Medical Device Single Audit Program (MDSAP)

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MDSAP

International consortium of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in an Audit and Assessment Pilot Program

Mission

Jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers

IMDRF

The International Medical Device Regulators Forum (IMDRF) recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices

IMDRF

The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group to develop specific documents for advancing the concept of the Medical Device Single Audit Program (MDSAP)

IMDRF

This global approach included the development of an international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in a Pilot Program starting in January 2014

MDSAP Statement of Cooperation

The heads of the regulatory agencies of Australia, Brazil, Canada and the United States signed a Statement of Cooperation on the MDSAP International Consortium program at the Head of Agency Summit in Manaus, Brazil in November 2012

Pilot International Consortium

The international consortium of countries for MDSAP as of January 2018 :

Therapeutic Goods Administration (TGA)

Agência Nacional de Vigilância Sanitária (ANVISA)

Health Canada (HC)

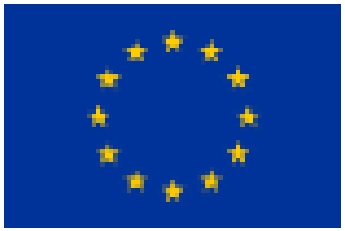
Pharmaceuticals and Medical Devices Agency (PMDA)

U.S. Food and Drug Administration (FDA)

International Consortium

- Official Observers to MDSAP as of June 2017:

World Health Organization (WHO)



European Union (EU)

International Consortium

The mission of the MDSAP International Consortium is to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers

Objectives

- To operate a single audit program that provides confidence in program outcomes

- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry

Objectives

- To promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority

- To leverage, where appropriate, existing conformity assessment structures

Objectives

- To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices

- To promote consistency, predictability and transparency of regulatory programs

Third Parties and Regulatory Inspectorates

The development of MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates.

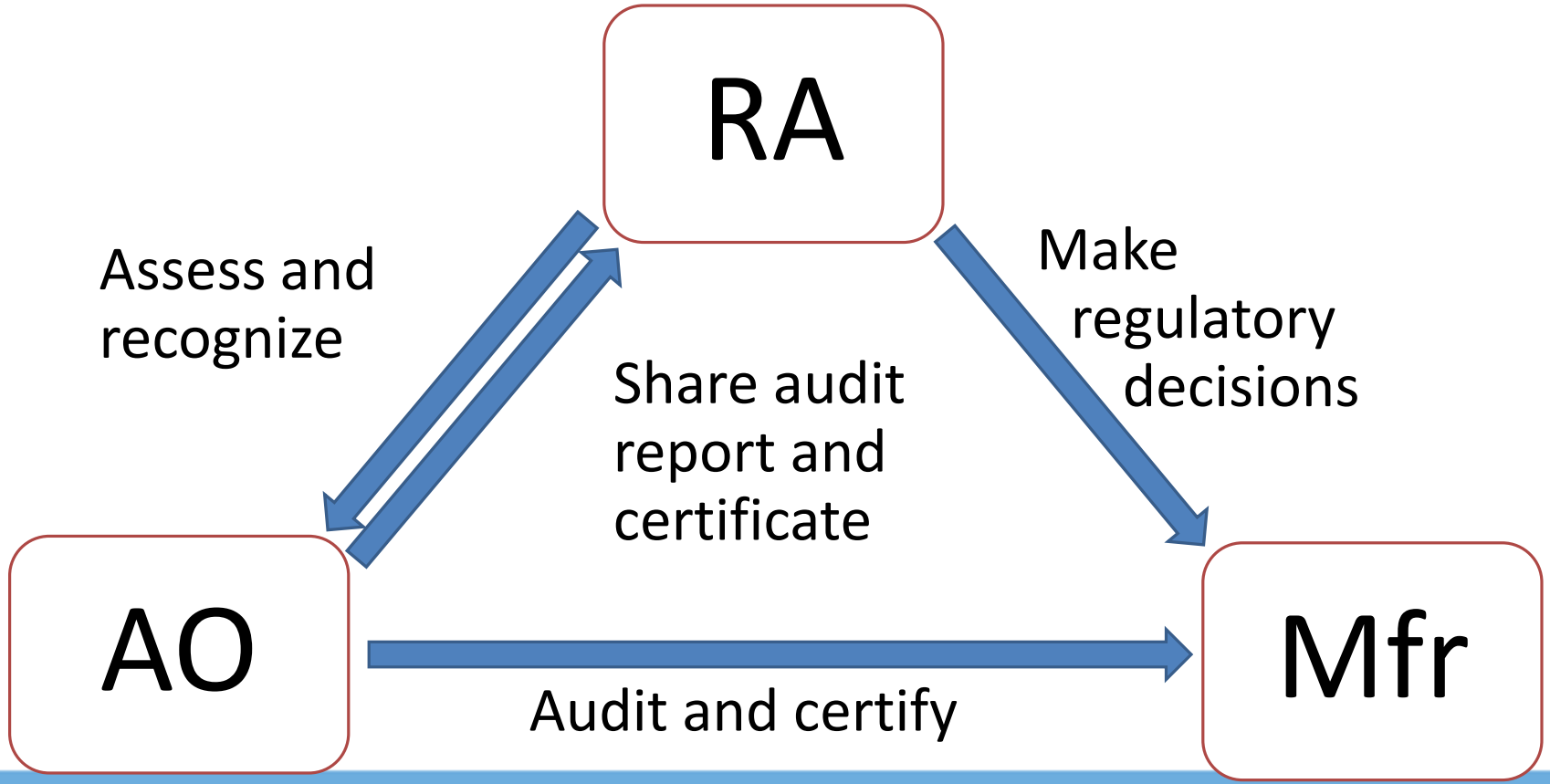
Use of third party auditors, in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers around the globe

Third Parties and Regulatory Inspectorates

The government resources can then be focused on high risk or problematic medical devices, manufacturers that are not in compliance with the regulations, and oversight of the third party auditing organizations

Concept

***RA**: Regulatory Authorities; **AO**: Auditing Organizations; **Mfr**: Manufacturers*



MDSAP Audit Criteria

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the quality management system requirements:

- ISO 13485:2003 (now includes ISO 13485:2016)
- Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- Japanese requirements (MHLW MO 169)
- FDA's Quality System Regulation (21 CFR Part 820)

MDSAP Audit Criteria

AND other specific requirements of medical device regulatory authorities participating in the MDSAP program such as:

- registration
- licensing
- adverse event reporting and more

Regulatory Authority Operational Organization

- Regulatory Authority Council (RAC)
- International Subject Mater Expert (SME) Working Groups

Regulatory Authority Council

The MDSAP governing body is the Regulatory Authority Council (RAC) which is comprised of two senior managers from each participating jurisdiction, as well as representation from observing jurisdictions

Regulatory Authority Council

Responsibilities:

- Perform executive planning, strategic priorities, sets policy and makes decisions on behalf of the MDSAP Consortium.
- Reviews and approves MDSAP documents, procedures, work instructions, etc.
- Makes Auditing Organization authorization and recognition decisions

Regulatory Authority Council

RAC Constitution:

- Chair, ANVISA (rotates)
- Vice Chair, TBD (rotates)
- Executive Secretariat (rotates with Chair)
- Permanent Secretariat (US FDA)
- Permanent Information Technology (IT) Director (currently being established)

International Subject Matter Expert (SME) Working Groups

- MDSAP IT Portal SME Working Group
  - Developed IT requirements for the MDSAP Portal to include business requirements, IT specifications, security needs, and other procurement specifications
  - WG will work with the MDSAP IT Director and oversee the Cooperative Agreements with the IT Director and the IT Host Organization

International Subject Matter Expert (SME) Working Groups

- MDSAP Audit and Assessment SME Working Group
- Develops procedures, work flows, work instructions, templates, training, etc.
  - The auditing of medical device manufacturers by recognized Auditing Organizations
  - The assessment of Auditing Organizations by Regulatory Authorities
  - The Quality Management System

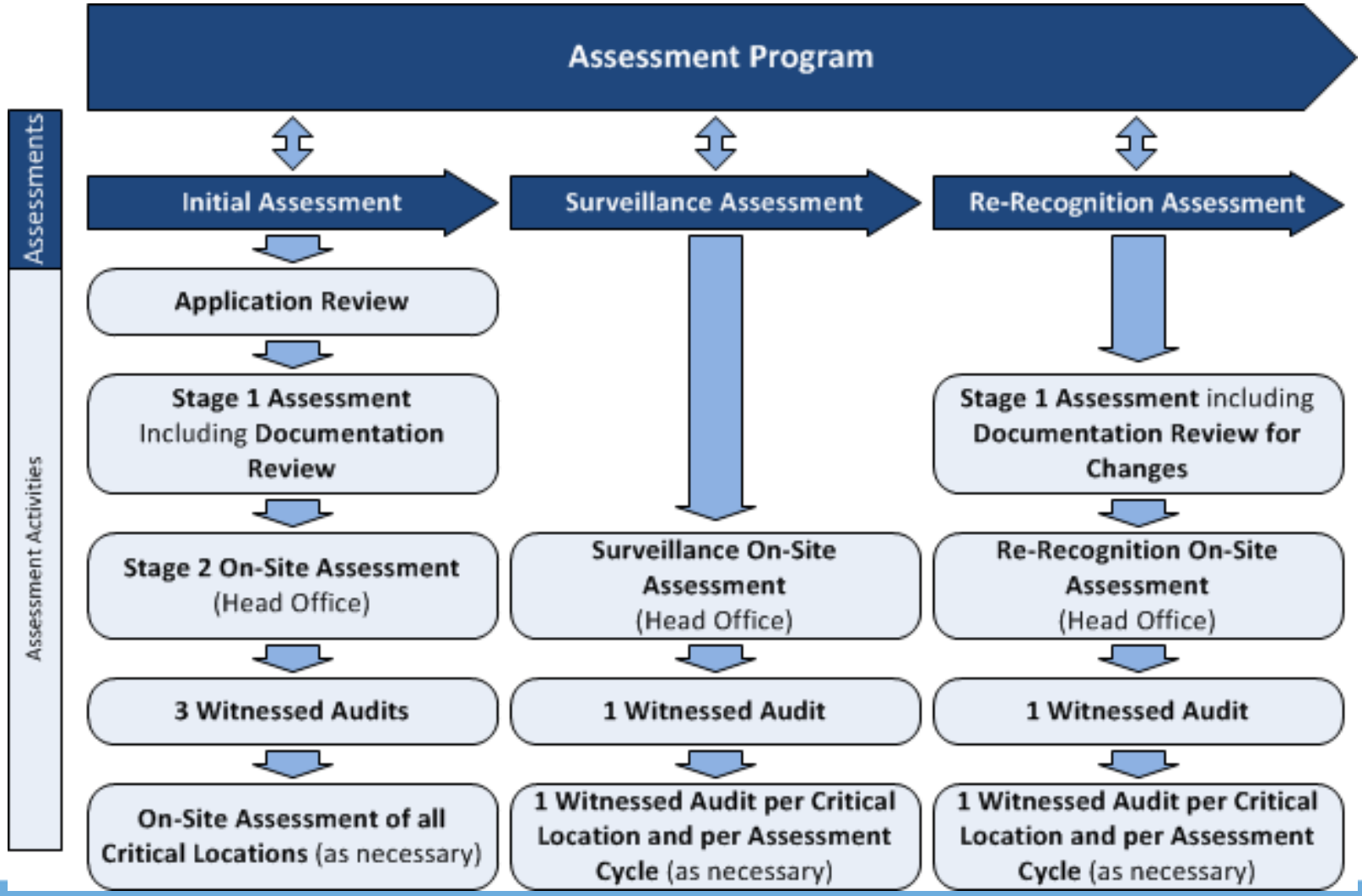
Audit-Related Documents

- Audit Model
- Audit Model Companion Guidance
- Web based Audit Model Training
- Audit Report Fillable Form
- Audit Time Calculations
- MDSAP Certificate Procedures

Regulatory Authorities Oversight of the Auditing Organizations

In accordance with these best practices, the Consortium has developed a transparent and robust plan/schedule of assessing the competence and compliance of MDSAP Auditing Organizations as part of a four year recognition process

Assessment Process



IMDRF Documents

The MDSAP audit-related documents just described are based on the foundation established by the International Medical Device Regulatory Forum (IMDRF) MDSAP documents

www.imdrf.org

IMDRF MDSAP Documents

Recognition, monitoring and re-recognition of Auditing Organizations documents:

- IMDRF/MDSAP WG/N3FINAL:2016 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
- IMDRF/MDSAP WG/N4FINAL:2013 – “Competence and Training Requirements for Auditing Organizations”
- IMDRF/MDSAP WG/N22 FINAL:2014 – “MDSAP Overview of Auditing Organization Assessment and Recognition Decision Related Processes”
- IMDRF/MDSAP WG/N24 FINAL:2015 – “MDSAP Audit Report Guidance”
- IMDR/MDSAP WG/N29 FINAL:2015 – “Clarification of the Team “Legal Entity” for MDSAP Recognition Purposes”

IMDRF MDSAP Documents

Documents for the Regulatory Authority assessments of AOs are based on:

- IMDRF/MDSAP WG /N5 FINAL:2013 – "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations"
- IMDRF/MDSAP WG /N6 FINAL:2013 – "Regulatory Authority Assessor Competence and Training Requirements"
- IMDRF/MDSAP WG/N8 FINAL:2015 – "Regulatory Authority Assessment Method Guidance"
- IMDRF/MDSAP WG/N11 FINAL:2014 – "MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

MDSAP Nonconformity Grading System

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

http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n19-2012-nonconformity-grading-121102.pdf

Pre-Pilot Milestones

2012

- Jan: Initiation of the project
- Nov: Memorandum of Understanding signed in Manaus, Brazil (TGA, ANVISA, Health Canada, FDA)

2013

- Jun: MDSAP Audit Model and associated on-line training modules
- Dec: IMDRF/MDSAP WG documents N3, N4, N5, and N6
- Dec: Approval of the Assessment Procedures

Pilot Milestones

2014

- Jan: Announcement of the MDSAP Pilot
- Jan: 1st Application from candidate Auditing Organization
- May: 1st Authorization to perform MDSAP audits
- Sept: 1st MDSAP audit
- Sept: IMDRF/MDSAP WG/N11

2015

- Jun: 1st MDSAP Forum with RAs, AOs, and manufacturers
- Jun: Announcement of Japan joining the coalition
- Jun: ISO/IEC 17021-1:2015
- Aug: Mid-Pilot report

Pilot Milestones

2015

- Nov: 1st GMP Certificate delivered by ANVISA, using MDSAP audit report
- Dec: Health Canada publish transition plan to replace CMDCAS by MDSAP

2016

- Jan: 1st Canadian device license supported by an MDSAP certificate
- Mar: ISO 13485:2016
- Jun: 2nd MDSAP Forum
- ~ Dec: Review of MDSAP Pilot, using Proof of Concept criteria

Transition Milestone

2017

- Jan 1: Auditing Organizations other than CMDCAS registrars can apply

2019

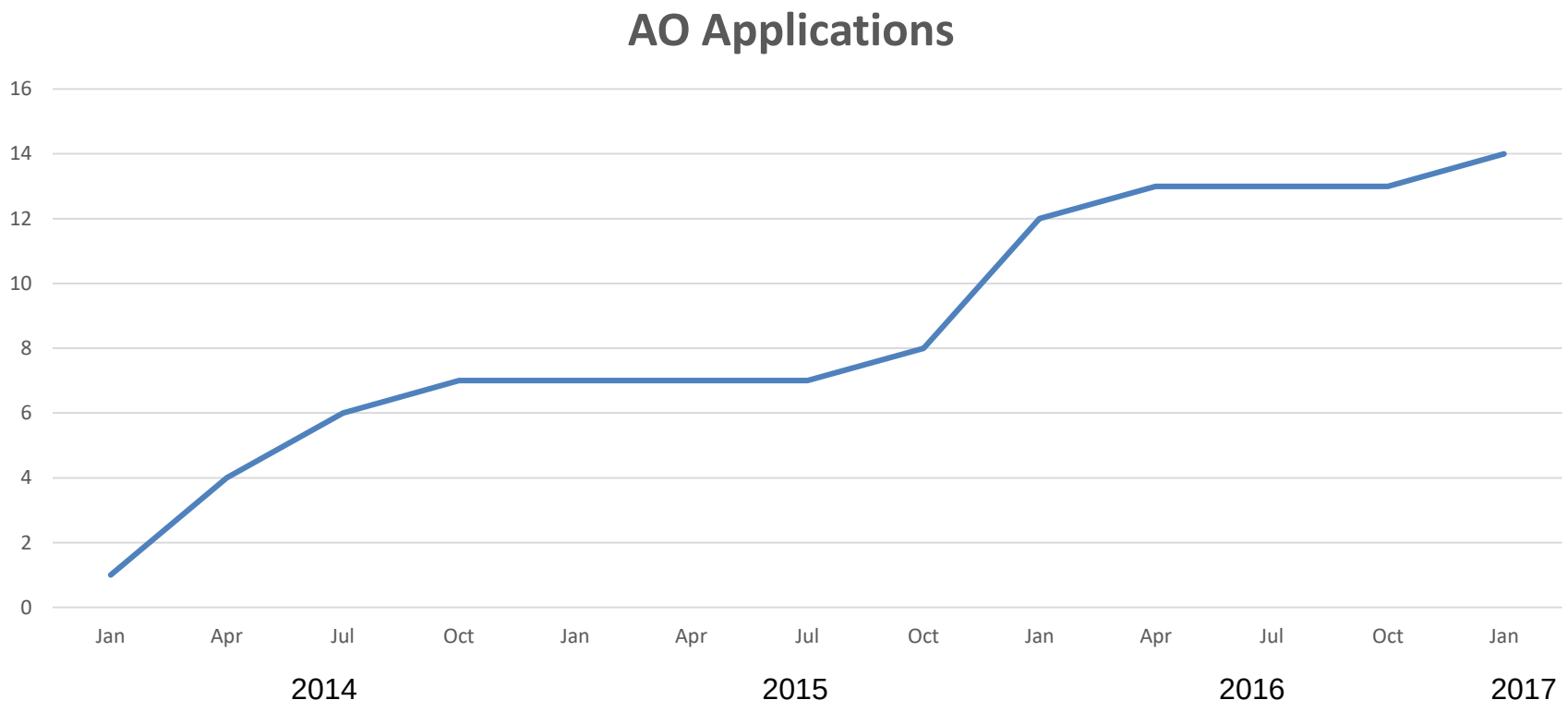
- Jan 1: MDSAP replaces CMDCAS

  Health Canada will cease to accept certificates issued under CMDCAS as of midnight December 31st, 2018

  If manufacturers have not transitioned, their device licenses will be suspended.

  See: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/mdsap-trans-notice-avis-eng.php

Auditing Organization Applications



AOs Conducting MDSAP Audits

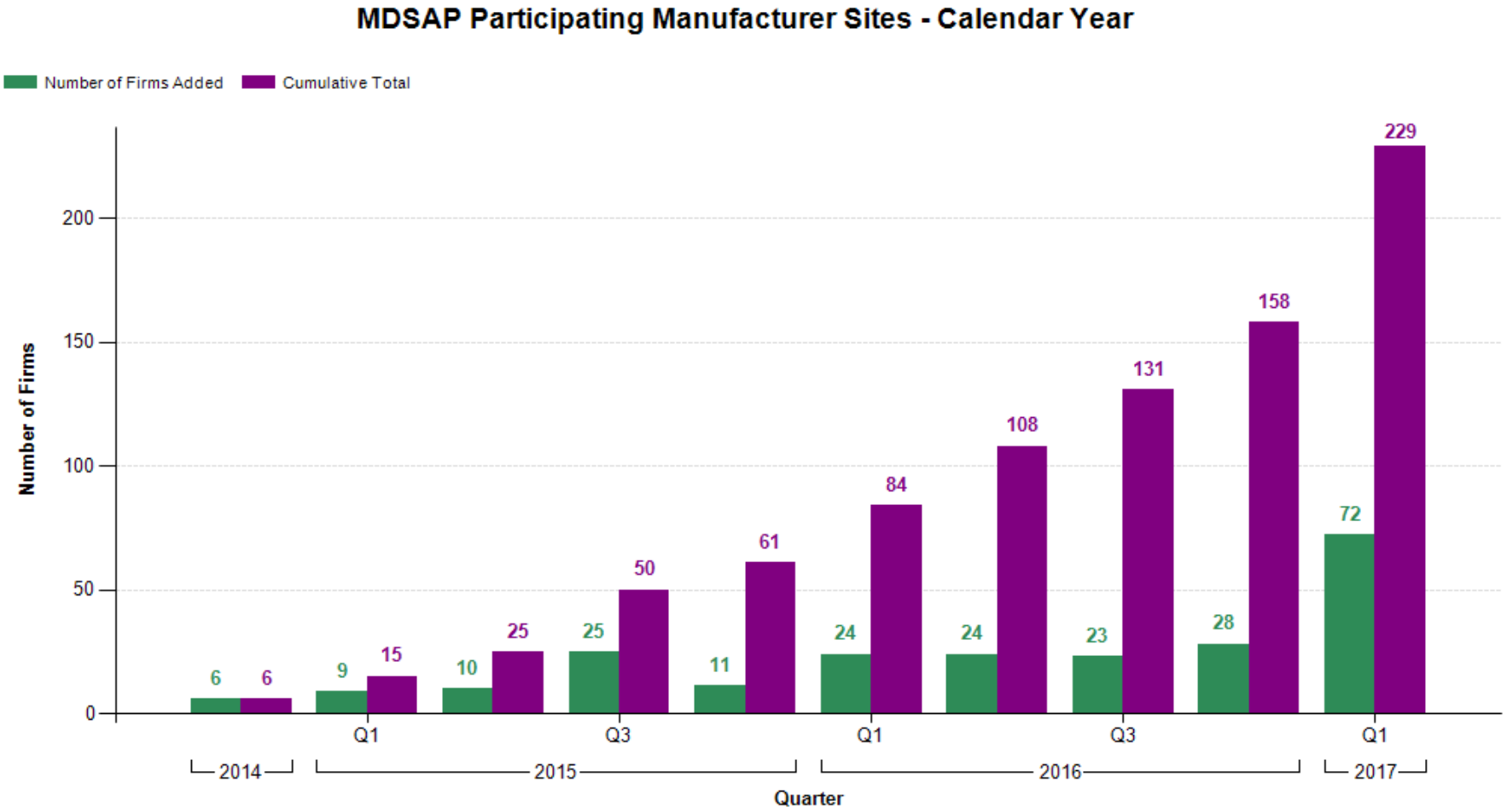
Initially, 15 Health Canada Recognized Certification Bodies were invited to participate in the Pilot Program

- 2 dropped out
- 5 are now fully ‘recognized’ as AOs
- 9 are currently ‘authorized’

NSF Health Sciences Certification, LLC is the only post-pilot authorized AO

https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf

Participating Manufacturers (March 2017)



Frequently Asked Questions

- What, if any, will be the role of Accreditation Bodies?
- Will MDSAP audit reports be subject to ATI/FOI legislation?
- How will this affect existing MRAs and MOUs?
- What will be the expansion strategy for MDSAP?
- How will the information from audit reports be used by the individual regulatory authorities?
- What will be the framework for information exchange between regulatory authorities?

https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf

Resources

CDRH Learn:
http://www.fda.gov/Training/CDRHLearn/ucm372921.htm

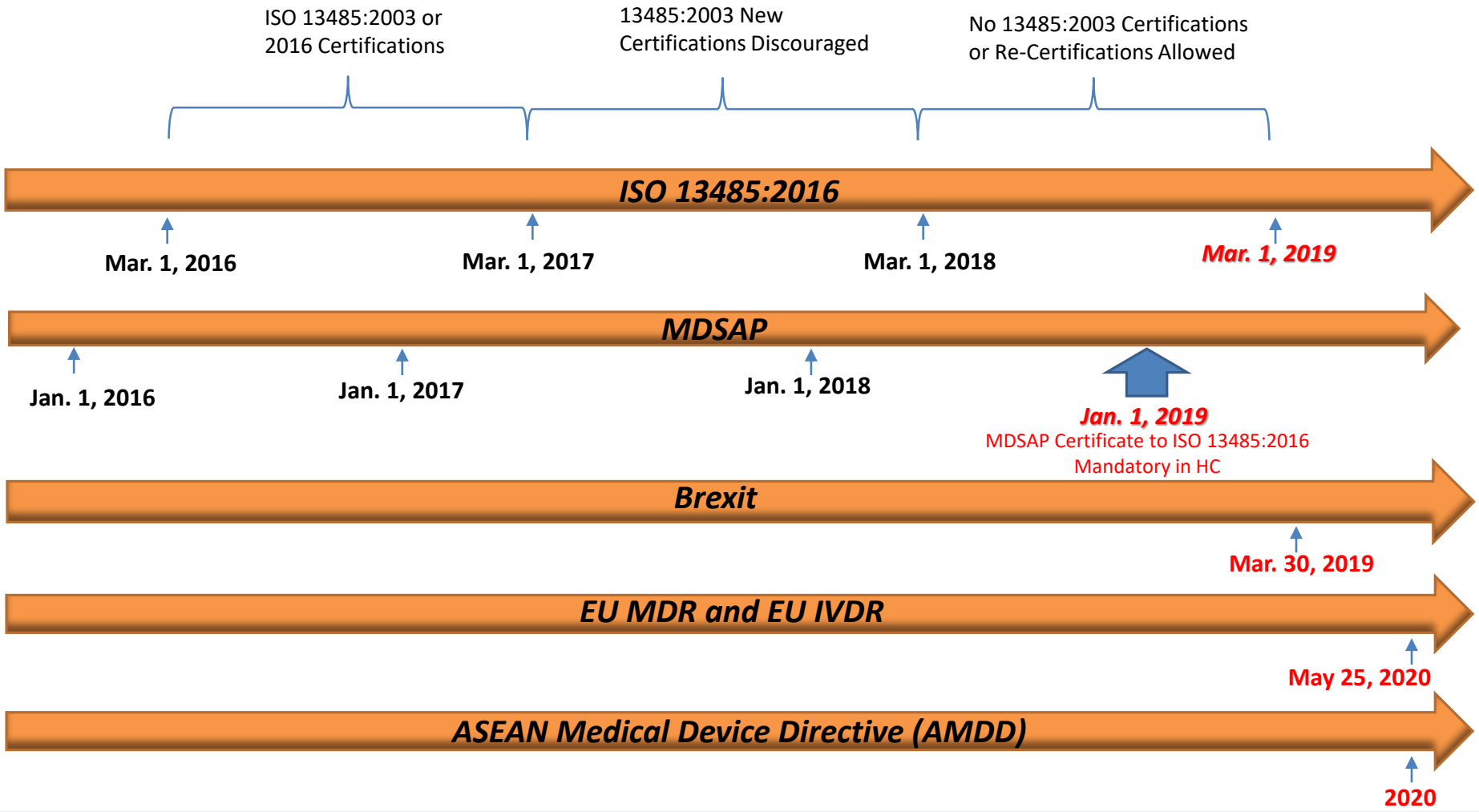
MDSAP Documents:
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

IMDRF Final Documents:

http://www.imdrf.org/documents/documents.asp

Requirement's and Regulations: The "Other" Perfect Storm



Thank you

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