MDSS Roadshow

Draft Agenda (subject to change)

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