ed is based in Washington, D.C. where he works on U.S. and overseas government affairs, reimbursement policy and health economics. In order to meet growing political, policy and market challenges, Ed was asked in March 2014 to take on an expanded leadership role for Intuitive Surgical as the company's new VP of Global Government Affairs and Health Economics. In addition to his external affairs activities, Ed is also a member of the ISI executive staff and partners with the Intuitive Surgical communications team on communications-related issues for the company.

Before joining ISI as VP, Government Affairs, Ed was a Senior Advisor to the Medical Device Manufacturers Association (MDMA) where he advised start-up and growing medical device companies on how to navigate challenging and increasingly cost-conscious medical device markets. Prior to MDMA, in his role as VP of Global Government Affairs for Stryker Corporation, Ed was responsible for creating, launching and managing that company's global government affairs program. While at Stryker, he helped to shape health reform legislation in the U.S., participated on Presidential and Cabinet-level partnerships to improve U.S. manufacturing competitiveness, and opened up new market access and reimbursement opportunities in Japan, China, India and Germany.

Earlier in his career, Ed worked with St. Jude Medical, Inc., the Advanced Medical Technology Association (AdvaMed), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Office of the U.S. Trade Representative (USTR) where he designed and negotiated U.S. commercial treaties and trade agreements to protect and promote U.S. investment and trade overseas. During his career, Ed has also been a consultant to many small and large U.S. medical device manufacturers and has helped many of these companies to penetrate and secure favorable health policies and reimbursement rates in Europe and Asia-Pacific. In 2010, Ed was awarded only the 10th Distinguished Alumni award granted by UNC-Greensboro's School of Business and Economics.

Darren Thain

Director, Global Regulatory Policy & Intelligence, Smith+Nephew

Darren Thain is the Regulatory Affairs Director for Global Policy and Intelligence at Smith+Nephew. He has over 10 years' experience working in a variety of Regulatory and Quality roles. He has worked for a range of different companies including Medical Device, Pharmaceutical, SME and large organisations - and covering a multitude of different product technologies.

Darren formulates regulatory strategy and advise to his company and has been involved in a number of different key projects during his tenure at Smith+Nephew. Prior to his role as Director for Global Policy and Intelligence, Darren was the European Regulatory Affairs Director. He has also held roles as an EU MDR Regulatory lead for the Wound franchise within Smith+Nephew – and developed strategies and produced the necessary submissions to allow the transition to the new EU MDR requirements.

Most recently, Darren has been studying the UKCA consultation proposals and response issued by the UK government to best inform company and industry strategy moving forward.

Kimberly Trautman

Managing Director and Vice President, MEDIcept Inc. & Former Associate Director of International Affairs, FDA

Kim Trautman, former Associate Director of International Affairs at FDA, is an experienced medical device, IVD, and combination product expert with over 30 years of industry and regulatory agency experience.

As Managing Director and Vice President, Kim is an integral part of the MEDIcept executive management team. She provides strategic client consulting services, develops business relationships with new clients, and leads the MEDIcept Training Immersion Program, developing the next generation of medical device consultants.

An expert in global medical device regulations, she wrote and harmonized the current FDA Quality System Regulation. Kim was also on the FDA authoring committee for 21 CFR Part 4 and FDA Combination Product GMP guidance documents. In addition, Trautman developed the International Medical Device Single Audit Program (MDSAP) and consortium from conception through its pilot. She is a 25-year veteran of the Global Harmonization Tasks Force (GHTF) and a foundational member of the International Medical Device Regulators Forum (IMDRF).

After retiring from FDA, she established an Authorized MDSAP Auditing Organization and launched a new Notified Body for EU IVDR/MDR Designation. She currently serves on the Board of Directors at the Regulatory Affairs Professionals Society (RAPS), has been on TC 210 Working Group 1 for ISO13485 since its 1994 inception, and is a member of the ASTM E55 Combination Product Definitions standard. Kim also serves as the College of Engineering Vice Chair for the Industry & Professional Advisory Council at Penn State.

Trautman received her M.S. in Biomedical Engineering from the University of Virginia and her B.Sc. in Molecular Cell Biology from the Pennsylvania State University.

Graeme Tunbridge

SVP Global Regulatory and Quality, Medical Devices, BSI

Graeme is Senior Vice President, Global Regulatory and Quality, Medical Devices at BSI. He has responsibility for BSI's regulatory compliance to undertake a range of global medical device certification and accreditation activities.

Prior to joining BSI, Graeme was Director of Devices at the UK Medicines and Healthcare products Regulatory Agency (MHRA), where he was responsible for ensuring the safety and performance of medical devices in use in the UK. Graeme first joined the MHRA in 2011 and spent much of his time at the MHRA negotiating and implementing a package of measures to strengthen the regulation of medical devices.

Graeme was a civil servant for nearly 20 years and spent his early career working on healthcare policy. He has previously held Deputy Director roles at the Department of Health and Social Care and spent 18 months as Private Secretary to the Secretary of State for Health.

Graeme has a Master's degree in biochemistry from the University of Oxford.

Jane Wilson

Senior Manager RA QA, Intuitive

Jane Wilson has been navigating the medical device world for circa 20 years, starting by medical device design sales to big pharma and project management of the design, development, manufacture and launch of drug delivery, combination products. Jane then moved into regulatory and quality management, where she led pre and post market regulatory requirements, responsible for regulatory strategy, technical file creation, labelling input, submissions and hosted many an inspection. Having been integral to the design control process, Jane has experienced the full-lifecycle of medical devices. This was done in order achieve deliverables globally, within the context of evolving requirements for market access into the US, along with 50 other countries. Jane has introduced a post market surveillance system, been chair of an internationally applied change control board and managed world-wide complaint investigation, vigilance reporting and field actions. Risk management per ISO 14971 has been a special interest for Jane throughout her journey so far, given how integral it is to all elements of medical device creation and real-world use of products. Jane has managed the risk management lifecycle for a portfolio of over 70 technical files.

Since, moving into the sector of robotic surgical systems, Jane has become deeply involved in the preparations for the new regulatory landscape in the UK and is vice-chair of our ABHI UKCA mark working group. In her current role, Jane has implemented a quality management system to integrate the UK into the Intuitive global business and takes care of pre and post-market regulatory and quality for the UK and Ireland.

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https://www.psephos.com/

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Venue Details
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020 7706 7700

Toilets
Ladies: Located on the lower ground level adjacent to the Whittington
Gents: Located on the lower ground level adjacent to the Whittington
Disabled: Located on the lower ground level adjacent to the Whittington

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Password: 12345cav

Smoking Area.
The smoking area is located to the left or right of the building

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How to get to the Cavendish Conference Centre

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