Medical Device Single Audit Program

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MDSAP Pilot is over; Welcome to MDSAP

Participants and Observers

Participants

- Therapeutics Goods Administration (TGA)
- Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada
- MHLW* and PMDA**
- Food and Drug Administration (FDA)

Observers

- World Health Organization (WHO)
- European Union

* *Ministry of Health, Labor and Welfare*

** *Pharmaceuticals and Medical Device Agency*

Operational Organization

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

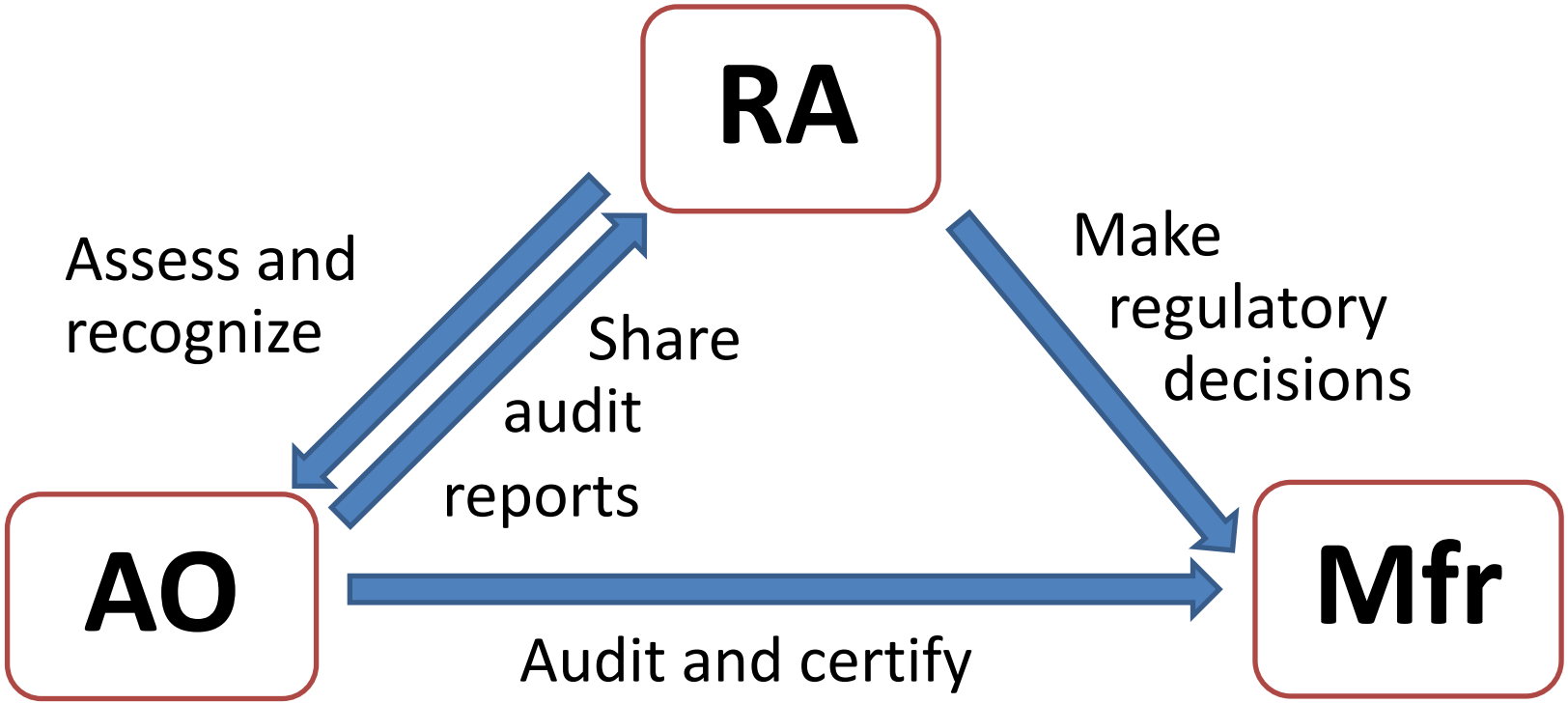
Regulatory Authority Council (RAC)

- MDSAP governing body:
  - two senior managers from each participating jurisdiction.
  - representation from observing jurisdictions.

Subject Matter Experts (SME)

- Permanent or ad-hoc working groups to:
  - Develop policies and documents.
  - Develop tools.
  - Implement the program.

Concept



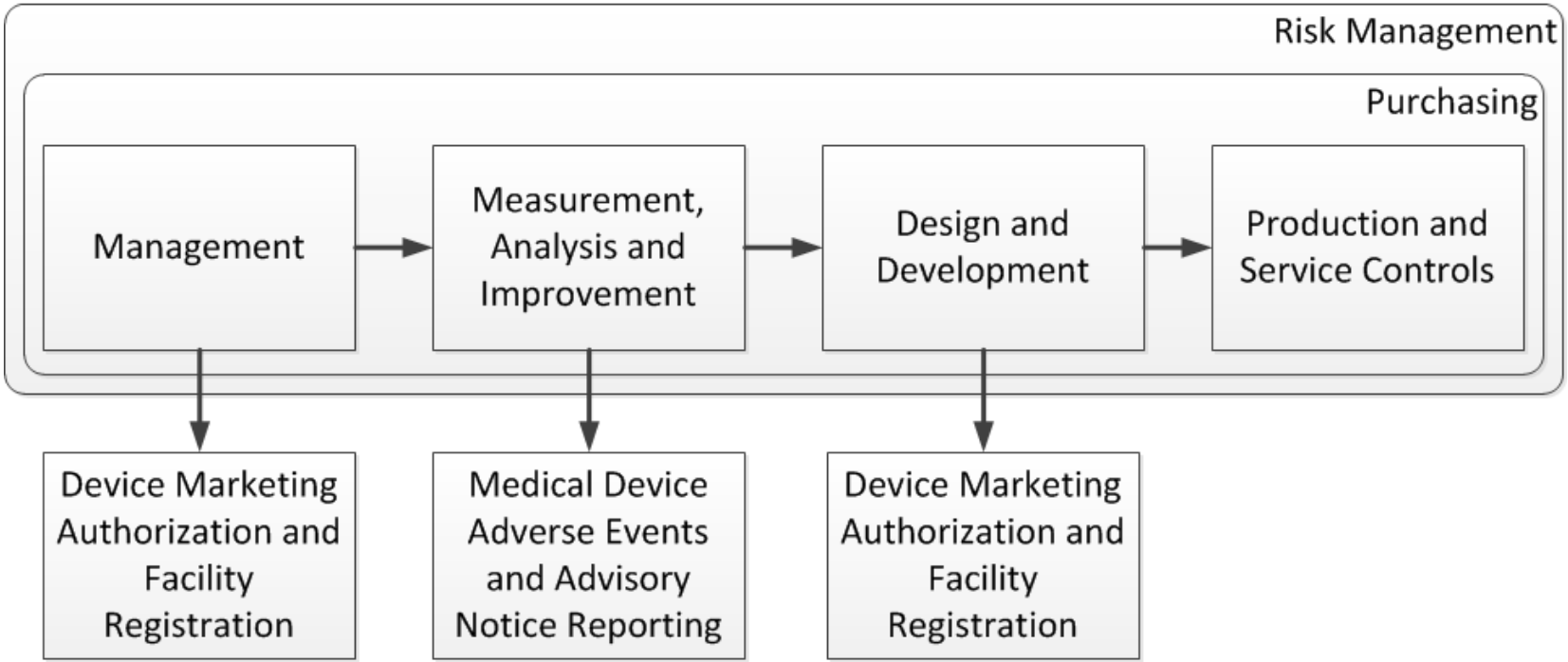
***RA**: Regulatory Authority;* ***AO**: Auditing Organization;* ***Mfr**: Manufacturer*

Audit Criteria

- ISO 13485 (2003 → 2016)
- Regulatory requirements on Quality Systems
  - Brazilian Good Manufacturing Practices (ANVISA RDC 16).
  - Japanese requirements (MHLW MO 169).
  - FDA's Quality System Regulation (21 CFR Part 820).
- Specific national requirements on:
  - Registration of manufacturer sites.
  - Licensing of medical device.
  - Reporting adverse event and advisory notices.
  - Device tracking.

Audit Method

- MDSAP Audit Model –



Audit Method

- Recently updated to
  - Align with ISO 13485:2016.
  - Add clarifications on the audit of technical documentation.
  - Add clarification on the audit of sterile products.
- Training modules:
  - For auditors: Articulate-online (including quiz).
  - For all: on the FDA CDRH Learn webpage. (http://www.fda.gov/Training/CDRHLearn/default.htm)

Audit Nonconformity (NC) Grading

- GHTF/SG3/N19:2012
  Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange.

QMS Impact	Repeat NC	Lack of Document	Released Device
• Direct: 3 • Indirect: 1	• Yes: 1 • No: 0	• Yes: 1 • No: 0	• Yes: 1 • No: 0

NC Grade = sum of 4 parameters, capped at 5

AO Journey To Recognition

Assessment Activity	Status
Application reviewed favorably	Application Received
Stage 1 + Stage 2 (+ Critical Locations) + Response to any nonconformity deemed acceptable	Authorized to conduct MDSAP audits (the first 3 to be witnessed)
3 Witnessed Audits + Response to any nonconformity deemed acceptable Recognition Decision	Recognized

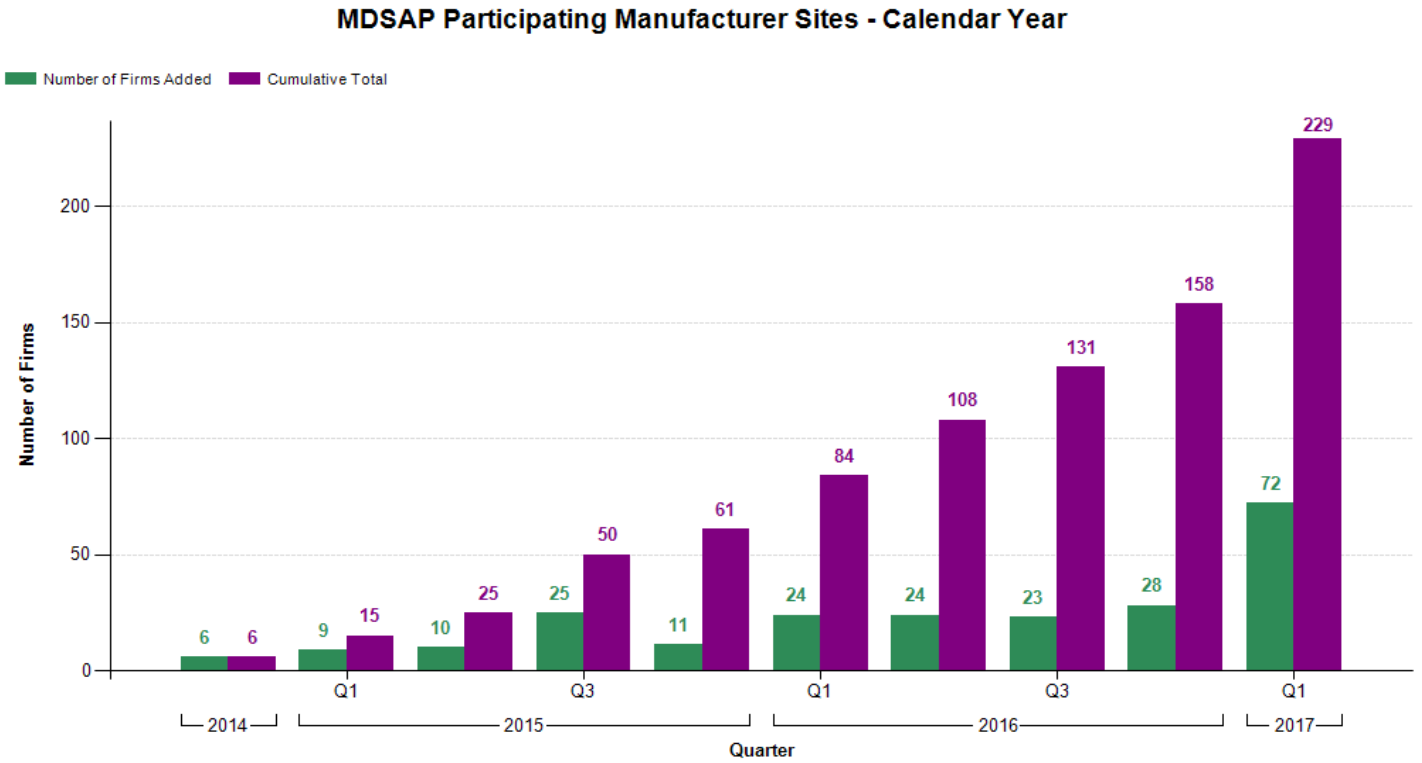
Auditing Organizations

Application Received	Authorized to Conduct MDSAP Audits	Recognized
Lloyd's Register LRQA NSAI National Standards Authority of Ireland Údarás Um Chaighdeáin Náisiúnta na hÉireann NSF	DEKRA DQS MED LNE G MED SGS QMI SAI GLOBAL TÜVRheinland TÜV USA UL	bsi. intertek Total Quality. Assured. TÜV SÜD

Manufacturer Participation

- Required to maintain *Canadian Device Licences* after 2018-12-31
- Voluntary and encouraged to -
  - Register devices in Australia – especially combination products.
  - Obtain ANVISA GMP certificate – devices class III and IV.
  - Substitute to PMDA audits.
  - Substitute routine FDA inspections – any devices.

Manufacturer Participation

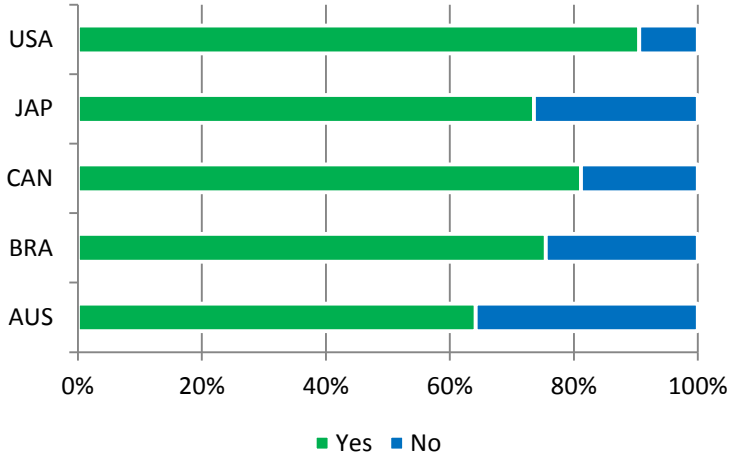


Feedback From Industry – DITTA Survey

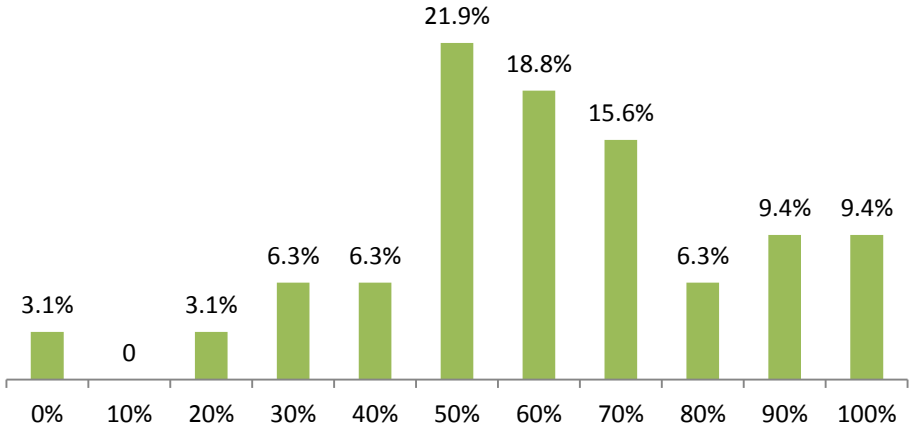
- DITTA: Global Diagnostic Imaging, Healthcare Information and Communication Technology , and Radiation Therapy Trade Association.
- DITTA surveyed their members from Jan. 15 to Feb. 24.
- 53 organizations responded.

Feedback from Industry – DITTA Survey

In which countries do respondents distribute devices?
(53 responses)



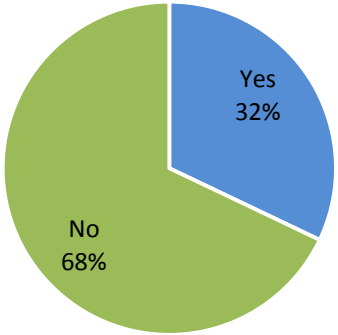
Business Percentage in MDSAP Jurisdictions (32 responses)



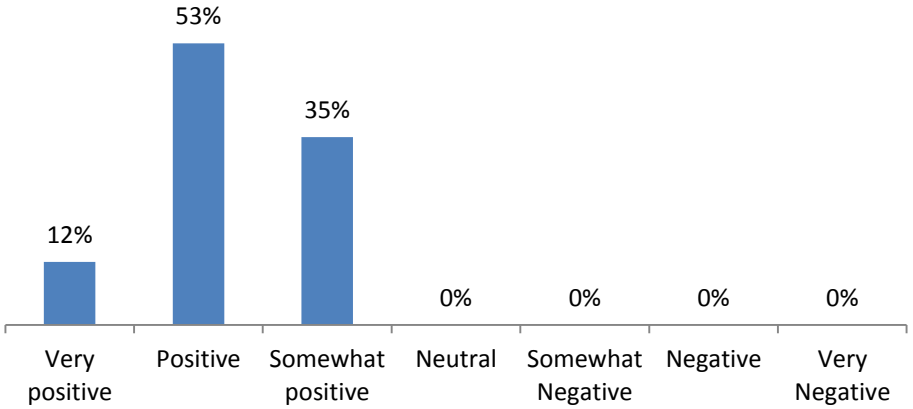
More than 80% of respondents make more than 50 % of their business in MDSAP jurisdictions

Feedback from Industry – DITTA Survey

Has your company participated in the MDSAP Pilot? (53 responses)



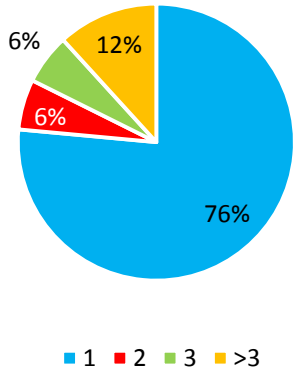
Overall opinion on experience with MDSAP (17 responses)



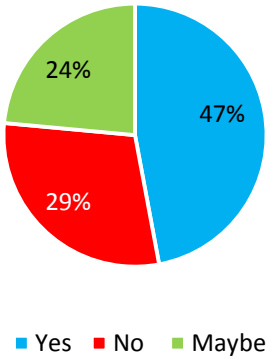
- 100% saw value in their participation.

Feedback from Industry – DITTA Survey

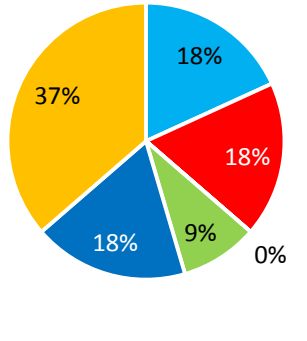
How many sites participated ?
(17 responses)



Do you plan to enroll more sites ?
(17 responses)

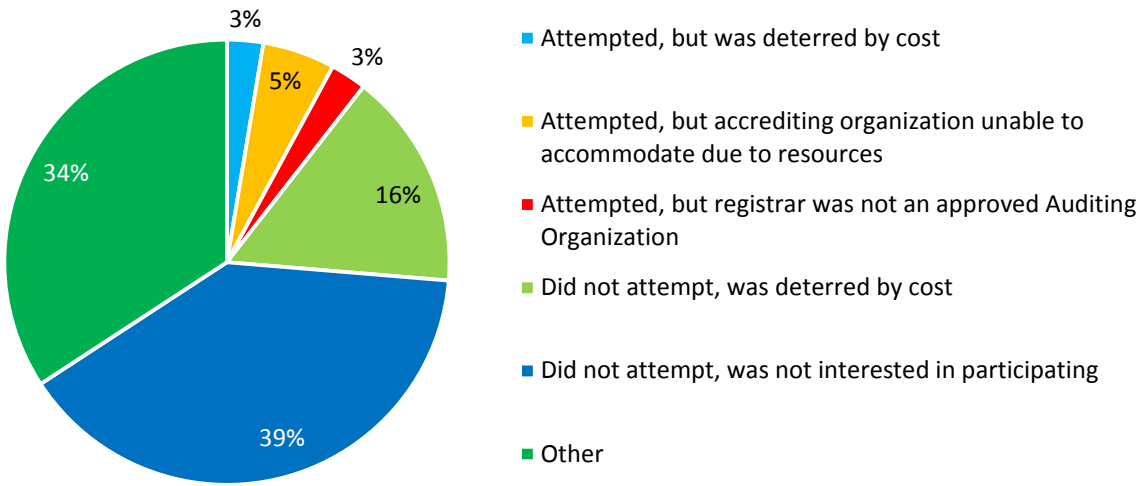


If yes, how many?
(11 responses)



Feedback from Industry – DITTA Survey

Reasons for not participating?
(38 responses)



- 75% respondents used resources available on FDA's website
- 21% indicated that they have concerns about an aspect of MDSAP that were not addressed in the survey

Feedback from Industry - Concerns

- Auditing Organization readiness and capacity.
- Health Canada timeline to transition from CMDCAS to MDSAP.
- Potential impact of audit frequency
  (MDSAP audits > Regulators audit).
- Complexity of multi-site organization / multi-certification schemes.
- Learning curve regarding the preparedness for audits.
- Processing of audit reports by each Regulatory Authority.

Multi-site organizations

- Definition of the scope of certification, including organization sites, considering:
  - Applicable jurisdictions.
  - Regulatory roles and activities performed at each sites.
  - Perimeter of the quality management system (QMS)
- Regulators' perspective
  - QMS-based vs. Site-based approaches.
  - Sites audited for only part of their activities.
  - Audit frequency at each site.

Feedback from Industry

- Expect MDSAP to grow:
  - Broader use of MDSAP audit reports by participating Regulatory Authorities.
  - Inclusion of additional Regulatory Authorities.
  - Use of MDSAP audit outcomes by other regulators requiring compliance to ISO 13485.
  - Increased harmonization among regulators.

Regulators Exchange Platform secure (REPs)

- Development started.
- Hosted by the Pan American Health Organization (PAHO).
- Phase 1:
  - Management of the list of participating manufacturers
  - Submission of audit reports.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