The Convergence of International Regulatory Changes Through 2020

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Medical Device Single Audit Program (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)

MDSAP Consortium

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 for three years before operational.

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

MDSAP International Consortium

The international consortium of countries for MDSAP as of June 2015 :

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)

MDSAP International Consortium

- Since Spring 2014:
  - World Health Organization (WHO) Diagnostic Prequalification Program
  - European Union as Observers

MDSAP 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

Third Parties and Regulatory Inspectorates

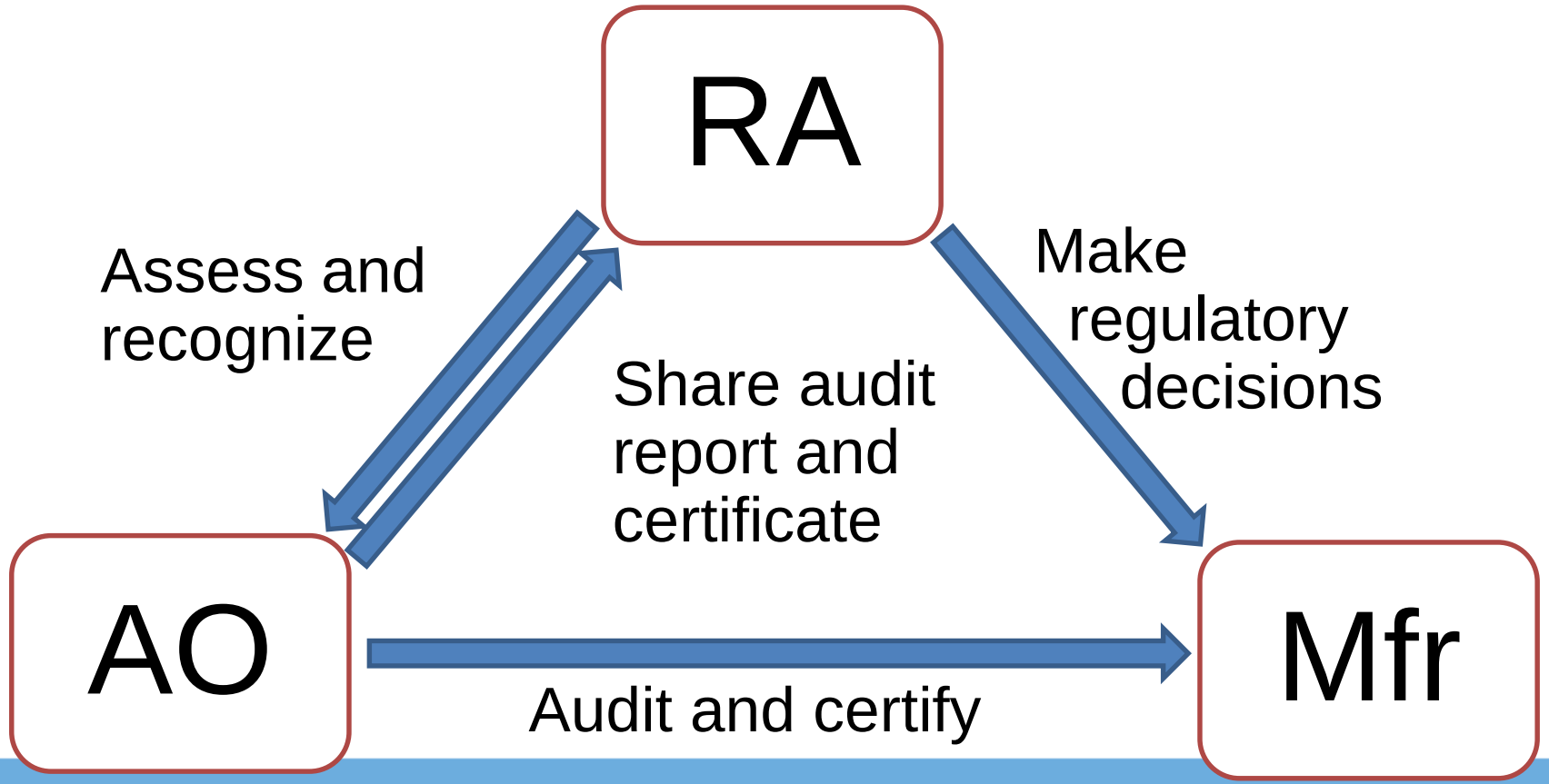
The development of MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Use of third party auditors, in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers around the globe

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
- Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- Japanese requirements (MHLW MO 169)
- FDA's Quality System Regulation (21 CFR Part 820)

MDSAP Audit Process

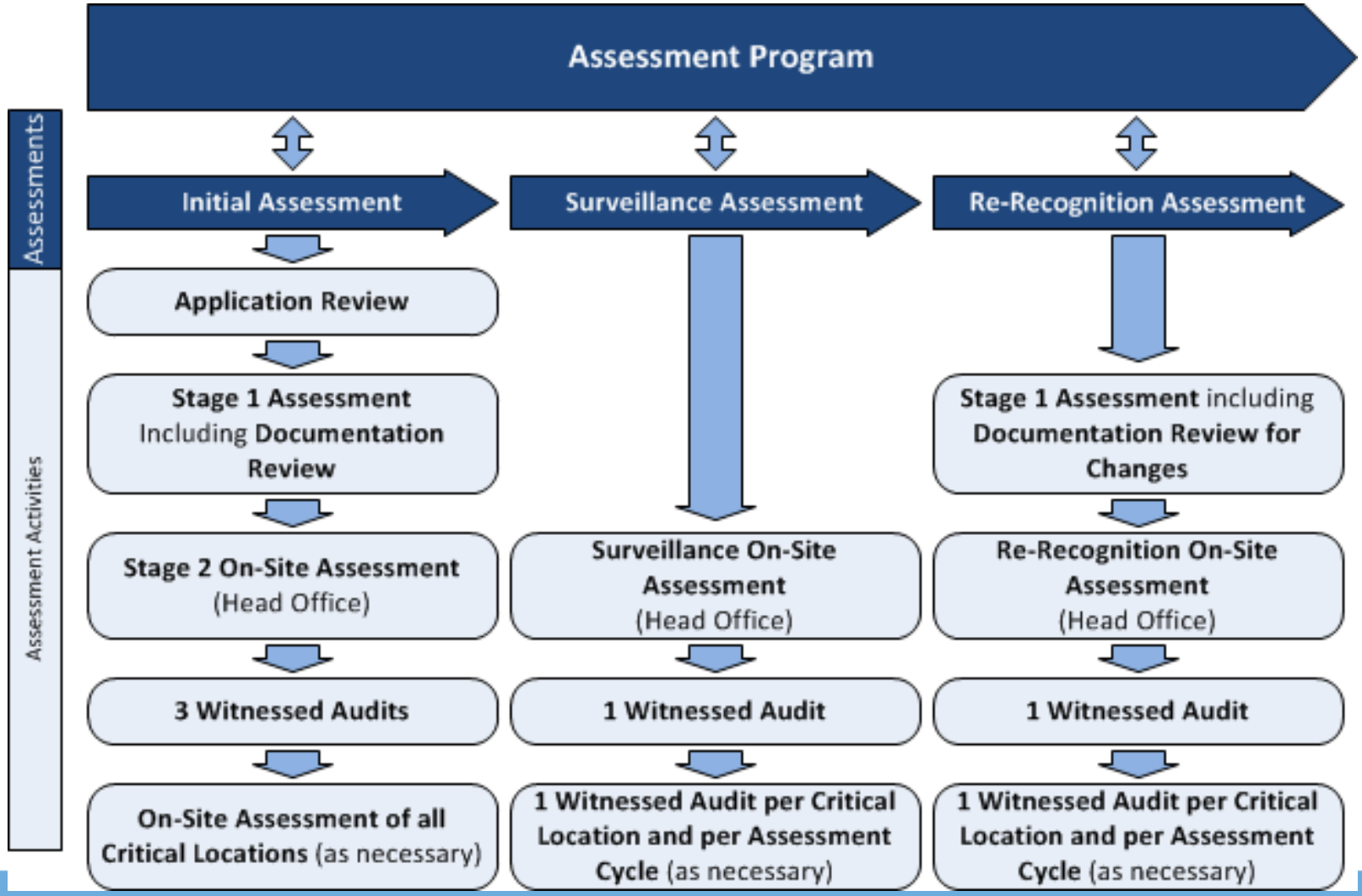
AND other specific requirements of medical device regulatory authorities participating in the Pilot MDSAP program such as:

- registration
- licensing
- adverse event reporting and more

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



MDSAP Documents

The MDSAP documents just described are based on the foundation established by the International Medical Device Regulatory Forum (IMDRF) MDSAP documents www.imdrf.org

Further deployed by the MDSAP International Consortium with documents, work instructions, templates, etc. found at:

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

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: Auditing Organizations other than CMDCAS registrars can apply
  - One new Auditing Organization Application in January 2017 to date

2019

- ***Jan 1: MDSAP replaces CMDCAS***

MDSAP Official Announcements

Health Canada – December 4, 2015

Notice: Transition Plan for the Medical Device Single Audit Program (MDSAP)

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

MDSAP Official Announcements

Health Canada – April 22, 2016

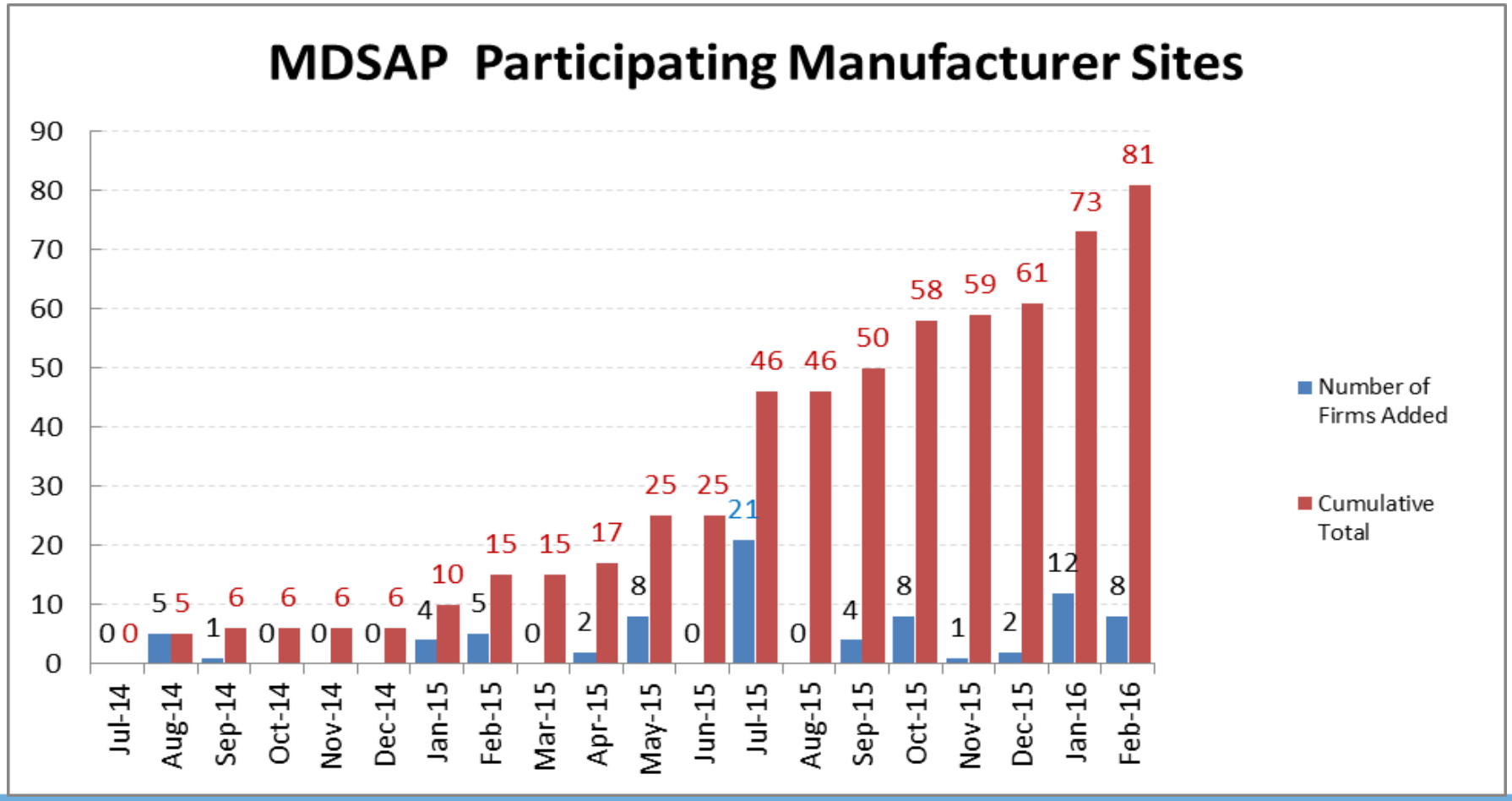
Notice: Medical Device Single Audit Program (MDSAP) Transition Plan – Frequently Asked Questions (FAQ)

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

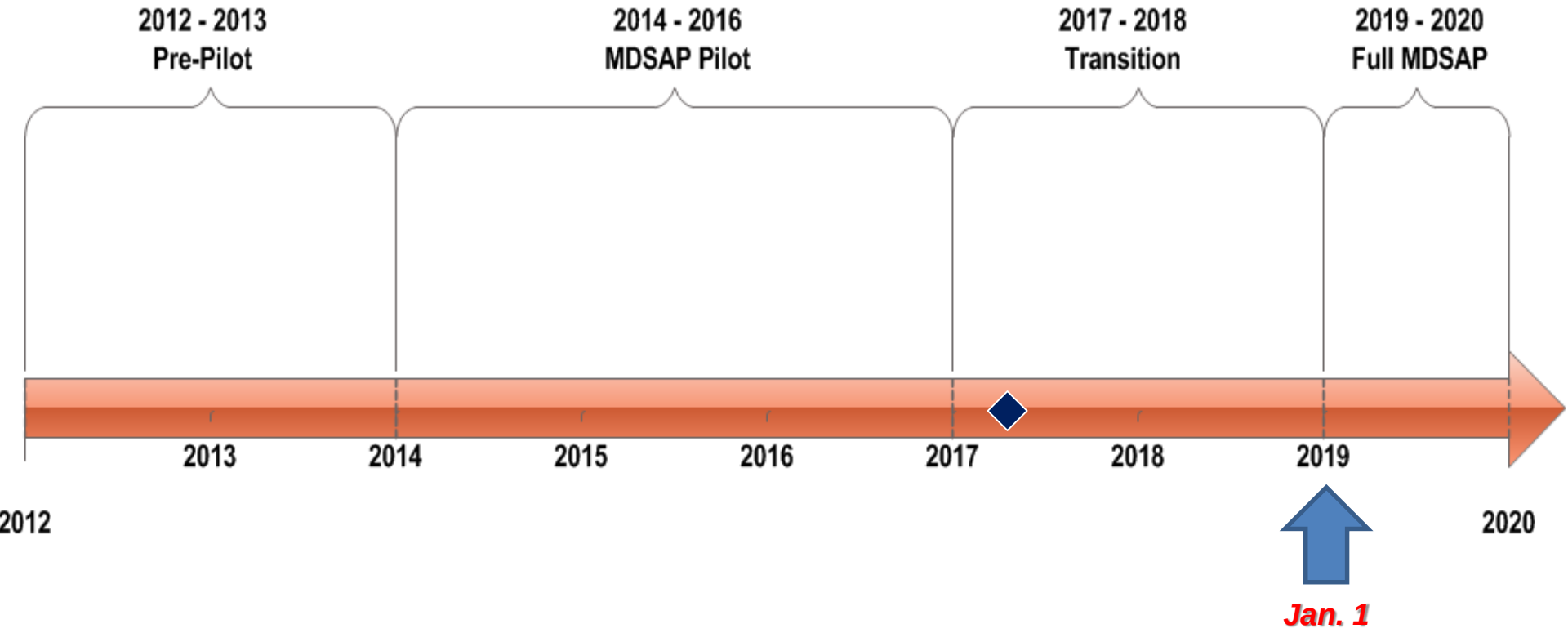
Participating Manufacturers (Feb. 2016) As of Feb. 2017 over 200

Corporations: 41

Individual sites: 81



MDSAP Timeline



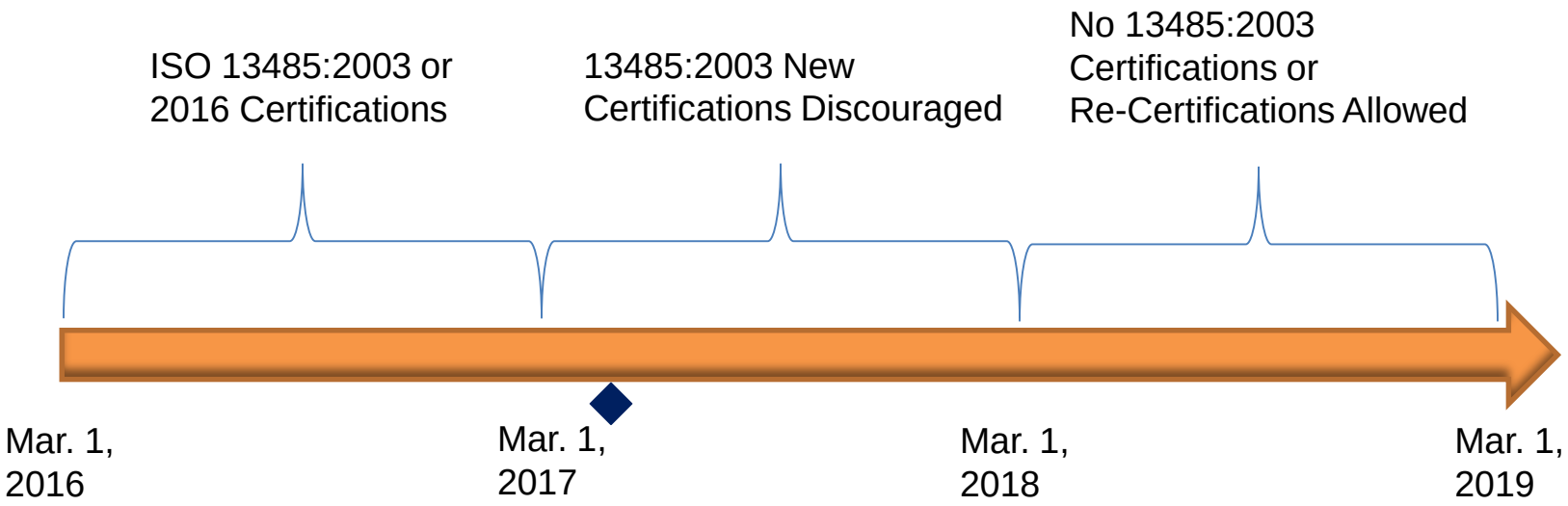
Background – ISO 13485 Revision

- International Organization Standardization (ISO) standard published first in 1996, revised in 2003, and now in 2016
- Sector specific standard based off ISO 9001
- Represents the requirements for a comprehensive quality management system (QMS) for the design and manufacture of medical devices and in vitro diagnostic devices, as well as their related processes and services

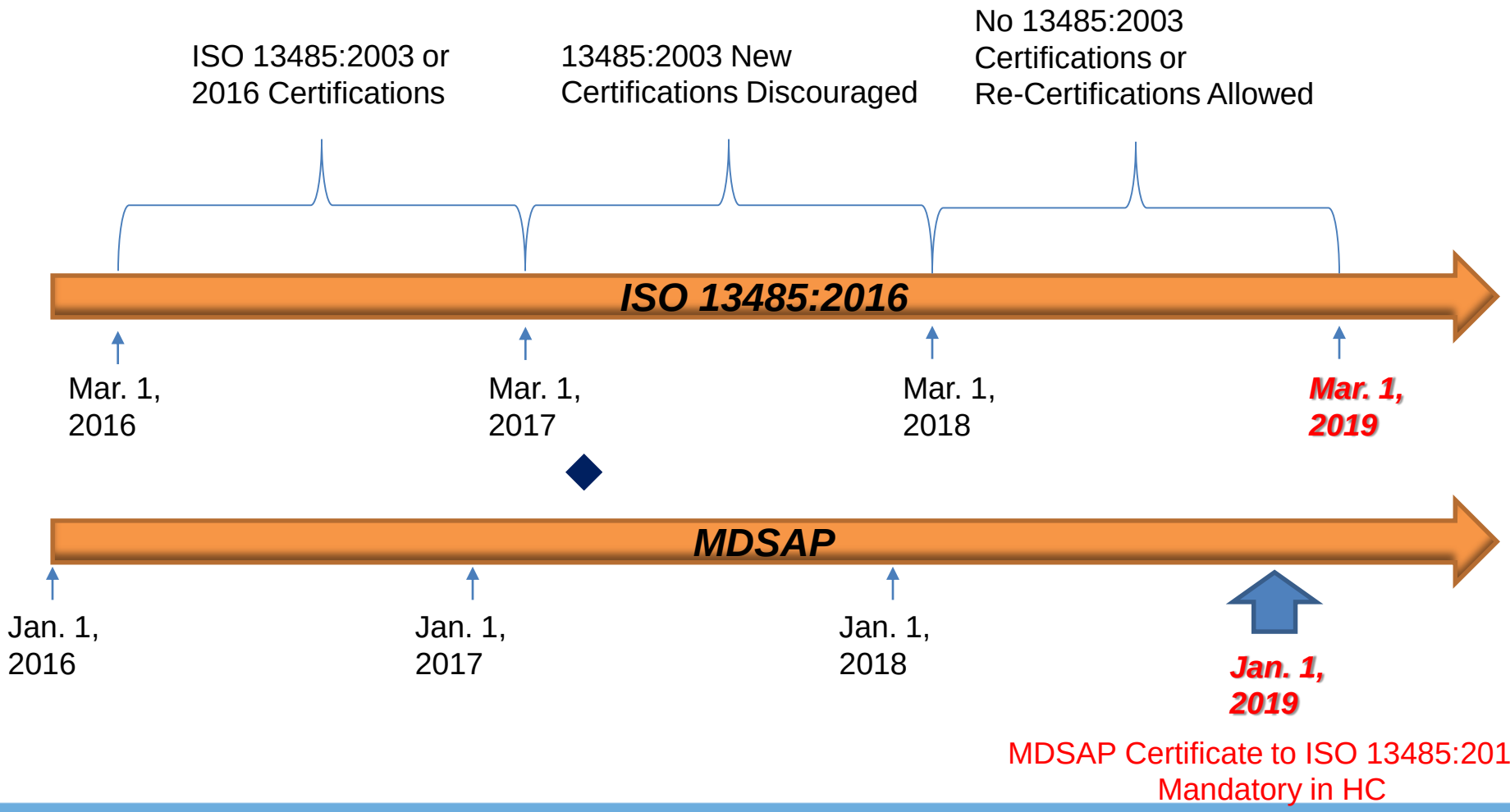
Objectives

- Improve clarity of the requirements
- Increase confidence that the requirements are consistent with cGMPs or current Quality System regulatory requirements/objectives
- Increase harmonization of QMS regulatory requirements
- Increase medical device manufacturers' ability to meet customer requirements

ISO 13485:2016 Timeline



ISO 13485:2016 and MDSAP Timeline



EU MDR and EU IVDR

In 2012, the EU Commission adopted measures on two regulation proposals to revise existing legislation on general medical devices and in vitro diagnostic medical devices.

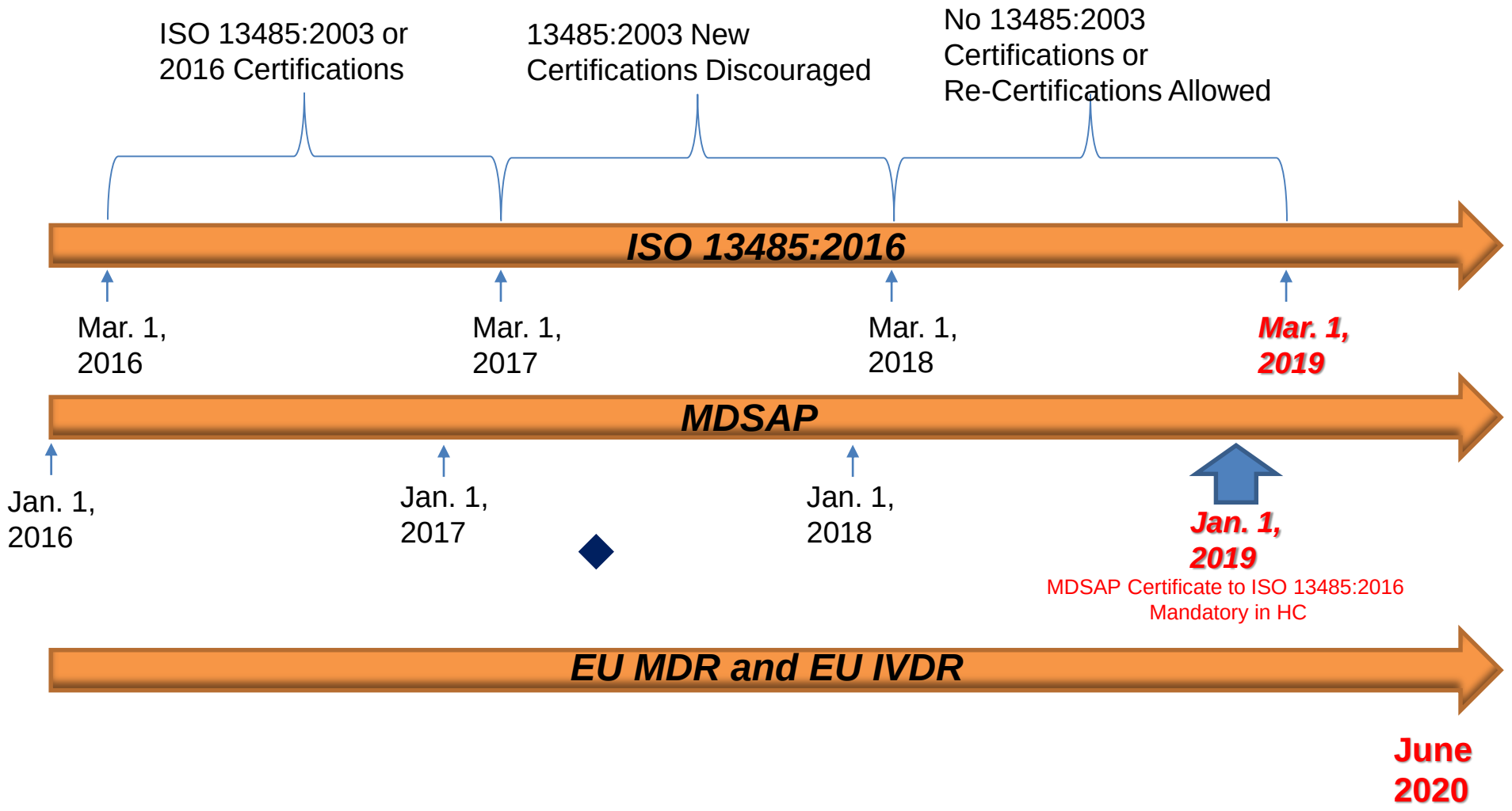
In particular, the Directives on active implantable medical devices (90/385/EEC) and on medical devices (93/42/EEC) are intended to be replaced by a Regulation on medical devices, while the Directive on in-vitro diagnostic medical devices (98/79/EC) is intended to be replaced by a Regulation on the same subject.

EU MDR and EU IVDR

Revisions include:

- the extension of the scope of legislation,
- better supervision of independent assessment bodies,
- clear rights for economic operators, and
- stronger requirements for clinical evidence.

MDSAP and ISO 13485:2016 Timeline



Other Emerging Regulatory Consortiums – AHWP

Asian Harmonization Working Party (AHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

AHWP List of Member Economies:

- Abu Dhabi
- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- India
- Indonesia
- Jordan
- Kazakhstan
- Kingdom of Saudi Arabia
- Republic of Korea
- Laos
- Malaysia
- Mongolia
- Myanmar
- Pakistan
- People's Republic of China
- Philippines
- Singapore
- South Africa
- State of Kuwait
- Tanzania
- Thailand
- Vietnam
- Yemen

Other Emerging Regulatory Consortiums - PAHO

- The Pan American Health Organization (PAHO), through the Medicines and Health Technologies area, supports countries of the Americas Region with Medical Device Regulation, Health Technology Management and Health Technology Assessment (HTA). PAHO undertakes several activities in order to build capacity in Member States through Regional meetings and workshops, technical cooperation, information sharing, and training through online courses.
  - Medical Device Regulation
  - Health Technology Management

Other Emerging Regulatory Consortiums - PAHWP

- Pan African Harmonization Working Party on Medical Devices and Diagnostics (PAHWP) is a voluntary body that aims to improve access to safe and affordable medical devices and diagnostics in Africa though harmonized regulation. Our first priority is in vitro diagnostic devices. A new generation of diagnostic tests are being developed for use at the point of care that could save lives and stop the spread of infectious diseases. It is important patients in Africa have access to these tests without delay.

http://www.pahwp.org/

Other Emerging Regulatory Consortiums - PAHWP

- Housed under the African Union-New Partnership for Africa's Development (AU-NEPAD) Planning and Coordinating Agency. Founding members include the East African Community Health Secretariat (EAC) and the EAC partner States, Ethiopia, Nigeria and South Africa and the London School of Hygiene & Tropical Medicine. Partners include German International Co-operation (EAC-GIZ), the African Society for Laboratory Medicine (ASLM) and the World Health Organization (AFRO, WHO). Companies that develop and manufacture IVD Medical Devices are partners and PAHWP is currently expanding through the incorporation of SADC Partner States.

The current chair of PAHWP is Tanzania - Agnes Sitta Kijo

Other Emerging Regulatory Consortiums - Eurasian

- Eurasian Economic Union Agreement include Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia.

- Implementation efforts are expected to transition until 2021.
- Supposedly medical device manufacturers will have the option of registering their products for all five countries via the Eurasian framework or with individual countries' market regulators such as Roszdravnadzor in Russia or Kazakhstan Department of medical and pharmaceutical activity monitoring (MoH).

Other Emerging Regulatory Consortiums - Eurasian

- For firms opting to seek approval through the Eurasian system, registration in one market will be accepted by regulators in all other participating markets according to early indications.

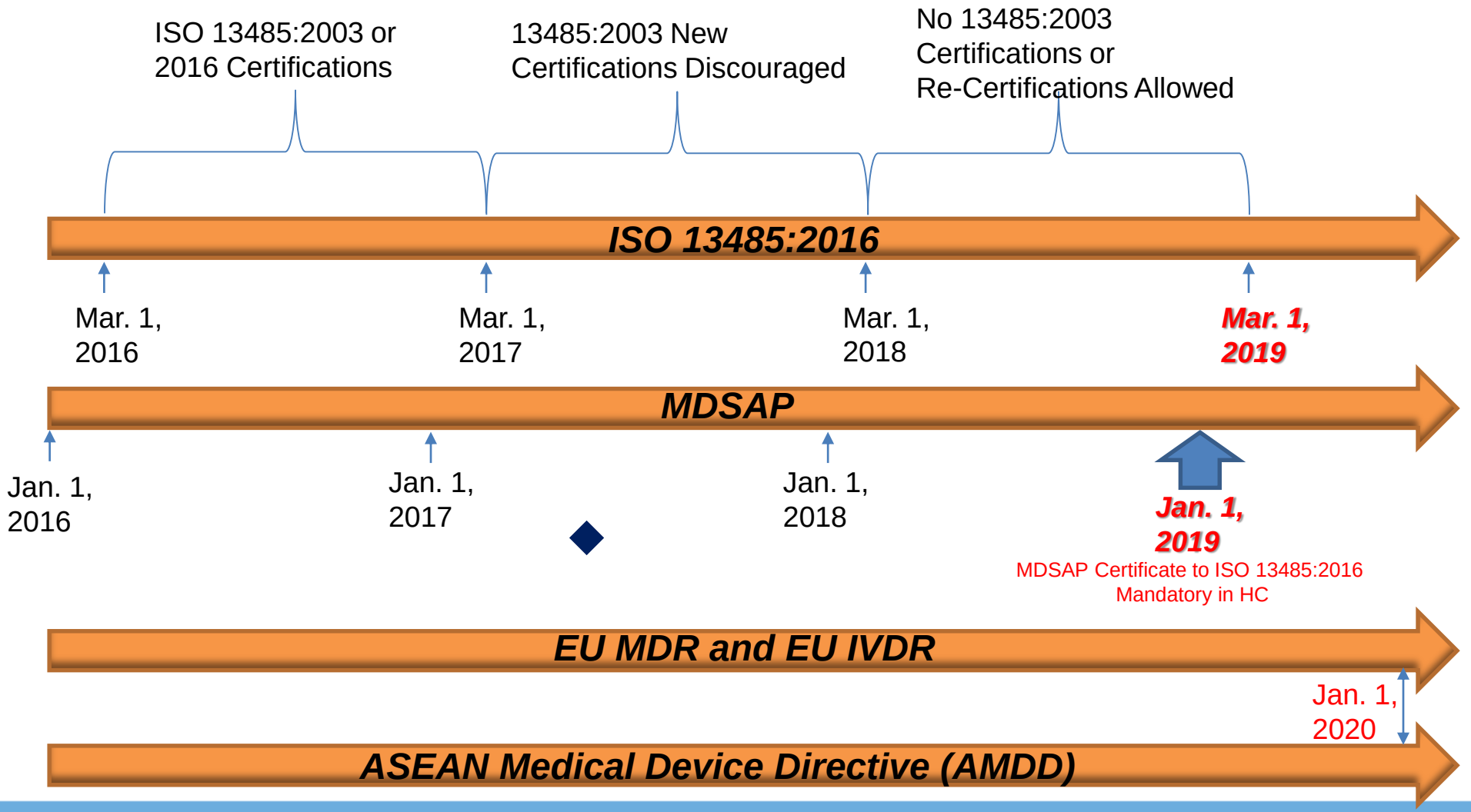
- However, the agreement does not preclude participating governments from implementing their own national medical device regulatory requirements,

Other Emerging Regulatory Consortiums – ASEAN

- ASEAN Membership: 10 States — Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

- Singapore and Malaysia – moving rapidly within ASEAN and working very closely with WHO on medical device assessment
- Several of the ASEAN members also recently joined the Pharmaceutical ICH meetings officially
- ***Agreed to promulgate Medical Device Directives by 2020***

MDSAP and ISO 13485:2016 Timeline



Questions?