Essential training for a thorough understanding of all processes from concept to post-market with a focus on the new Medical Device Regulation
AUTUMN 2019 SPEAKERS

**Mika Reinikainen** set up his own medical device consulting company Abnovo Ltd after leaving Quintiles from the position of Vice President in 2007. His practice focuses on regulatory strategy and compliance as well as resolving manufacturers’ conflicts with Notifies Bodies and Competent Authorities. He also provides regulatory interpretation and advocacy, in particular on borderline determination between legal regimes.

He has more than 30 years of experience in the European medical device field: as regulatory affairs manager in industry, as healthcare legal counsel and as regulatory consultant. He was directly involved in the development of the Medical Devices Directives and of technical standards. He chaired the working group that developed the European medical device classification system.

He is currently a member of the European Commission’s Medical Device Expert Group and of the Commission’s Working Groups on Software, Borderlines and Classification as well as New & Emerging Technologies. He is a founder and Chairman of the European Association of Authorised Representatives (EAAR).

**Howard Dobbs** is the Managing Director of Howard Dobbs Consulting Ltd, which provides regulatory affairs and quality assurance services for the medical devices industry. He is an assessor for a notified body and is chairman of the BSI and CEN technical committee for surgical implants. Today, he specializes in the compilation and review of design dossiers and clinical evaluations. In particular, he helps companies prepare for the application of the Medical Devices Regulation.

**Clive Powell** has worked for ABHI since 1990 specialising in medical device regulation and ethical compliance issues. He co-ordinates the work of ABHI’s Technical Policy Group and Legal Issues and Compliance Committee which are the main forums for developing the association’s policy and positions on these matters. He also deals with quality management systems and sterilisation and microbiology through the relevant groups. He has coordinated a number of successful conferences on these subjects over the years.

He is also the principal contact for matters relating to the ABHI Code of Business Practice and works on issues relating to credentialing, including the industry-supported MIA scheme.
AUTUMN 2019 SPEAKERS

David Harding is a qualified accountant and has been an NHS Director of Finance/Deputy CEO for 20 years. Before joining the NHS he studied Business Studies and Accountancy in Birmingham whilst working in the Petro-Chemical Industry and Motor Industries. David is a visiting lecturer at Keele University and has been a Non-Executive Director for a Housing Association.

Matthew Theobald has over 25 years’ experience working at strategic, site and project levels with organisations across Europe and the US. He has worked in medical device, combination product and pharmaceutical development and Quality Management. Matthew has presented at conferences throughout Europe, delivered more than 70 training events, co-authored two books about Human Factors for Medical Devices, including “How Humans Factor (in medical device design)” and one on project leadership. Matthew is currently the Director of New Product Development at his own Consultancy Firm, Three Circles.

Philip Clay is Director and principal toxicologist at Chorley Consulting. He is a registered toxicologist and specialises in product safety assessment with over 30 years’ experience. He has published and presented widely in his expert field of genetic toxicology and also in the wider area of safety assessment. Chorley Consulting designs safety assessment programmes for medical devices and consumer healthcare products for a range of businesses.

Phillip has recently joined the BSI Ch/194 Committee to provide UK input to ISO/Tc 194 and CEN/TC 206 for standards relating to biological evaluation of medical devices.
Sinan Utku is Special Counsel at Covington & Burling LLP. He focuses on international intellectual property law. His practice includes intellectual property transactions and licensing, the drafting of original patent applications, patent prosecution, drafting patent opinions, technology transfers and client counselling, especially in the areas of US and UK patent law. He has had significant experience in the technology areas of pharmaceuticals, medical devices, biotechnology, telecommunications, fiber optics, cryptography, computer software, business methods, and the electrical arts generally.

Dr. Utku has also had significant experience with formal dispute resolutions involving patents, including US district court litigation, ITC litigation, international arbitration, re-examination and inter partes review before the U.S. PTO. His patent-law and technology expertise assists him in litigations and arbitrations involving complex, hi-tech technologies. He also teaches part-time at Bilkent University Law School in Ankara, Turkey, including courses on technology start-up companies, patent and competition law, and contract law.

Richard Saunders has over 20 years’ experience of International and European Quality and Regulatory Affairs in medical devices (including IVDs) and currently is the Technical Director International RA at Ortho-Clinical Diagnostics.

In addition, Richard plays an active role in providing guidance and lobbying on new and revised legislation, primarily via the trade associations MedTech Europe and BIVDA (British In Vitro Diagnostics Association).

He is an active member of the MedTech Europe Globalisation Working Group, Clinical Evidence Working Group, Technical Forum Working Group and is Chair of the MedTech Europe Labelling Working Group and BIVDA Regulatory Affairs Working Party. He is also a member of the British Standards Institute CH/212 Committee on IVD medical devices and ISO/TC 212/WG3 In vitro diagnostic products.

Richard trained as a medical microbiologist, spending his first working years at St George’s Hospital Public Health Laboratories before starting in industry. His previous industry experience has been with Wellcome Diagnostics, Murex Biotech and Abbott Diabetes Care. His roles have included quality control, quality assurance, compliance and regulatory affairs.
MEDICAL DEVICE SCHOOL

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