

# BIVDA Regulatory Affairs Seminar

## Agenda - Day One - International

10 February 2026

09:30	Registration and Coffee
10:00	Welcome, Introduction and Housekeeping
10:15	Keynote: International Harmonisation
10:45	EU Update
11:15	Workshop: On EU Topics
12:00	LUNCH
13:00	International Global Harmonisation
13:30	Workshop: On Global Harmonisation Topics
14:10	The Future of Regulatory Affairs
14:40	Panel Discussion and Member Questions on the Future of Regulatory Affairs
15:20	BREAK
15:40	AI Digital Trust
16:20	Workshop: On AI Topics
17:00	BIVDA Team Wrap-Up of Day 1
17:30	CLOSE

# BIVDA Regulatory Affairs Seminar

## Agenda - Day Two - United Kingdom

11 February 2026

08:45	Registration and Coffee
09:00	Introduction and Housekeeping
09:10	BIVDA Reflection
09:40	UK MDR Pre-Market Requirements
10:10	Workshop: On Topics Related to Changes to the UK MDR
10:50	International Recognition/Reliance Leveraging US, HC, TGA, and CE for the UK
11:20	Workshop: On UK MDR International Reliance
12:00	LUNCH
13:00	Performance Evaluation and Technical Documentation for the UK MDR
13:30	Workshop: On Topics Related to Performance Evaluation and Technical Documentation for the UK MDR
14:10	Meet the Sponsors/Ask the Experts with coffee and cake
15:00	Closing Speech: MHRA Chief Executive Lawrence Tallon
15:30	BIVDA Wash-Up and Actions
16:00	EVENT CLOSE