SYLLABUS

DAY 1 - 07/12/2021

Medical Device School

GMT (Greenwich Mean Time)

Introduction to Medical Devices

09:00 - 09:45

- The history and development of the directives and the regulations
- An overview of the MDR
- The articles, the annexes and the definitions
- The main requirements and the associated guidance

Participants

Howard Dobbs - Principal Consultant, Howard Dobbs Consulting

Implementing the Medical Device Regulation

09:45 - 10:25

- The unfinished regulatory regime
- New enforcement pathways: responsibilities of the EU Commission and member states
- The technological challenge of new general safety and performance requirements
- The challenge of new compliance concepts

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Introduction to Drug Device Combination Products

10:25 - 11:00

- What are drug device combination products?
- Borderline determination
- Conformity assessment as a medical device
- Approval as a medicinal product

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Break

11:00 - 11:20

Introduction to In Vitro Diagnostic Devices (IVD)

11:20 - 11:40

- Transition from IVDD to IVDR
- What is an In Vitro Diagnostic Device?
- Implementation issues
- New risk classification system

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Conformity Assessment to the Medical Devices Regulation

11:40 - 12:30

- Overview of the conformity assessment requirements
- Compiling the technical documentation
- Reviewing the general safety and performance requirements
- The role of standards and common specifications
- The important changes and how to comply with the MDR requirements

Participants

Howard Dobbs - Principal Consultant, Howard Dobbs Consulting

Lunch

12:30 - 13:30

Operating a Quality Management System

13:30 - 14:20

- Overview of ISO 13485 – the scope and contents
- The new requirements in ISO 13485: 2016
- The benefits of a Quality Management System
- The design and development process

Participants

Howard Dobbs - Principal Consultant, Howard Dobbs Consulting

Break

14:20 - 14:40

Brexit, CA Marking and the impact on the Medical Devices Industry

14:40 - 15:10

- CA Mark requirements
- Consultation Process
- Medicines and Medical Devices Act
- Hottest topics

Participants

Phil Brown - Director, Regulatory & Compliance, Association of British HeathTech Industries (ABHI)

A day in the life of a Trade Association and the role of the 'collective voice'

15:10 - 15:40

- How ABHI interacted with the Consultation
- Interactions with Government and MHRA
- International work

Participants

Phil Brown - Director, Regulatory & Compliance, Association of British HeathTech Industries (ABHI)

Medical Device Classification

15:40 - 16:20

- Basic principles and regulatory purpose
- What are the key concepts of classification? – time, invasiveness, active nature
- Reviewing the rules and their use
- A changing system – recent evolution and future outlook

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

EXERCISE: Practical Exercise on Classification

16:20 - 16:50

- Presentation of examples of medical devices
- Classification by delegates
- Presentation of results by delegates
- Review and discussion of results

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

SYLLABUS

DAY 2 - 08/12/2021

Access to the UK Market

09:00 - 09:40

- Current status of transition
- Issues and timelines
- The UK RP and their Role
- Notified Body access
- Future predictions

Participants

Richard Young - Technical Director, Sensus Group

Risk Management Strategies

09:40 - 10:40

- ISO14971:2019 key deliverables and changes
- Interaction with risk management in everyday operations
- Reference to standards and other sources
- Key documents and deliverables
- Maintenance

Participants

Richard Young - Technical Director, Sensus Group

EXERCISE: Practical Session on Risk Management

10:40 - 11:10

- A simple practical example, lifecycle risk management for a simple sterile wound dressing

Participants

Richard Young - Technical Director, Sensus Group

Break

11:10 - 11:30

Examine the Importance of Human Factors Engineering / Usability

11:30 - 12:15

Participants

Greg Thay - Founder, THAY Medical

EXERCISE: Practical Session on Human Factors Engineering / Usability

12:15 - 12:45

Participants

Greg Thay - Founder, THAY Medical

Lunch

12:45 - 13:50

Biocompatibility - Biological evaluation of Medical Devices

13:50 - 14:50

- What is biocompatibility?
- Biological evaluation: a risk management process
- Reviewing ISO 10993 and other standards
- What goes into a biological evaluation?
- Device and material characterization
- The Biological Evaluation Plan
- Evaluating biological endpoints
- Biological testing
- Biological evaluation reports

Participants

Jeremy Tinkler - Director of Regulatory Consultancy and Quality Assurance, ICON plc.

Clinical Evidence for Medical Devices

14:50 - 15:30

- Clinical evidence and your medical device
- The impact of MDR of clinical evidence requirements
- Clinical Evaluations and Clinical Investigations

Participants

Victoria Cavendish - Clinical Affairs Specialist, ORCA Solutions Ltd.

SYLLABUS

DAY 3 - 09/12/2021

Labelling - The Requirements and Challenges for Labelling Medical Devices

09:00 - 09:40

- Current label content requirements for EU and UK markets, where are we seeing changes
- Strategies for labelling
- Electronic labelling
- Focus on UKCA requirements

Participants

Richard Young - Technical Director, Sensus Group

Understanding the Person Responsible for Regulatory Compliance

09:40 - 10:00

- What is the Person Responsible for Regulatory Compliance (PRRC)?
- Responsibilities of the PRRC
- Qualifications of the PRRC
- Relations with the management of the manufacturer

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

The Role & Responsibilities of Economic Operators

10:00 - 10:20

- What are the economic operators (EOs)?
- Requirements for EOs
- Interaction of economic operators
- Potential problems

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Break

10:20 - 10:40

Post-Market Surveillance Overview

10:40 - 11:40

- What is Post-Market Surveillance (PMS)?
- PMS in the context of the overall regulatory framework
- How the MDR changes the PMS
- Post-Market clinical follow up (PMCF)

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Vigilance

11:40 - 12:25

- What is vigilance?
- Importance of vigilance
- Management of incidents
- Corrective action

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Lunch

12:25 - 13:25

EXERCISE: Practical Session on Vigilance

13:25 - 14:00

A concrete scenario will be used to enable students to react as managers responsible for vigilance to a developing adverse event.

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK

Discussion: Future Challenges for the Industry

14:00 - 15:30

- Potential issues arising from the new regulatory system
- New areas of regulation covered by the MDR
- New known technological challenges
- The next 40 years

Participants

Mika Reinikainen - Managing Director, Abnovo Ltd., UK