ABHI

ABHI UK HEALTHTECH CONFERENCE

30th September - 1st October 2024

Cavendish Conference Centre, 22 Duchess Mews, London, W1G 9DT

Day 1

AGENDA

Time	Topic	Speaker
08:30	Registration & Coffee	
09:30	Welcome & Introductions	**Phil Brown** Director, Regulatory & Compliance, ABHI
09:40	The Pulse of the Sector	**Peter Ellingworth** CEO, ABHI **Sharon Lamb** Partner, McDermott Will & Emery
10:00	Keynote Address	**Dame June Raine DBE** CEO, Medicines and Healthcare products Regulatory Agency (MHRA)
10:45	Coffee Break	
11:15	Focus on Post-Market Surveillance	**Megha Deviprasad Iyer** Director, Global Strategic Regulatory Affairs, Thermo Fisher **Michael King** Senior Director, Product & Strategy, IQVIA **Cait Gatt** Senior Manager, Regulatory Affairs, Northern Europe, Boston Scientific
12:30	Lunch	
13:30	Introductions	**Steve Lee** Director, Diagnostics and Digital Regulation, ABHI
13:40	Innovation in the UK	**Jeanette Kusel** Director - NICE Advice, National Institute for Health and Care Excellence **Heather Hobson** Head of Regulation and Access | Innovation and Growth, Office for Life Sciences **Dr Iain Miller** CEO, Presymptom Health
14:45	Coffee Break	
15:30	MHRA Update	**Dr Laura Squire OBE** Chief Healthcare Quality & Access Officer, MHRA
15:45	How Can Regulated SaMD and AI Move Fast and Still be Safe?	**Dr Roberto Liddi** VP Regulatory & Compliance, NuraLogix **James Dewar** Co-Founder, Scarlet
16:15	International Perspectives	**Tammy Steuerwald** Global Head of Regulatory Policy, Foundational Principles and Supranational Organizations, Roche **Daniel Delfosse** Vice Director, Head of Regulation & Innovation, Swiss Medtech **Erin Cutts** Senior International Policy Analyst, FDA
16:45	Regulatory Opportunities	**Sue Spencer** Head of In Vitro Diagnostics & Principal Consultant, Qserve Group **Adam Spinks** Director of Governance and Legal Affairs, 8foldGovernance **Diogo Geraldes** Director, Regulatory Strategy, Veeva Systems
17:15	Event Close	

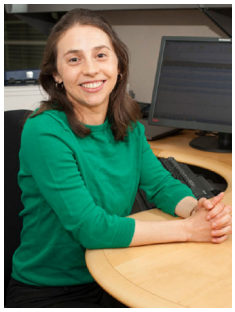
MEET THE SPEAKERS

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.



Erin Cutts

Senior 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.

Daniel Delfosse

Vice Director, Head of Regulation & Innovation, Swiss Medtech

Daniel Delfosse is Vice-Director of the industry association Swiss Medtech and responsible for Regulation & Innovation. His mantra is “innovation despite regulation” and he pursues the goal of keeping Switzerland an attractive location for the MedTech industry.

Daniel graduated from ETH Zurich as a materials engineer and did his doctorate at EPF Lausanne. After a research stay at the University of British Columbia in Vancouver, Canada, he moved to the MedTech industry. For almost 20 years he worked as head of development and member of the executive board for a Swiss orthopaedics company, always at the crossroads between regulation and innovation.

James Dewar

Co-Founder, Scarlet

James co-founded Scarlet with Jamie Cox in 2021 to hasten the transition to universally accessible and affordable healthcare. After graduating with a Masters in AI & Machine Learning from Imperial College, he worked as a Data Scientist before meeting Jamie and starting Scarlet. He has spent nearly four years developing Scarlet into Europe’s only software & AI-specialised Notified Body, which certifies medical software under MDR more efficiently and frequently than ever before.

Peter Ellingworth

Chief Executive, ABHI

Peter is Chief Executive of the Association of British HealthTech Industries (ABHI), the UK's leading HealthTech Trade Association, with 400 members operating across medical devices, diagnostics and digital health. Working at both national and regional levels with senior government and the NHS, ABHI is focused on ensuring that policies and practices support the growth of our members and industry, thus enabling access to effective and life-changing technologies for patients.

Peter represents our industry on several formal government bodies and committees. This includes the Secretary of State led Life Sciences Council, the sector specific Health Technology Partnership which supports it, and a number of the expert groups that feed into the delivery of the Life Sciences Vision. He is the leading voice for our industry on the Advisory Group for the Innovation System Programme, overseen by Roland Sinker on behalf of NHS England, and also serves as a workstream Chair. In addition, he is a Board member of the Accelerated Access Collaborative, led by Lord Ara Darzi, and he also advises the Department of Health and Social Care's MedTech Strategy Programme Board. As a newly appointed Board member for the Office for Strategic Coordination of Health Research (OSCAR), Peter is seeking to develop a productive relationship for our industry with the wider science and research community.

At a regional level, Peter has a long history of involvement, beginning with the inception of the Academic Health Science Networks and continuing through their evolution into Health Innovation Networks. He has held Board-level roles with Manchester and South London, and since 2018, he has served as a Board Director at Oxford & Thames Valley, where his leadership culminated in his appointment as Chair in 2024. Additionally, Peter leads ABHI's partnership agreement with the Shelford Group, a collaboration of ten major research and teaching hospitals in England, designed to strengthen NHS-industry relationships and accelerate research and innovation.

He is a Board Member of MedTech Europe and Chairs its UK Working Group, which focuses on developing support for the harmonisation of critical policy matters for our industry, such as regulation, sustainability, and data. He also leads ABHI's engagement with AdvaMed, through a joint memorandum of understanding, and the Global Medical Technology Alliance.

Peter has an extensive background in business with international companies in the UK and Europe and holds non-executive roles with early stage HealthTech companies. He is a committed champion for ABHI's important work on inclusion, health equity and women's health.

Cait Gatt

Senior Manager, Regulatory Affairs, Northern Europe, Boston Scientific

Cait has over 20 years of Regulatory Affairs experience, gained both within industry and a Notified Body. She has special interests in clinical investigations and post-market surveillance where her role at Boston Scientific has primarily focused. Cait has been instrumental in leading Boston Scientific through the UK's evolving regulatory environment, and is a continued advocate of proportionate regulation. Cait is the Vice-Chair of ABHI's Regulatory Group.

Diogo Geraldes

Director, Regulatory Strategy, Veeva Systems

Diogo is a Director for Regulatory Strategy at Veeva Systems, specialising in the EU MedTech market. Before this role, Diogo was the UKCA certification manager and a principal technical assessor at DNV, ensuring the safety and compliance of medical devices for the EU and UK markets. Diogo's career also includes work as a designer at Stryker/ Stanmore Implants, where he contributed to the development of over 250 patient-specific implants, particularly focusing on complex cases in limb salvage and paediatric oncology. With a background in Biomechanics, Diogo earned his PhD at Imperial College London, where he focused on computational modelling of bone adaptation in the femur. He followed this with a Post-Doctorate at Imperial, where he developed and patented a novel glenoid implant. Diogo combines academic rigour with design, research, modelling and clinical experience in orthopaedic implants and regulatory affairs.

Heather Hobson

Head of Regulation and Access | Innovation and Growth, Office for Life Sciences

Heather is the Head of Regulation and Access at the Office for Life Sciences, where she also has responsibility for MedTech. In this role she has played a key role in coordinating the delivery of Dame Angela Mclean's regulatory review work on life sciences, is responsible for major programmes on accelerated assessment of innovative MedTech and the development of real world evidence, and leads on cross cutting engagement on regulatory matters with the sector. Previously she led the development of the Life Sciences Vision Mental Health Mission.

She is a scientist by background with a varied civil service career including roles in HM Treasury, where she was the lead official on a variety of critical issues including life sciences, global health, nuclear decommissioning, and sectors' spending, and the Medicines and Healthcare products Regulatory Agency. Prior to joining the civil service, she worked in the Life Sciences Sector.

Megha Deviprasad Iyer

Director, Global Strategic Regulatory Affairs, Thermo Fisher

Megha is a seasoned Regulatory Affairs professional with extensive experience in the Life Sciences, Medical Devices, and In Vitro Diagnostic devices industry. She has successfully led global teams with diverse portfolios and collaborated with regulatory authorities to shape new policies and regulations. Currently, Megha serves as the Director of Global Strategic Regulatory Affairs at Thermo Fisher Scientific, responsible for regulatory intelligence, policy, and advocacy across the organization's varied business segments. Megha is the Vice-Chair of ABHI's IVD Regulatory Affairs Committee and holds a leadership position in MedTech Europe. She has been recently honoured with the Fellow designation by the Regulatory Affairs Professional Society (RAPS) in recognition of her significant global volunteering contributions both within and outside RAPS.

Michael King

Senior Director, Product & Strategy, IQVIA

As Senior Director of Product and Strategy within the Digital Products & Solutions business of IQVIA Technologies, Michael King (Mike) is responsible ensuring that the global Quality, Regulatory and Safety solutions have the necessary functionality to support the increasingly complex and diverse global landscape. He is particularly focused on optimising business workflows and driving improved patient outcomes through intelligence driven simplification and automation.

Mike has around 20 years of knowledge and experience leading localised and global teams in Regulatory Affairs and Quality Assurance and has worked within the Medical and Surgical, Orthopaedic, In Vitro Diagnostic, Diagnostic Imaging, Dental and Urology sectors. Before joining IQVIA Mike was the Vice President of International Regulatory Affairs for a Dental Technology organisation and had oversight of the International Product Registration, Adverse Event Reporting and country-based Quality Management Systems.

Mike holds a degree in Physics from Oxford University and briefly worked for a consulting firm in the telecommunications industry prior to beginning his career in the Medical Industry.

Jeanette Kusel

NICE Advice, National Institute for Health and Care Excellence

Jeanette joined NICE in November 2018. She is responsible for the stewardship and growth of the NICE Advice team, which provides early support services to the life sciences industry. Jeanette takes an active role in the sign-off and quality assurance of work across all services offered by the team. She also chairs many of the national and parallel scientific advice meetings for medical device and pharmaceutical product developers. Jeanette is the senior responsible officer from NICE for the Innovative Devices Access Pathway (IDAP).

Previously Jeanette held the positions of Head of HTA and Health Economics and Scientific Director at Costello Medical, a consultancy within the life science sector. She has broad research interests across different methods for health technology evaluation and has previously worked on clinical trial design, health economic modelling and quality of life measurement.

Jeanette studied undergraduate natural sciences at the University of Cambridge and postgraduate health economics at the University of York.

Sharon Lamb

Partner, McDermott Will & Emery

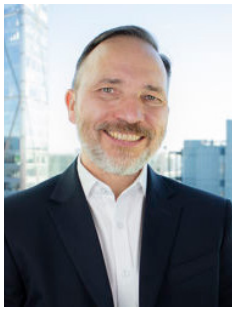
Sharon Lamb focuses her practice on transactional and regulatory advice in the health and life sciences sector and is Head of McDermott's UK Healthcare Practice Group.

Sharon advises on global transactional mandates, including mergers and acquisitions and joint ventures in health services, pharma and life sciences, digital health and health 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 procurement, regulatory and contracting matters, including payment and reimbursement and market access. 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 and life sciences 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.



Steve Lee

Director, Diagnostics and Digital 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.

Dr Roberto Liddi

VP Regulatory & Compliance, NuraLogix

Roberto is an experienced regulatory professional with a history of working in the medical device manufacturing industry. Skilled in U.S. Food and Drug Administration (FDA) Regulations, Regulatory Strategy, Corrective and Preventive Action (CAPA), Quality Auditing, Risk Management and CE marking, he has experience in a variety of medical device industries, spanning from orthopaedic device, to neurosurgical and3D printed implantable devices, IVD and Software as Medical Device. He is a strong healthcare services professional with a Doctorate in Biological Sciences focused in Human Biology and Immunology from Università degli Studi di Bari.

Previously a member of the Advisory Group to the European Commission, he is the current Chair of the ABHI Digital Health Group, a Caldicott Guardian, DPO listed and a member of the NHS NIHR D4D Committee.

Dr Iain Miller

CEO, Presymptom Health

Dr Iain Miller holds a PhD in biomedical engineering from the University of Strathclyde and an MBA from Edinburgh Business School, Heriot-Watt University. He has extensive medtech commercial experience, including leading three medtech SMEs before becoming the CEO of Presymptom Health in 2019. Presymptom is one of 8 companies participating in the MHRA Innovative Devices Access Pathway pilot program. Iain's experience in the medtech sector was gained from various positions across the US and Europe, with companies including GE Healthcare, bioMérieux, Myriad Genetics, Philips, Variagenics and PathoGenetix. Iain has also served as medtech licensing lead at Massachusetts General Hospital, as an assessor and panellist for Innovate UK, and has completed a 3-year term on a technology appraisal committee at NICE.

Dame June Raine DBE

CEO, Medicines and Healthcare products Regulatory Agency (MHRA)

Dr June Raine DBE is CEO of the Medicines and Healthcare products Regulatory Agency. She trained in medicine in Oxford after completing a master's degree by research in Pharmacology. Her interest in drug safety led to a career in medicines regulation which has spanned a number of roles in assessment, management and strategic development within the UK national authority. She was elected in 2012 as the first chair of the European Pharmacovigilance Risk Assessment Committee and is also co-Chair of the WHO Advisory Committee on Safety of Medicinal Products. Her special interests are in monitoring the outcomes of regulatory action, risk communication and patient involvement in the regulatory process.

Sue Spencer

Head of In Vitro Diagnostics & Principal Consultant, Qserve Group

Sue leads Qserve's IVD service, is EU Regulatory and Quality Expert including CDx and Lead Auditor. She has over 30 years' of experience in the Medical Device and IVD industries including extensive notified body experience.

Before Qserve Sue worked for several IVD companies ranging from start-ups to large multinationals, where she has held positions in R&D, manufacturing and quality assurance. Sue worked for 3 Notified Bodies establishing two from scratch.

Sue chaired the European IVD Notified Body Working Group coordinating the Notified Body responses to the regulations. Sue also participated in the Commission IVD Technical Work Group for many years.

Sue is an experienced trainer on a variety of IVD topics and particularly enjoys creating workshops to improve hands on experience with the requirements.

Adam Spinks

Director of Governance and Legal Affairs, 8foldGovernance

Adam is the co-founder and Director of Governance and Legal Affairs at 8foldGovernance. With a background in law and IT, Adam specialises in data protection and information governance and has worked extensively with the NHS, private healthcare providers and digital health technology companies. He is an expert communicator and trusted advisor in the industry. Adam is also a lover of the great outdoors. You'll often find him exploring the UK in his VW campervan looking for the next mountain to climb or stream to cross. He has been volunteering with the Scout Association as an Explorer Scout Leader for over 10 years, and has a passion for supporting young people to learn skills for life.

Dr Laura Squire OBE

Chief Healthcare Quality & Access Officer, MHRA

Laura oversees a large portfolio that is designed to ensure the quality and access of products to the UK market - this includes scientific advice, clinical trials/clinical investigations, licensing assessment, marketing authorisations and device registrations, inspections, enforcement and standard setting through for example the British Pharmacopoeia and Target Product Profiles.

Laura started her career as a post-doctoral research assistant looking at resistance to anti-malarial drugs at the Liverpool Institute of Tropical Medicine following her PhD and BSc in Biochemistry and Physiology. She has spent most of her career as a Civil Servant. After many years in operational work Laura moved into government policy in 2014. In parallel, she went back to university, gaining an Executive Master's degree in Public Policy from the London School of Economics. Laura has extensive experience of regulatory and organisational transformation through her wider policy and operational work in other major government departments.

She joined the Medicines and Healthcare products Regulatory Agency from the Department of Health and Social Care, where she worked extensively on the COVID-19 vaccine deployment programme.

Tammy Steuerwald

Global Head of Regulatory Policy, Foundational Principles and Supranational Organizations, Roche

Tammy Steuerwald is the Global Head of Regulatory Policy for Foundational Principles and Supranational Organizations at Roche Diagnostics. In that role, she collaborates with the global regulatory community to identify modern and flexible solutions that drive improved access to safe and innovative healthcare products. Her work includes efforts to support regulatory convergence, implementation of Good Regulatory Practices, and Regulatory Reliance policies and involves organizations such as the World Health Organization, IMDRF and jurisdictions around the world. Ms. Steuerwald joined Roche in 2002 and served as the Director of Quality and Regulatory where she helped ensure compliance to established post market controls such as adverse event reporting and inspections. Prior to joining Roche, she supervised various diagnostic labs including blood banking, hematology, coagulation, and chemistry. Ms. Steuerwald holds a B.S. of Science from Indiana University, as well as a J.D. and Health Law Certificate from the Indiana University Robert H. McKinney School of Law.

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Get in touch with the team:
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Alasdair.gray@element.com

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020 7706 7700

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Directions to the Venue
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