Session 2: Reliance in a post market setting

Case studies in post market reliance implementation

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Therapeutic Goods Administration (TGA)
March 11, 2024

IMDRF International Medical Device Regulators Forum

Outline

- Overview of the Medical Device Single Audit Program (MDSAP)
- Post market reliance
- Key challenges and opportunities
- MDSAP Regulatory Authority Council initiatives

Medical Device Single Audit Program

WHAT

Single regulatory audit by an auditing organisation that satisfies the relevant requirements of the regulatory authorities participating in the program.

WHY

Promote more efficient and flexible use of regulatory resources, and consistency, predictability and transparency of regulatory programs.

Reduce regulatory burden and costs for manufacturers.

WHO

Regulatory authorities are Australia, Brazil, Canada, Japan, USA

+

Official observers

+

Affiliates

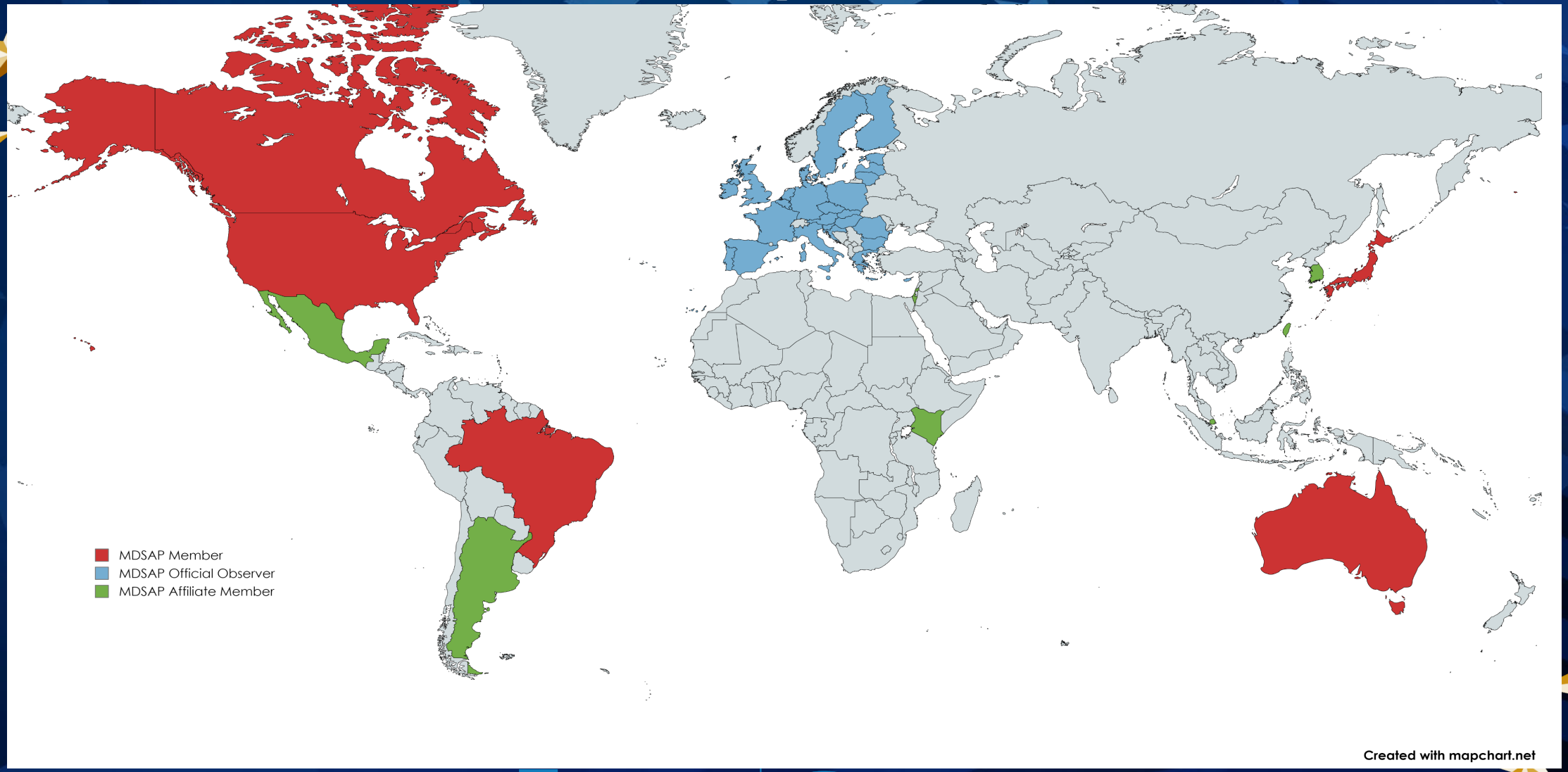
There is growing interest!

HOW

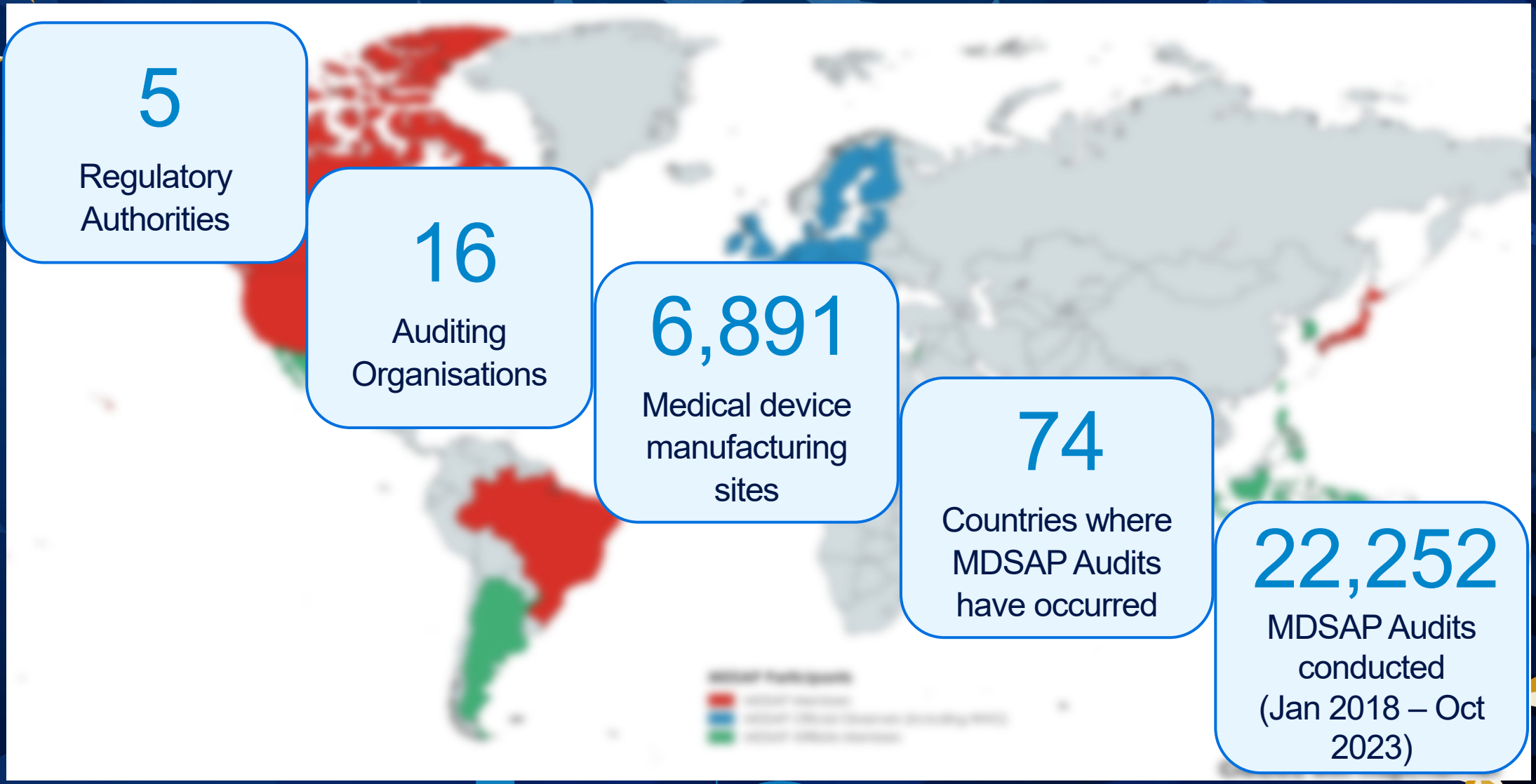
Regulatory authorities oversee the competence and compliance of auditing organisations as part of an ongoing 4-year recognition cycle.

ISO13485 + country specific requirements

MDSAP Membership



MDSAP statistics



5
Regulatory Authorities

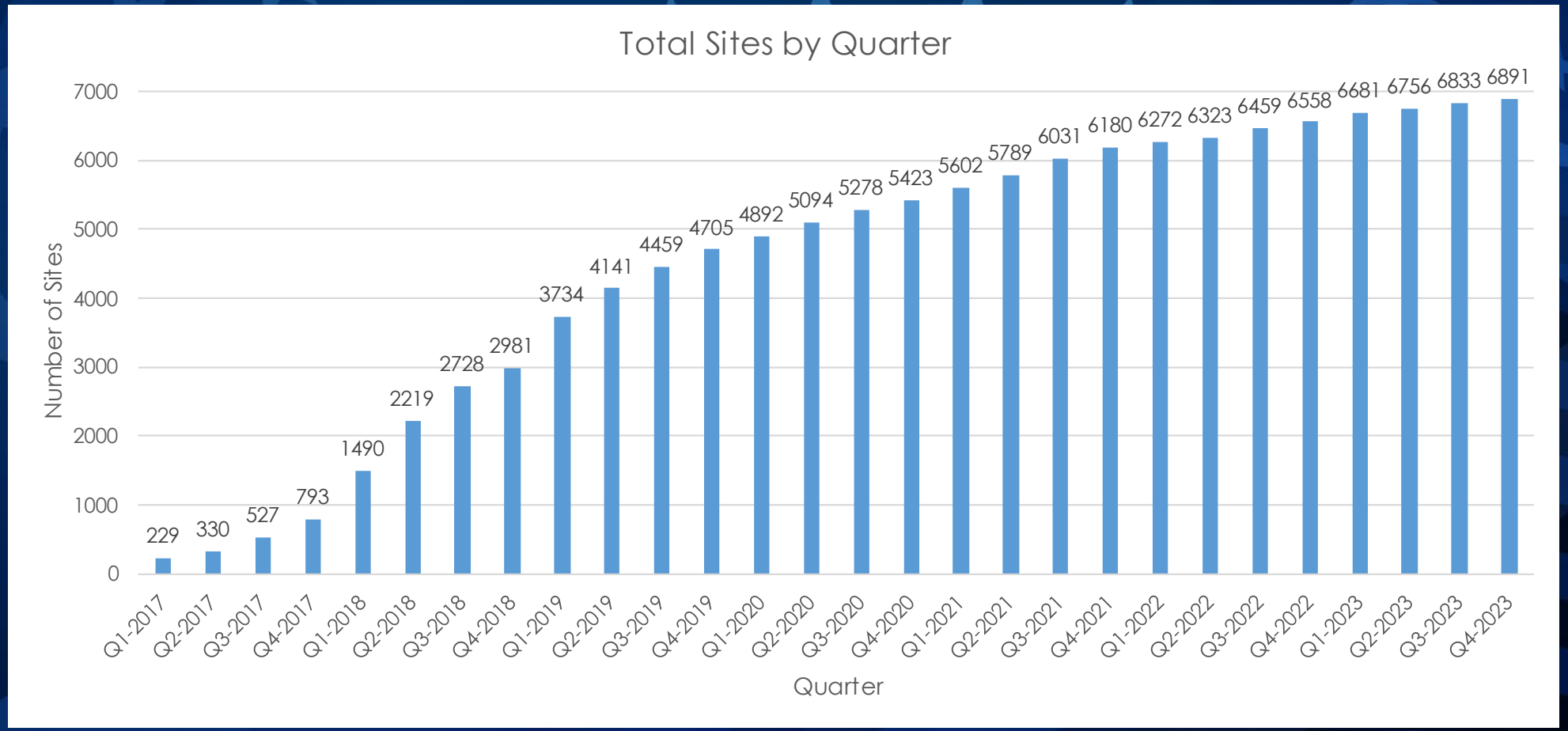
16
Auditing Organisations

6,891
Medical device manufacturing sites

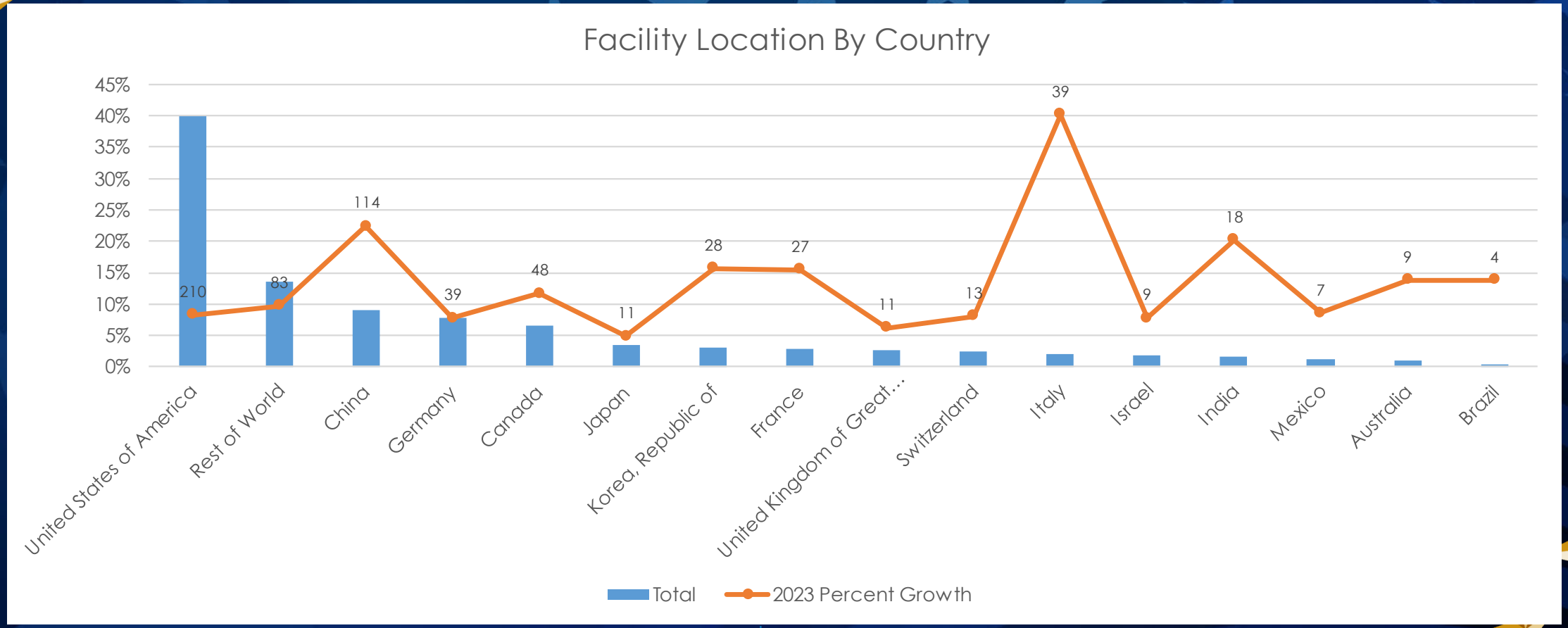
74
Countries where MDSAP Audits have occurred

22,252
MDSAP Audits conducted (Jan 2018 – Oct 2023)

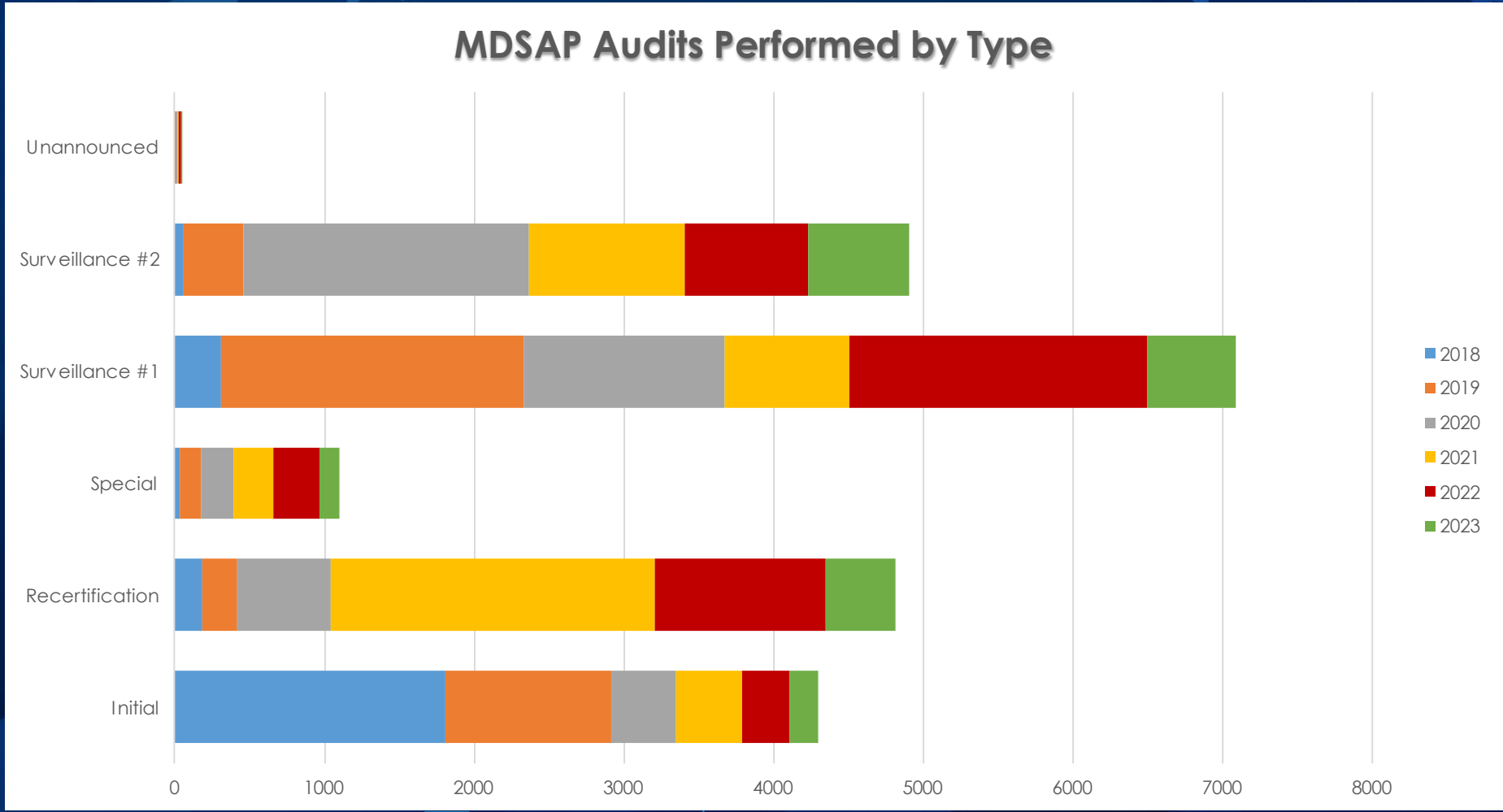
MDSAP Participating Facilities



MDSAP Sites by Country



MDSAP Audits



Post market reliance

- **Auditing Organisation reports**
  - Auditing Organisations audit manufacturers annually – reports are shared through the electronic platform REPs (Regulatory Exchange Platform – secure)
  - Regulatory Authorities can access reports on REPs
- **Australia's post market reliance implementation**
  - Auditing Organisation reports are utilized in post market reviews and investigations
  - E.g., adverse event reports may trigger an investigation. Auditing Organisation reports are then utilized, alongside other intelligence, to assess risk and determine appropriate compliance actions.

Key challenges and opportunities

Challenges

Consistency between Auditing Organisations

Country specific requirements

Centralised access to documents

Opportunities

Increasing capacity of Auditing Organisations

Monitoring performance of AOs, timelines and quality of AO reports

Quicker identification, escalation and resolution of issues

MDSAP RAC initiatives

Enhancements:

- Improve participation and awareness
- Strengthen capabilities for performance monitoring
- Improve transparency and reporting
- Increase stakeholder feedback

Thank you/ Questions


IMDRF
International Medical Device
Regulators Forum
United States
of America
2024