Regulatory Affairs Seminar
13-14 October 2022
The Belfry Hotel & Resort, Lichfield Rd, The Royal Town of Sutton Coldfield B76 9PR

Agenda

Day 1
13 October

8.30-9.00 (30 minutes)

Registration and refreshments

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1. 9.00-9.20 (20 minutes)

Opening welcome and scene setting
Stuart Angell, Chair of RAWP; Penny Wilson, MHRA

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2. 9.20-10.00 (40 minutes)

Industry spotlight: How is an SME managing the changing regulatory landscape?
James Shearn, RegCentrix

Navigating the IVD regulations from the perspective of an SME and what they wish they had known before started in their journey.

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3. 10.00-10.30 (30 minutes)

Swiss Regulations: Overview of the Swiss Regulatory structure and the key differences from IVDR
Emilia Berg, Confinis

How is the Swiss Regulatory structure aligned to IVDR and what do industry need to know to ensure compliance?

10.30-10.45 (15 minutes)

Break

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4. 10.45-11.45 (1 hour)

Sustainability: The impact on IVDs
Valerie Rampi, MedTech Europe

Updates on the Green Deal and other crucial changes happening in Sustainability.

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5. 11.45-1.00 (1 hour 15 minutes)

The role of software and AI in IVDs
Tim Davison, QServe

Regulation of software and AI products under the legislation.

1.00-2.00 (1 hour)

Lunch

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6. 2.00-2.45 (45 minutes)

UKCA Regulations: MHRA perspective and what is still to come
Penny Wilson, MHRA

MHRA published their response to the UKCA consultation in July. This session aims to inform members on what is still to come from MHRA and how the regulations will be actioned.

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7. 2.45-3.30 (45 minutes)

UKCA Regulations: Industry perspective and what is still needed
Mike Messenger, FIND & ACT-IVD; Camilla Fleetcroft, ECLEVAR; Ashleigh Batchen, BIVDA

An insight into how industry can realistically prepare themselves for new UK regulations, including the key messages you should know.

3.30-3.45 (15 minutes)

Break

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8. 3.45-4.45 (1 hour)

UKCA panel session
Penny Wilson, MHRA; Mike Messenger, FIND & ACT-IVD; Camilla Fleetcroft, ECLEVAR; Ashleigh Batchen, BIVDA; Stuart Angell, Chair of RAWP

Representatives submersed in the UKCA world on a panel with audience engagement.

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9. 4.45-5.00 (15 minutes)

End of day summary

6.30-9.00

Dinner and refreshments, quiz, networking

Day 2
14 October

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1. 9.30-9.40 (10 minutes)

Welcome to day 2 and recap
Stuart Angell, Chair of RAWP

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2. 9.40-10.30 (50 minutes)

Update from MedTech Europe
Petra Zoellner, MedTech Europe; Andrew Rutter, Vice Chair of RAWP

Updates on the work being conducted by MedTech Europe. This will cover organisational updates, the current topics of discussion within the key working groups, and information on the IVDR implementation across Europe.

10.30-10.45 (15 minutes)

Break

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3. 10.45-11.15 (30 minutes)

UKAS update on ISO 15189
Alyson Bryant, UKAS

Summary of the upcoming changes to ISO 15189 and how it may affect the IVD industry.

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4. 11.15-12.15 (1 hour)

IVDR: Significant changes (40 minutes)
Petra Zoellner, MedTech Europe; Andrew Rutter, Vice Chair of RAWP

Discussion on the guidance published by the MDCG on significant changes to devices under the IVDR.

Audience interaction (20 minutes)

12.15-1.15 (1 hour)

Lunch

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5. 1.15-2.15 (1 hour)

Workshop: What is the reality of determining if a change is significant?
Petra Zoellner, MedTech Europe; Stuart Angell, Chair of RAWP; Dominique Huxham, Vice Chair of RAWP; Andrew Rutter, Vice Chair of RAWP; Ashleigh Batchen, BIVDA

Breakaway discussion and activity on determining when something is a significant change and how that needs to be actioned.

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6. 2.15-2.55 (40 minutes)

Industry spotlight: How is a multi-national organisation managing the changing regulatory landscape?
Simon Richards, Abbott; Richard Saunders, Ortho Clinical Diagnostics

Navigating the IVD regulations from the perspective of a global organisation and the tips and tricks they have learned along the way.

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7. 2.55-3.45 (50 minutes)

Notified Body and Approved Body panel session
Suzanne Halliday, BSI; Craig Milner, DEKRA; Andreas Strange, TUV SUD; Andrew Rutter, Vice Chair of RAWP

An oversight of reviewing technical documentation across evolving regulation, the things you can do to make it a smoother process, and common pitfalls from leading conformity assessment bodies in the IVD field.

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8. 3.45-4.00 (15 minutes)

Close of seminar