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 – 1:15 PM	Lunch Break & Networking
1:15 – 2:15 PM	Session 4: topic TBA | Presented by DQS (Notified Body)
2:15 – 3:00 PM	Session 5: How to navigate the EU, UK & Swiss markets efficiently – Similarities & Differences
3:00 – 3:15 PM	Coffee Break & Networking
3:15 – 4:00 PM	Session 6: Navigating Australia's Medical Device Regulations: Leveraging Overseas Approvals for TGA Registration
4:00 – 4:45 PM	Session 7: Post-Market Surveillance & Vigilance – What You Must Know
4:45 – 5:00 PM	Open Q&A & Networking

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ABOUT THE SPEAKERS

Ludger Möller is the owner of MDSS GmbH and the founder of MDSS Consulting GmbH, ITN Holding GmbH, MDSS-UK RP Ltd, MDSS CH GmbH, MDSS USA LLC, MDSS Impex GmbH, and MDSS AU PTY LTD.
With a distinguished career spanning over two decades in the medical device regulatory sector, he has played a pivotal role in shaping regulatory frameworks and compliance strategies across global markets:

- Founding Member and Chairman of the **European Association of Authorized Representatives** (EAAR)
- Founding Member of the **UK Responsible Person Association** (UKRPA)
- Member of the **Ethics Committee** of the Medical Council for Lower Saxony
- Member of the **Regulatory Affairs Professional Society** (RAPS) USA
- Founding Member of the **RAPS Germany Chapter**

- 1996-2000 Lead Auditor and Expert with leading Notified Body (TÜV Rheinland)
- 1997-2000 Manager of the San Diego TUV office
- 1995-1996 Research and Development of Medical Devices
- University degree (Dipl. Engineer), Aachen University of Technology
- On behalf of EAAR, member of the Stakeholder Group of the European Union's Medical Device Coordination Group (MDCG and MDCG-PMSV)

Colm O'Rourke is a seasoned medical device professional with 13 years of experience spanning notified bodies, diagnostics manufacturing, and clinical laboratory settings. For the past three years, he has worked as a quality and regulatory consultant, helping medical device companies achieve compliance through strategic planning, the development of robust technical and quality documentation, and regulatory submissions—including managing deficiency responses to notified bodies.

Based in Sydney, Australia, Colm leads the **Australian Sponsor Service** for MDSS, supporting international manufacturers in registering their medical devices with the **Therapeutic Goods Administration (TGA)** to enable market entry in Australia.

Colm holds a **BSc in Biomedical Science** from **University College Cork (UCC), Ireland**, and a **Diploma in Medical Device Science** from **NUI Galway, Ireland**.

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Yuan Li holds a doctorate degree in Mechanical Engineering. His research at the University of Memphis and the University of Tennessee Health Science Center produced 13 peer-reviewed publications on spinal pathologies and novel implants.

After entering the medical device industry, Yuan specialized in Regulatory Affairs, managing product **approvals/clearances** (510K, CE certification) across the **US, EU, and APAC regions**. He moved into **notified bodies** in 2015, initially as an Orthopedic product reviewer and lead auditor, later advancing to management roles. He currently **oversees North American operations at DQS,** supporting market expansion and regulatory compliance.