



BSI/AAMI International Standards & Regulations Conference

Date: 29 June 2022 **Time:** 13:00 - 17:35 UK time

Date: 30 June 2022 **Time:** 13:00 - 17:35 UK time

Agenda

Wednesday 29 June 2022

13:00 - 13:05 Chairman's Welcome & Introduction

Dr Eamonn Hoxey, Director, EV Hoxey Ltd

13:05 - 13:50 Opening Keynote Address: UKCA, MDR and beyond – devices regulation in a global market

Graeme Tunbridge, Senior Vice President Regulatory and Quality - Regulatory Services, British Standards Institution (BSI)

13:50 - 15:05 UK Medical Device Regulations

Jay Katta, Regulatory Director & Head of Medical Devices - Regulatory Services, BSI

Manufacturers perspective on the UK MDR

Helen Forsdyke, Senior Director, Regulatory Compliance, Johnson & Johnson

Update on UK Designated Standards, relationship of standards and "State of the Art"

Lena Cordie-Bancroft, Sector Lead – Medical Devices, BSI

15:05 - 15:20 Break

15:20 - 16:15 Clinical data & clinical investigations - a refresh and common pitfalls

Camilla Fleetcroft, VP Clinical & Regulatory Affairs, Eclevor UK

16:15 - 17:00 EU IVDR update

Judith Prevoo, Regulatory Lead - Regulatory Services, BSI

Manufacturer perspective on the EU IVDR

Stephen Lee, Director of Diagnostics Regulation, ABHI

17:00 - 17:30 Update from Association for the Advancement of Medical Instrumentation (AAMI)

Pamela Arora, President & CEO, AAMI;

Amanda Benedict, VP Standards, AAMI;

17:30 - 17:35 Chairman's closing remarks

Dr Eamonn Hoxey, Director, EV Hoxey Ltd



Agenda

Thursday 30 June 2022

13:00 - 13:10 Chairman's Welcome & Introduction

Dr Michael Kipping, Director Medical Technologies EMEAA, Element Materials Technology

13:10 - 13:40 Opening Keynote Address - MHRA, Innovation, the new Organisation enhancing Patient Safety

Dr Alison Cave, Chief Safety Officer, MHRA

13:40 - 14:40 Sustainability/NHS Net Zero/ Remanufacture/reprocessing

Cormac O'Prey, Director, Kestrel Consulting Group

Lena Cordie-Bancroft, Sector Lead – Medical Devices, BSI

Nicole Fletcher, Sustainable Procurement Lead, NHSE&I

13:40 - 15:10 Evolution of Assurance services during pandemic – Hybrid Audits in other high risk sectors; transport, food, built environment, can we learn from this experience

Ahmed Alkhatib, Business Development & Systems Certification Director – Assurance, BSI

15:10 - 15:25 Break

15:25 - 16:15 Artificial Intelligence - Round Table Discussion

Rob Turpin, Head of sector – Healthcare, BSI

Johan Ordish, Head of Software & AI, Innovative Devices Division, MHRA,

Dr Allison Gardner, Senior Scientific Adviser for AI, NICE

16:15 - 17:00 FDA Final Rule adoption of ISO QSR's/13485

Scott Sardeson, Convenor ISOTC 210 WG1. Medical devices representative ISOTC 176 TF15

Melissa Torres, Associate Director, FDA

17:00 - 17:30 The Standards & Structure to Deliver a Cost Effective High - Quality eHealth System to support and Integrated Care Model

Professor Michael Miller, Member of the WHO Digital Health Technical Advisory Group Roster of Experts

17:30 - 17:35 Chairman's closing remarks

Dr Michael Kipping, Director Medical Technologies EMEAA, Element Materials Technology
