AdvaMed
Advanced Medical Technology Association
Events & Education

The new EU Medical Devices and IVD Regulations: How to make the transition and stay in the EU market?

AdvaMed Offices | 701 Pennsylvania Avenue NW | Washington, DC
December 4, 2017

December 4

8:30 – 9:00 am	**Registration Check-In and Continental Breakfast**
9:00 – 9:45 am	**Introduction and overview of major changes**
9:45 – 10:30 am	**Medical devices and IVDs specifics under MDR and IVDR** • Issues specific to medical devices (e.g. new classification rules for software and substance based devices) • Issues specific to IVDs (e.g. reclassification) • Implications of MDR/IVDR transition planning
10:30 – 10:45 am	**Break**
10:45 – 12:00 pm	**Setting up your overall transition plan and discussion of timelines** • Mobilizing your organization and defining relevant elements • Defining transition scenarios and dependencies
12:00 – 1:00 pm	**Lunch**
1:00 – 3:00 pm	**How to set up and perform a gap assessment?** • Defining who does what and when • Gap assessment templates (how to develop and use them)
3:00 – 3:15 pm	**Break**
3:15 – 4:00pm	**Implementing your transition plan and their party dependencies** • How to make the transition plan operational • Common pitfalls • Third party dependencies and supply chain issues, e.g. distributors, insurance company, fulfillment service providers
4:00 – 5:00 pm	**Q&A Session**

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.

AdvaMed
Advanced Medical Technology Association
Events & Education

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.