MTAA RegConnect Summit 2026 Draft Agenda

Version 2.0 July 2026

Day 1: Thursday, 24 September 2026

Time	No.		Session
8.30am		Registration opens | Coffee Cart opens	
9.00 - 9.10am		10 min	Introduction Welcome to Country
9.10 - 9.20am		10 min	Welcome and Official Opening
9.20 - 9.30am	1	10 min	**Beyond the Paperwork: A Lived Experience** Behind every regulatory submission, clinical trial, and compliance decision is a patient whose life depends on getting it right. This opening keynote brings that reality into the room through a powerful personal story, highlighting to the sector why the work of medical technology regulation is not just a professional obligation, but a profound human one.
9.30 - 10.30am	2	60 min	**IMDRF Priorities: Setting the Global Agenda** This session offers an insider view of IMDRF's current work programme and ongoing consultations, with international regulators presenting on the priorities and concerns shaping the global harmonisation agenda.
10.30 - 11.00am		30 min	Morning Tea
11.00am- 12.00pm	3	60 min	**EU MDR: State of Play** The EU medical device regulatory landscape is undergoing revision to ensure efficiency and confidence, while maintaining Europe's high standards for patient safety. This session will discuss the implications for all players in the EU.
12.25 - 12.55pm	4	30 min	**EU MDR Meets Australia: Managing Two Systems** This session translates the latest EU reforms into practical implications for Australian sponsors and manufacturers. Featuring perspectives from European and Australian regulatory experts.
1.00 - 1.45pm		45 min	Lunch

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1.30 - 2.30pm	5	60 min	**Signals & Systems: Post-Market Surveillance in Practice** This session examines the evolving nature of post-market surveillance, how different jurisdictions approach signal detection and market actions, and how emerging tools are changing the way the sector monitors device performance in the real world.
2.35 - 3.05pm	6	30 min	**Sustainability by Design: ESG Meets MedTech** This session examines emerging regulatory obligations and industry expectations across key ESG themes, including chemical restrictions such as PFAS, battery and e-waste regulation, and how organisations can build compliant, future-ready approaches to sustainability in medtech.
3.10 - 3.30pm		20 min	Afternoon Tea
3.30 - 4.10pm	7	40 min	**The Art of Regulatory Dialogue** Effective communication between industry and regulators, and within organisations navigating complex regulatory environments, is a professional skill that can be learned and refined. Drawing on case studies and interactive roleplay this professional development session builds practical capabilities for clearer, more impactful regulatory dialogue.
4.10 - 4.25pm	8	15 min	**The Human Factor: Why Usability Matters More Than Ever** This session explores why regulatory expectations for human factors engineering have grown, how standards guidance address use-related risk, and why use-related problems often stay hidden in complaint and post-market data.
4.25 - 5.00pm	9	35 min	**The Fine Print: Advertising Compliance in Focus** This session walks through the upcoming changes to the advertising framework and brings them to life through real-world case studies, with practical implications for sponsors and their compliance programs.
5.00 - 5.15pm	15 min		Break
5.15 - 6.15pm	Welcome Reception		

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Day 2: Friday, 25 September 2026

Time	No.		Session
8.30am			Registration Opens
9.00 - 9.05am	5 min		Welcome to Day 2
9.05 - 10.05am	10	60 min	**Inside TGA Reform** Australia's regulatory landscape is undergoing significant reform, with TGA implementing changes across pre-market, post-market, and conformity assessment pathways. This session brings together TGA representatives to take stock of what has changed, what is still in progress, and how sponsors and manufacturers should be adapting their regulatory strategies - with a dedicated segment on UDI implementation, comparing where Australia stands against international approaches and exploring both regulator and industry perspectives on the path ahead.
10.05 - 10.55am	11	50 min	**Lessons Learnt from Around the Globe: The World's Best Ideas #1** A high-level international regulatory update from attending regulators, each sharing examples of successful regulatory initiatives from their jurisdiction over the past year.
10.55 - 11.20am	25 min		Morning Tea
11.20am - 12.10pm	12	50 min	**Lessons Learnt from Around the Globe: The World's Best Ideas #2** A high-level international regulatory update from attending regulators, each sharing examples of successful regulatory initiatives from their jurisdiction over the past year.
12.10 - 12.45pm	13	35 min	**Innovation's Front Door: Priority Pathways** This session maps the priority and expedited access pathways available across key jurisdictions, and examines what qualifies a product for these designations, helping attendees understand where opportunity exists and how to build a compelling case.
12.45 - 1.30pm	45 min		Lunch

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1.30 - 2.15pm	14	45 min	**Certifying at the Speed of Software** As software and AI increasingly define the medical device landscape, certifying these products demands a fundamentally different approach to conformity assessment. This session explores what it takes to certify SaMD and AI as a Medical Device, the regulatory and clinical evidence considerations unique to iterative, continuously-updating AI models, and how a certification process built specifically for software differs from traditional device pathways.
2.15 - 3.00pm	15	45 min	**AI at Work: Reshaping the Regulatory Lifecycle** As AI tools increasingly support regulatory processes, from submission preparation to evidence generation via digital twins and virtual patient models, this session offers a high-level look at how these tools are being applied across the regulatory lifecycle.
3.10 - 3.30pm	20 min		Afternoon Tea
3.30 - 4.15pm	16	45 min	**MDSAP: State of the Union** This session brings regulators and industry together to take stock of where MDSAP stands, what the Industry Group means, and how the program is maturing across participating jurisdictions.
4.20 - 4.50pm	17	30 min	**Straight to the Source: TGA Q&A Panel** TGA representatives answer questions submitted and upvoted by attendees throughout the day via Slido.
4.50 - 5.00pm	10 min		Break
5.00 - 6.00pm	Closing Reception		

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