

For Immediate Release

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340 Global Regulators, Health Authorities and Industry Partners Gather in Sydney for Australia Regulatory Device Summit 2025

Sydney, AU — 21 July 2025 — The [Regulatory Affairs Professionals Society \(RAPS\)](#) and the [Medical Technology Association of Australia \(MTAA\)](#) just concluded the [Australia Regulatory Device Summit 2025](#), held at the ICC Sydney 17-18 July. The Summit, which attracted 340 attendees from 12 countries and 5 continents, addressed Australian regulatory reforms and international harmonization. The event also offered participants insights and access to representatives from organisations like ANVISA (Brazil), HSA (Singapore), PMDA (Japan), FDA (U.S.), TGA (Australia), and the European Commission, as well as other healthcare leaders and MedTech professionals.

“Our landmark MTAA/RAPS partnership is the first collaboration of its kind in Australia,” said MTAA CEO, Ian Burgess. “This year’s Summit brought together an extraordinary group of experts and professionals united by a shared goal— improving regulatory systems to support innovation, safety, access and ultimately better patient outcomes. It also reinforced the importance of a strong, connected regulatory community; one that engages openly with regulators, shares insights across borders, and drives improvements in both policy and practice.”

The programme featured 48 expert presenters across 13 in-depth sessions throughout the two days. Discussion topics included:

- Global Regulators Down Under: A Taste of IMDRF in Australia
- U.S. Regulations & AU Reliance
- Cleared for Launch: UDI Takes off in Australia
- Australian Regulatory Reforms: Pre and Post Market
- New Zealand Regulations
- MedTech Match: What Role Fits You Best? (Career Development Session for Students)
- MDR State of Play
- All Things AI: A 360° Perspective on Artificial Intelligence in Health
- Global and Local Regulatory Pathways for Australian Manufacturers
- Global Insights, Local Impact: The Evolving Role of the MDSAP Program
- Talking to Decision Makers: What to Say and How to Say It
- Environmental Sustainability and Regulatory Implications
- Vision 2030 Fireside Chat – A Shared Future for the Australian MedTech Regulatory Landscape

Amy Fisher, RAPS Vice President, Engagement, Marketing & Member Development, commented that “it was exciting to see the community come together with such enthusiasm and engagement. From in-depth presentations and insightful audience questions to high quality networking and hallway conversations, there was certainly a buzz that seemed to spark new ideas, innovations and collaboration opportunities. RAPS was thrilled to work with MTAA to offer a distinct forum for these interactions to happen.”

For more information about the Australia Regulatory Device Summit 2025, visit www.ausregsummit.org.

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ABOUT REGULATORY AFFAIRS PROFESSIONALS SOCIETY (RAPS)

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of professionals involved with regulatory and quality for healthcare products, including medical devices, pharmaceuticals and biologics, diagnostics, and digital health. Founded in 1976 as a neutral, nonprofit organization, RAPS supports and elevates the regulatory profession with education and training, professional standards, publications, research, networking, career development, and other valuable resources. RAPS is home to the Regulatory Affairs Certification (RAC), the only post-academic professional credential to recognize regulatory excellence. The society is headquartered in suburban Washington, D.C., with chapters and affiliates worldwide. www.raps.org

ABOUT MEDICAL TECHNOLOGY ASSOCIATION OF AUSTRALIA (MTAA)

The Medical Technology Association of Australia (MTAA) is the peak association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA's membership spans Australian start-ups through to global MedTech leaders. Our members develop, manufacture and supply medical technologies used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse, with products ranging from familiar items such as syringes and wound dressings, to high technology implantable devices such as pacemakers, defibrillators, and orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines, as well as digital health technologies such as remote monitoring devices and digital therapeutics.

MTAA members distribute the majority of non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure the safe and effective use of medical technology. www.mtaa.org.au