ABHI

ABHI UK HEALTHTECH CONFERENCE

16th - 17th October, 08:30 – 17:10

Cavendish Conference Centre 22 Duchess Mews London W1G 9DT

Day 2

AGENDA

Time	Topic	Speaker
08:30	**Registration & Coffee**	
09:15	Introductions & Welcome	**Phil Brown** Director, Regulatory & Compliance, ABHI
09:30	Enabling Regulation & Growth	**Heather Hobson** Head of Regulation and Access, Office for Life Sciences
10:00	Regulation & Market Access: Why it Matters for the UK's Attractiveness	**Sharon Lamb** Partner, MWE
10:20	**Coffee Break**	
10:45	*Innovation*	**Phil Brown** Director, Regulatory & Compliance, ABHI
11:00	Innovation through Progressive Technology Regulation	**Dr Camilla Fleetcroft** Strategy & Innovation Director for Regulatory Services, BSI
11:30	Member Perspectives	**Dr Roberto Liddi** Vice President, Regulatory & Compliance, NuraLogix Corporation
12:00	Recognition, Capacity, Innovation: The MHRA's Vision	**Dr Laura Squire OBE** MHRA
12:30	**Lunch**	
13:30	Capacity	**Steve Lee** Director, Diagnostics Regulation
13:35	Attracting & Retaining Regulatory Talent	**Emma Carter** Talent Lead, UKI Pharmaceuticals, Bayer
13:55	Training & Development in HealthTech Regulation	**Kevin Pay** & **Elizabeth Brookfield** CEO & Director of Professional Development, TOPRA
14:15	Regulatory Recruitment	**Elena Kyria** CEO & Founder, Elemed
14:35	Conformity Assessment Body Panel Discussion	**Vishal Thakker** Head of UK Approved Body & Senior Regulatory Lead, Regulatory Services (Medical Devices), BSI **Dr Monisha Phillips** Head of Certification Body (Medical and Health Services UK), TÜV SÜD **Dhruti Shah** Head of Approved Body, DQS

AGENDA (cont.)

Time	Topic	Speaker
15:00	**Coffee Break**	
15:25	*Recognition*	**Steve Lee** Director, Diagnostics Regulation
15:30	International Recognition Panel Discussion	**Ivan Perez Chamorro** CEO & Co-Founder, MedBoard **Sue Spencer** Head of In Vitro Diagnostics & Principal Consultant, Qserve **Lynn Heaver** Director, Regulatory Affairs, UK / Ireland, Johnson & Johnson MedTech
16:00	Swiss You Were Here?	**Dr Daniel Delfosse** Director of Professional Development, TOPRA
16:30	Transatlantic Perspectives	**Erin Cutts** Senior International Policy Analyst, Center for Devices and Radiological Health, U.S. Food and Drug Administration
17:00	Final Reflections	**Steve Lee** Director, Diagnostics Regulation **Phil Brown** Director, Regulatory & Compliance, ABHI
17:10	**Event Close**	

MEET THE SPEAKERS

Elizabeth Brookfield

Director of Professional Development, TOPRA

Elizabeth oversees TOPRA training courses and educational resources as well as ensuring that the development of professionals in regulatory affairs throughout their career journey is supported. She has a background in all areas of professional education having developed training programmes for the construction industry, FE teachers and trainers, engineers, construction project managers, surgeons, gynaecologists and obstetricians. Liz is also interested in how technology can be deployed to increase access to training and development opportunities while maintaining a positive learning experience.

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.

Emma Carter

Talent Lead, UKI Pharmaceuticals, Bayer

Emma Carter is an accomplished professional with over 20 years experience in the field of human resources. Throughout their career, Emma has demonstrated expertise in various aspects of human resources from employee relations, talent acquisition and compensation and benefits and now focusses on strategic partnering within the business. Having begun her career in the automotive industry with the car manufacturer Jaguar LandRover, Emma has also worked within the automotive supply chain before joining her current employer Bayer PLC in 2018 where she works as a strategic HR Business Partner within their Pharmaceutical division for the UK and Ireland. Emma is vice-chair of the ABHI HR Network, is an active mentor and has a special interest in evolving working models and the future of work.

Ivan Perez Chamorro

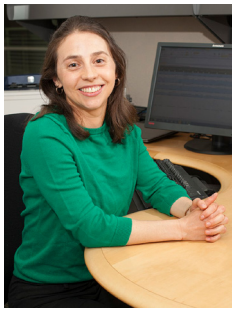
CEO & Co-Founder, MedBoard

Ivan Perez Chamorro is CEO and Founder of MedBoard, a technology company that organises medical technology information and data, makes it fast accessible to manufacturers and key stakeholders, and it is integrated with breakthrough tools as the Vigilance automation. MedBoard is made up of leading engineers, scientist and medical professionals. This big data platform covers from Regulatory, to Clinical, Market and Technical.

Ivan has both strong science and business background, he holds a degree and MSc in Physics from Universidad de Salamanca, and an MBA from IE Business School. Ivan is very active in medical device industry, and he is also part of the TOPRA MedTech SPIN.

After having a chronic sports injury while playing basketball, and spending many years in rehabilitation, he decided after physics graduation to work in the medical devices industry. Ivan has lived in different countries and likes travelling, painting, and adventure sports, and has special interest in innovation, entrepreneurship, and technology. MedBoard is not the first project, and Ivan has have a number of entrepreneurship projects in the past, in the medical and outside of medical devices industry.

Before Medboard, Ivan had worked for many years within the industry, as an employee of leading medical companies and as a consultant in the areas of product and business development, regulations, and strategy, from operational roles to advising technical and top management. He has broad experience with different types and classes of medical devices and combination products, supporting a variety of organization models, from start-ups to large corporations.



Erin Cutts

Senior International Policy Analyst, Center for Devices and Radiological Health, U.S. Food and Drug Administration

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.

Dr Daniel Delfosse

Vice-Director, Swiss MedTech

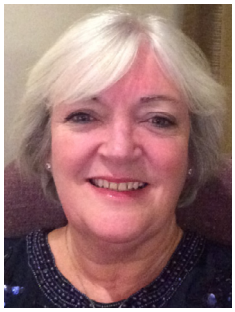
Daniel Delfosse is Vice-Director of the industry association Swiss Medtech and responsible for Regulation & Innovation. His mantra is "innovation despite regulation" and he pursues the goal of keeping Switzerland an attractive location for the MedTech industry.

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.

Dr Camilla Fleetcroft

Strategy & Innovation Director for Regulatory Services, BSI

Camilla brings a wealth of knowledge and experience across the MedTech sector. After qualifying as a medical doctor, she worked for 9 years at the Medicines and Healthcare products Regulatory Agency (MHRA) and recently joined BSI to lead on strategy and innovation within the regulatory Services team. Earlier in the year she supported the UK Government as a champion for the Pro-Innovation Regulation of Technologies Review. Working hand-in- hand with Sir Patrick Vallance & Sir John Bell, the review set out key recommendations to accelerate development and deployment of emerging tech in the UK.



Lynn Heaver

Director, Regulatory Affairs, UK / Ireland, Johnson & Johnson MedTech

Lynn boasts 40 year's work experience across a variety of scientific disciplines, with 28 years having been spent in Life Sciences, particularly medical devices. Of which, 25 years have also been spent in Regulatory Affairs.

During that time, Lynn has worked in Research and Development in a pure research facility and a manufacturing facility. She has worked in a joint function of Regulatory and Quality, performed the analysis and interpretation of the MDD, AIMDD, IVD, Medicines, Human Tissues, Biocides, MDR and Environmental legislation. She has also set up new quality systems to meet the impacts and requirements of these regulations.

Having previously served as an Authorised Representative for Johnson & Johnson companies within the European Union, she is now the main contact for the UKRP, the local Johnson & Johnson operating company.

Lynn Chairs ABHI's Medical Device Regulatory Group.

Heather Hobson

Head of Regulation and Access, 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 Sir Patrick Vallance'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.

She has had 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 and sectors' spending, and the Medicines and Healthcare products Regulatory Agency. Prior to joining the civil service, she worked in the Life Sciences Sector.

Elena Kyria

CEO & Founder, Elemed

Elena Kyria is an award winning talent acquisition specialist, career coach and LinkedIn top voice. In 2015, she founded Elemed, a specialist talent management agency for the MedTech and IVD industry, focussed on recruitment, careers and skills building. She is also leader of the LinkedIn MDR/IVDR discussion forum, a network of over 11000 regulatory professionals.

In 2018, Elena was named one of the year's top Millennial Shepreneurs by Insights Success Magazine.

Sharon Lamb

Partner, McDermott Will & Emery

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

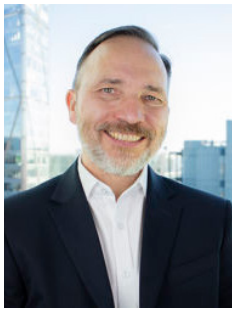
Sharon advises on global transactional mandates, including mergers and acquisitions and joint ventures in health services, pharma and life sciences, digital health and health data technologies.

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

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

Vice President Regulatory & Compliance, NuraLogix Corporation

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 Monisha Phillips

Head of Certification Body (Medical and Health Services UK), TÜV SÜD

Monisha has over 20 years of experience in medical devices including regulatory conformity assessments, quality assurance, biomaterials research and medical device development. She joined TÜV SÜD in June 2021 as Head of MHS Certification Body (UK) where she is Head of Approved Body for medical devices. She led TÜV SÜD from application to designation as an Approved Body for medical devices and continues to lead the strategic and procedural development of the Approved Body in order to maintain and further expand this designation.

Prior to joining TÜV SÜD she spent 13 years working for BSI, first as a Product Specialist and later as Global Head, Orthopaedic & Dental Devices, Regulatory Services. She has also worked at PowderJect Technologies Ltd, Smith & Nephew Medical Ltd and Queen Mary, University of London.

Monisha is a graduate in Polymer Materials Science from the University of Manchester and has PhD in Biomaterials from Queen Mary, University of London.

Dhruti Shah

Head of Approved Body, DQS

Dhruti Shah joined DQS Medizinprodukte UK Ltd (DQS MED UK Ltd) in March 2023 as Head of Approved Body. DQS MED UK LTD are an applicant organization in Great Britain. Prior to joining DQS MED UK Ltd, Dhruti spent 15 years at the Medicines and Healthcare Products Regulatory Agency (MHRA) working across various roles, the most substantial being the leader of the team responsible for the designation and monitoring of UK Approved Bodies (Notified Bodies prior to Brexit). Dhruti participated in EU Meetings related to Notified Bodies and has audited EU Notified Bodies through the joint audit process, nominated as a National Expert. Through her roles at MHRA she has also led various regulatory functions including exceptional use, proactive market surveillance, borderlines, overseeing clinical investigations as well as providing regulatory advice. Also supporting in the development of policies for the new UK Medical Device Regulations in Great Britain.

Dhruti provided significant regulatory input during the covid-19 pandemic, where she was appointed as Regulatory lead of the Ventilator challenge, provided longstanding regulatory input into covid-19 antigen and antibody self-test kits.

Sue Spencer

Head of In Vitro Diagnostics & Principal Consultant, Qserve

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.

Dr Laura Squire OBE

Chief Healthcare Quality & Access Officer, MHRA

As the Chief Healthcare Quality and Access Office in the Medicines and Healthcare products Regulatory Agency (MHRA), Laura's principle role is overseeing a large portfolio designed to ensure the quality and access of products to the UK market - this includes scientific advice, licensing assessment, marketing authorisations and device registrations and regulations, inspections, enforcement and standard setting through for example the British Pharmacopoeia and Target Product Profiles. Since August, Laura has stepped aside from that role for an 18 month period, to focus solely on delivering the programme of reform of the UK Medical Devices regulatory framework.

Laura joined the Medicines and Healthcare products Regulatory Agency in 2021, from the Department of Health and Social Care, where she worked extensively on the COVID-19 vaccine deployment programme. 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.

Vishal Thakker

Head of UK Approved Body & Senior Regulatory Lead, Regulatory Services (Medical Devices), BSI

Vishal joined BSI over 7 years ago and is currently the Head of the UK Approved Body and a Senior Regulatory Lead for Medical Devices. He is responsible for the regulatory oversight of the Medical Devices Approved Body and wider BSI strategy, policies, procedures, and documentation to meet the various legislative and designation requirements. Prior to his current role, he has been a Regulatory Lead, Technical Team Manager, Technical Specialist & Scheme Manager with expertise in Active Devices.

Vishal holds a Masters in Medical Engineering from Queen Mary University of London and has over 10 years' experience with medical devices working within industry, third party testing and Notified/Approved Body.

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BSI is a national Standards Body providing services to companies and organizations of all sizes since 1901. BSI is a leading full scope EU Notified Body and UK Approved Body. We provide conformity assessments for medical devices and IVDs to ensure that they conform to the requirements of the European Regulations and UK Regulation. BSI is also an accredited ISO 13485 Certification Body and a recognized auditing organization for the Medical Device Single Audit Program (MDSAP).

We are accepting MDR and IVDR applications. Contact: Shaheena.afini@bsigroup.com or Lara.Halleybone@bsigroup.com to start your application with BSI today.

Find out more

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Get in touch with the exhibitors

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Find out more

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Get in touch with the exhibitors

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Russell Regulatory Consultants is a highly regarded medical device regulatory consultancy. With a team of experienced and knowledgeable consultants, we provide exceptional services in various device therapeutic areas.

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Get in touch with the exhibitors

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Venue Details
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22 Duchess Mews
London
W1G 9DT
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
Accessible: Located on the lower ground level adjacent to the Whittington

WIFI
Network: Cavendish WIFI
Password: 12345cav

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

Parking
Nearest car par is NCP car park– 6-7 Weymouth Mews

Directions to the Venue
The nearest tube stations are Great Portland Street & Oxford Street.The nearest train station and over ground is Euston station. For full information please visit the venue website:
How to get to the Cavendish Conference Centre

ABH