

Major Partner



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Day 1 | Thursday, 24 September 2026

8:30am Registration opens | Coffee cart available

9:00am - 9:25am Plenary

Introduction

Ian Burgess, MTAA

Welcome to Country

Dr Jasjit Baveja, MTAA

9:25am - 9:35am Plenary

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.

9:40am - 10:35am Plenary

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.

Dr Jasjit Baveja, MTAA

Tracey Duffy, Therapeutic Goods Administration

Dr Robert Reid, UK Medicines and Healthcare products Regulatory Agency (MHRA)

Nada Alkhayat, European Commission

Dr Kenneth Cavanaugh, US FDA Center for Devices and Radiological Health

10:40am - 11:05am Morning tea in the Showcase Arena

11:05am - 12:00pm Plenary

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.

Dr Bassil Akra, AKRA TEAM

Diana Kanecka, MedTech Europe

Nada Alkhayat, European Commission

Ludger Moeller, MDSS

12:05pm - 12:35pm	Plenary	
EU MDR Meets Australia: Managing Two Systems	This session translates the latest EU reforms into practical implications for Australian sponsors and manufacturers.	Hasan Zarin Mehr, Documedex Kellie Shaw, Olympus Jillianne McKenzie, Field Orthopaedics John Jamieson, Therapeutic Goods Administration
12:40pm - 1:30pm	Lunch in the Showcase Arena	
1:30pm - 2:25pm	Plenary	
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.	Harpreet Kaur, Medtronic Dr Marcelle Noja, Therapeutic Goods Administration Yuhua Tan, Health Sciences Authority Erin Skuce, Health Canada
2:30pm - 3:00pm	Plenary	
Sustainability by Design: ESG Meets MedTech	This session examines emerging regulatory obligations and industry expectations across key ESG themes, and how organisations can build compliant, future-ready approaches to sustainability in MedTech.	Pravin Siriwardena, MTAA
3:05pm - 3:30pm	Afternoon tea in the Showcase Arena	
3:35pm - 4:05pm	Plenary	
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.	Michelle Stewart, Device Technologies
4:10pm - 4:25pm	Plenary	
The Human Factors: Why Usability Matters More Than Ever	As medical devices become more sophisticated, connected and AI-enabled, human capabilities haven't kept pace, widening the gap between what devices can do and what users can safely manage. This session explores why regulatory expectations for human factors engineering have grown, how standards address use-related risk, and why use-related problems often stay hidden in complaint and post-market data.	Sue Lynch, Humonics

4:30pm - 5:00pm	Plenary	
The Fine Print: Advertising Compliance in Focus	Current advertising landscape for therapeutic goods, including the Therapeutic Goods Advertising Code and the general compliance obligations facing sponsors and manufacturers.	Michael Shum, Therapeutic Goods Administration
5:00pm - 5:30pm	MTAA Regulatory Excellence Awards Celebrating excellence and innovation in the medical technology sector, the Industry Awards recognise the individuals, teams, and organisations driving meaningful progress in MedTech, from groundbreaking product development to outstanding contributions in regulatory, clinical, and patient outcomes. Join us as we honour the achievements shaping the future of the industry.	
5:30pm - 7:30pm	Welcome Reception	

Welcome Reception Partner



3:05pm - 3:30pm	Registration opens Afternoon tea in the Showcase Arena	
3:35pm - 5:00pm	Concurrent (Student Session)	
MedTech Match: Student Career Development Session	This interactive session brings together professionals from across the MedTech ecosystem to share real insights into their career pathways. Whether you're drawn to the lab, the clinic, the boardroom, or the regulator's desk, this session will help you match your interests and skills to the diverse career paths available in MedTech.	Laila Abdul Waheed, MTAA Jamal Moussa, ResMed Dr Kelly Tsang, Therapeutic Goods Administration Amanda Plusnin, Terumo Nely Psico, Philips Healthcare Thaniya Panapiti, Medtronic Bhavisha Patel, Teleflex Jiao Jiao Li, University of Technology Sydney Brad Betty, Stryker

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Day 2 | Friday, 25 September 2026

8:30am Registration opens | Coffee cart available

9:00am - 9:05am Plenary

Welcome

Dr Jasjit Baveja, MTAA

Acknowledgement of Country

9:10am - 9:35am Plenary

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.

Xin-Lin Goh, Therapeutic Goods Administration

9:40am - 10:05am Plenary

UDI in Practice: Data, Perspectives and the Path Ahead

Mandatory UDI came into effect from 1 July 2026 for Class III and IIb devices, marking a major shift in how medical devices are tracked and identified in Australia. This session takes stock of how implementation has gone so far, the lessons learnt, how Australia's approach aligns with overseas UDI systems, and what's ahead as UDI requirements extend to lower device classes.

Leanne Etherington, Device Technologies
Michael Marquez, Therapeutic Goods Administration
Colm O'Rourke, MDSS AU

10:10am - 10:55am Plenary

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.

Mahesh Datar, Medtronic
Dr Robert Reid, UK Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Jeff Brownscombe, Therapeutic Goods Administration
Nada Alkhayat, European Commission
Dr Kenneth Cavanaugh, US FDA Center for Devices and Radiological Health

11:00am - 11:25am

Morning tea in the Showcase Arena

11:25am -12:35pm	Plenary	
Lessons Learnt from Around the Globe: The World's Best Ideas	A high-level international regulatory update from attending regulators, each sharing examples of recent successful regulatory initiatives from their jurisdiction.	Dr Robert Reid, UK Medicines and Healthcare products Regulatory Agency (MHRA) Dr Kenneth Cavanaugh, US FDA Center for Devices and Radiological Health Yuhua Tan, Health Sciences Authority Erin Skuce, Health Canada
12:40pm -1:30pm	Lunch in the Showcase Arena	
1:30pm – 3:20pm	Plenary	
AI in Medical Technology	Speakers from this session join for a moderated panel discussion, covering the practical, regulatory and clinical questions raised throughout the block. Attendees will have the opportunity to put questions directly to the panel.	Laila Abdul Waheed, MTAA
Entering Medical Device Territory: Lessons from a Technology Company	This session examines what it takes for an established technology company to operate within the medical device regulatory environment. It covers the infrastructure, quality systems and organisational shifts required to move from a general technology mindset to one built around compliance, and what other organisations entering this space should expect.	Angell Zhang, Oracle Health
AI in the Quality System: Where It Belongs, and Where It Doesn't	This session follows a single customer complaint through the quality system, from intake and trending through to clinical review, regulatory assessment, risk assessment and CAPA, to demonstrate where AI can meaningfully support quality processes and where human judgement must remain central. It considers what this balance reveals about the core purpose of quality assurance.	Minta Chen, Harrison.ai
Clinical Evidence for AI-Enabled Products	AI-enabled medical devices present distinct challenges for clinical evidence generation, particularly where products continue to learn and update after reaching market. This session considers what regulators expect in terms of clinical evidence for AI and SaMD, where conventional evidence frameworks fall short, and how manufacturers can build evidence strategies suited to the full product lifecycle.	Heyam Kalla, Cencora
Closing the Distance: Clinical Governance for AI	Examine where accountability for AI in healthcare can quietly disappear, between data and decisions, from vendor to governance, and between a tool and clinical judgement. It considers what closing these gaps means as AI moves from pilot to everyday clinical practice.	Dr Monica Trujillo, Telstra Health

Certifying at the Speed of AI	As software and AI increasingly define the medical device landscape, certifying these products demands a fundamentally different approach. 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.	Hann Yee Son, Scarlet
3:25pm - 3:50pm	Afternoon tea in the Showcase Arena	
3:50pm - 4:00pm	Plenary	
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.	John Jamieson, Therapeutic Goods Administration Dr Jasjit Baveja, MTAA
4:05pm - 4:50pm	Plenary	
From Single Use to Circular Use: The Future of Sustainable Medical Technology	As healthcare systems around the world seek to reduce waste, improve resource efficiency and advance sustainability goals, increasing attention is being given to the role of key R concepts embedded in different medical device regulatory frameworks including reprocessing, remanufacturing and refurbishment of medical technologies. In this session, a global perspective on how these concepts have evolved internationally, with a particular focus tracing the journey of single-use device (SUD) reprocessing and remanufacturing across major healthcare markets. Attendees will gain insight into the policy, regulatory and sustainability drivers that are accelerating interest in circular healthcare approaches, as well as the practical implications for manufacturers, healthcare providers and regulators. The discussion will explore why "the R's" are becoming an increasingly important component of sustainability strategies, including their potential contribution to waste reduction, cost containment, supply resilience and environmental performance. It will also examine the impact on the MedTech sector, highlighting emerging opportunities, challenges and considerations for industry.	Daniel Vukelich Esq, Association of Medical Device Reprocessors Dr Jasjit Baveja, MTAA Xin-Lin Goh, Therapeutic Goods Administration Pravin Siriwardena, MTAA
4:35pm - 5:00pm	Plenary	
Straight to the Source: Therapeutic Goods Administration (TGA)	TGA representatives answer questions submitted and upvoted by attendees throughout the day via attendee app.	

4:35pm - 5:00pm	Plenary	
5:05pm - 5:15pm	Closing remarks	Dr Jasjit Baveja, MTAA
5:15pm - 6:15pm	Closing Reception	