

# Unique Device Identification Webinar 19

UDI project update and real-world benefits of UDI in healthcare



**Gary Pascoe**  
UDI Project Lead,  
TGA



**Mike Schiller**  
Senior Director,  
Supply Chain at AHRMM



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

[tga.gov.au](https://www.tga.gov.au)

# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and custodians of the lands on which we meet today and pay my respects to the Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

# Unique Device Identification Webinar 19

UDI project update and real-world benefits of UDI in healthcare



**Gary Pascoe**  
UDI Project Lead,  
TGA



**Mike Schiller**  
Senior Director,  
Supply Chain at AHRMM



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

[tga.gov.au](https://www.tga.gov.au)

# Agenda

1. **Guest speaker Michael Schiller**  
**Real world benefits of UDI**
2. Australian UDI Update
3. Questions and Answers





# Michael Schiller

Michael Schiller, CMRP, is the Senior Director of Supply Chain for the American Hospital Association (AHA) and the Association for Health Care Resource & Materials Management (AHRMM), a professional membership group of the AHA.

As the organisation's subject matter expert, he brings over 35 years of healthcare supply chain experience to this role. In this capacity, Mr Schiller collaborates with industry and regulatory leaders from across the health care field on various supply chain, advocacy and resiliency initiatives.

Working with AHA and AHRMM executive leaders, Mr Schiller participates in the development and implementation of the association's strategic direction and initiatives including:

- the Cost, Quality, and Outcomes Movement (CQO)
- Learning UDI Community (LUC)
- clinically integrated supply chain
- global labor practices and ESG
- the association's ongoing support to the health care field in addressing ongoing shortages, disruptions and identifying strategies which include AHRMM's Supply Chain Resource Council.

Mr Schiller holds a graduate certificate in information systems management from the Keller Graduate School of Management, a Bachelor's degree in business management from Northeastern Illinois University, is a Certified Materials & Resource Professional (CMRP) and a certified Lean Six Sigma Green Belt. Schiller was awarded the George R. Gossett Leadership Award in 2021.





**LEARNING UDI  
COMMUNITY**



**AHRMM**  
Advancing Health Care through  
**Supply Chain Excellence**

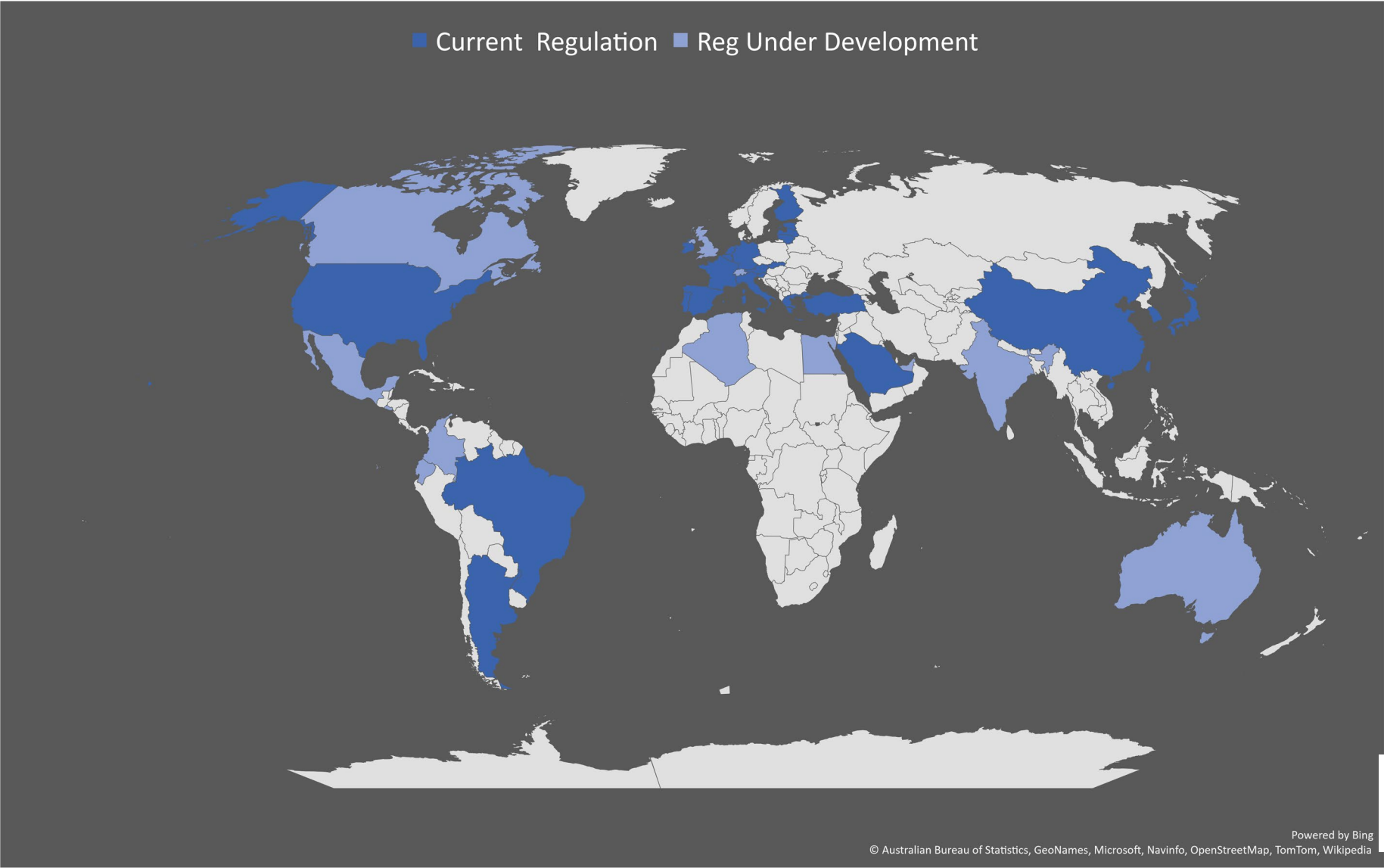
# UDI Benefits & Challenges

AHRMM Learning UDI Community  
Shared Learning. Shared Responsibility.



# Global UDI Landscape

Current UDI Regulation
USA
EU
China
South Korea
Turkey
Saudi Arabia
Taiwan
Brazil
Singapore
Japan
Argentina



UDI Reg Under Development
India
Ecuador
Australia
UK
Columbia
Algeria
Egypt
Canada
El Salvador
Switzerland
Mexico
UAE

# Barriers to adoption

- Lack of integration between Enterprise Resource Planning (ERPs) and Electronic Health Records (EHRs)
- Lack of understanding of available technology
- Technical barriers
- Financial barriers
- Trust barriers
- Clinical training
- Barcode inconsistencies





# Healthcare provider and manufacturer benefits

- Track and trace
- Transparency/visibility
- Transactional efficiencies
- Utilization/standardization
- Demand forecasting
- Call to action



# The road ahead



# THANK YOU!

# Agenda

1. Guest speaker Mike Schiller  
*Real world benefits of UDI*
2. **Australian UDI Update**
3. Questions and Answers





# Australian UDI update



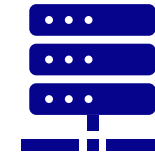
1338 records  
144 users  
81 sponsor organisations



Corrections features for all  
submission methods to be available  
by the end of November



Sponsor feedback on Patient  
Information Leaflet (PIL) and  
electronic Instructions for Use  
(eIFU)



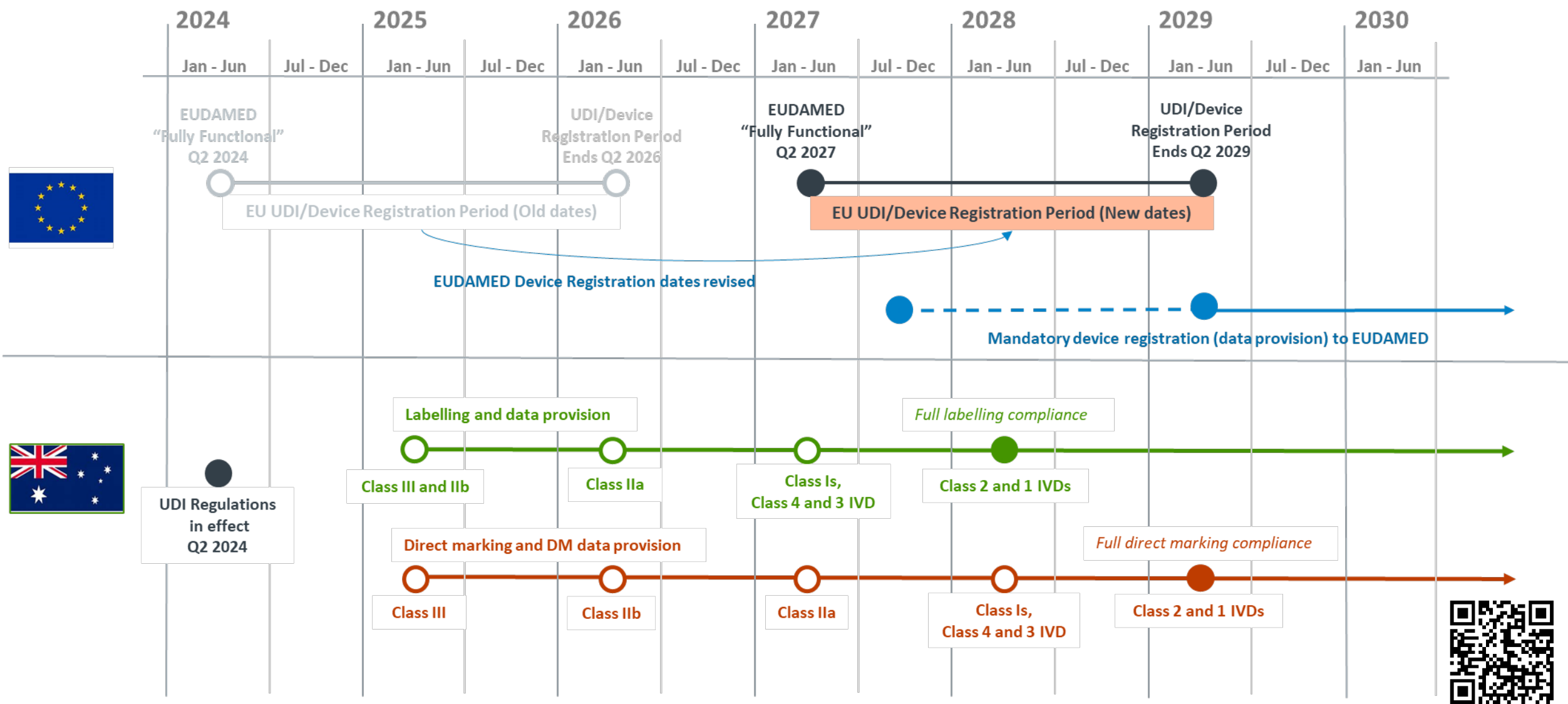
Machine to Machine  
submission method available  
in Pre-Production



Sponsor consultation on  
Australian implementation  
schedule



# Tentative implementation timetable



# Agenda

1. Guest speaker Mike Schiller  
*Real world benefits of UDI*
2. Australian UDI Update
3. **Questions and Answers**



Can you show real examples of when UDI has been used by medical/hospital institutions?

What is being done to improve the traceability capability for hospitals, clinics, GPs etc so that the full benefit can be seen?

Could someone talk about the differences between what the US is doing and what is being done in other countries to enter and provide UDI data for medical devices?

What is the vision of the government around the next stage of implementation - regulating healthcare facilities and cost.

## Pre-Webinar Questions



# Website and link references

UDI Hub	<a href="https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system">https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system</a>
Third UDI consultation paper	<a href="https://www.tga.gov.au/resources/consultation/consultation-detailed-considerations-implementing-proposed-australian-medical-device-udi-regulatory-framework">https://www.tga.gov.au/resources/consultation/consultation-detailed-considerations-implementing-proposed-australian-medical-device-udi-regulatory-framework</a>  *Closed on 11 <sup>th</sup> October
Second UDI consultation paper	<a href="https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system">https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system</a>
First UDI consultation paper	<a href="https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia">https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia</a>
Previous webinars	<a href="https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-communications-and-stakeholder-engagement">https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-communications-and-stakeholder-engagement</a>

# Unique Device Identification Webinar 19

UDI project update and real-world benefits of UDI in healthcare



**Gary Pascoe**  
UDI Project Lead,  
TGA



**Mike Schiller**  
Senior Director,  
Supply Chain at AHRMM



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

[tga.gov.au](https://tga.gov.au)



# Contact us

UDI Support Team

[UDI@health.gov.au](mailto:UDI@health.gov.au)

Phone: 02 6289 8557  
(+61 2 6289 8557 International)

# More information



TGA website

<https://www.tga.gov.au>



TGA Facebook

<https://www.facebook.com/TGAgovau/>



TGA Twitter

<https://twitter.com/TGAgovau>



TGA YouTube

<https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog

<https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn

<https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram

<https://www.instagram.com/tgagovau/?hl=en>



**Australian Government**

---

**Department of Health and Aged Care**  
Therapeutic Goods Administration