Session 2: Reliance in a post market setting

*Case studies in post market reliance implementation*

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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

**HOW**

Regulatory authorities oversee the competence and compliance of auditing organisations as part of an ongoing 4-year recognition cycle. ISO13485 + country specific requirements

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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

Total Sites by Quarter

Quarter: Q1-2017, Q2-2017, Q3-2017, Q4-2017, Q1-2018, Q2-2018, Q3-2018, Q4-2018, Q1-2019, Q2-2019, Q3-2019, Q4-2019, Q1-2020, Q2-2020, Q3-2020, Q4-2020, Q1-2021, Q2-2021, Q3-2021, Q4-2021, Q1-2022, Q2-2022, Q3-2022, Q4-2022, Q1-2023, Q2-2023, Q3-2023, Q4-2023

Number of Sites: 229, 330, 527, 793, 1490, 2219, 2728, 2981, 3734, 4141, 4459, 4705, 5278, 5423, 5602, 5789, 6031, 6180, 6272, 6323, 6459, 6558, 6681, 6756, 6833, 6891
MDSAP Sites by Country

Facility Location By Country

- United States of America: 210
- Rest of World: 82
- China: 114
- Germany: 39
- Canada: 48
- Japan: 28
- Korea Republic of: 27
- France: 11
- United Kingdom of Great Britain: 13
- Switzerland: 39
- Italy: 9
- Israel: 18
- India: 7
- Mexico: 9
- Australia: 4
- Brazil: 0

Total: 2023

Percent Growth
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