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

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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 – 4:00 pm 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

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