MDSS Roadshow - Boston

Draft Agenda (subject to change)

08:30 – 9:00 AM	Registration & informal networking
9:00 – 9:15 AM	Opening remarks & workshop objectives
9:15 – 10:00 AM	Keynote: The Evolving Regulatory Landscape – US, EU, UK, Switzerland and Australia
10:00 – 10:30 AM	Session 1: EU MDR/IVDR – Implementation Timelines & EUDAMED – Current Status & Next Steps
10:30 – 10:45 AM	Coffee Break & Networking
10:45 – 11:15 AM	Session 2: How to navigate the EU, UK & Swiss markets efficiently – Similarities & Differences
11:15 – 11:45 PM	Session 3: Differences ISO13485 vs. FDA Quality Management System Regulation (QMSR)
11:45 – 12:15 PM	Session 4: Clinical Data for the EU – What's Really Required?
12:15 – 1:00 PM	Lunch Break & Networking
1:00 – 2:00 PM	Session 5: Crucial Regulatory Insights for US and EU Market Access (with Q&A) | Presented by DQS (Notified Body)
2:00 – 2:45 PM	Session 6: Securing FDA medical device compliance: strategies for success | Presented by Qualio
2:45 – 3:15 PM	Session 7: Between the Lines of the MDR – Economic Operators' Pain Points
3:15 – 3:30 PM	Coffee Break & Networking
3:30 – 4:00 PM	Session 8: Navigating Australia's Medical Device Regulations: Leveraging Overseas Approvals for TGA Registration
4:00 – 4:45 PM	Session 9: Post-Market Surveillance & Vigilance – What You Must Know
4:45 – 5:00 PM	Open Q&A & Networking

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