Medical Device Single Audit Program (MDSAP)

FDA Small Business
Regulatory Education for Industry (REdI)
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Poll

How many times, during the same year, have you been audited or inspected by these regulatory authorities (RAs) [Australia, Brazil, Canada, Japan, USA]?

a. 1 or 2 RAs
b. 3 or 4 RAs
c. All
d. None

Learning Objectives

- Give an overview and background of the Medical Device Single Audit Program (MDSAP)
- Review the program's development timeline
- Explain the MDSAP Audit Model
- Discuss updates on Current Operating Status

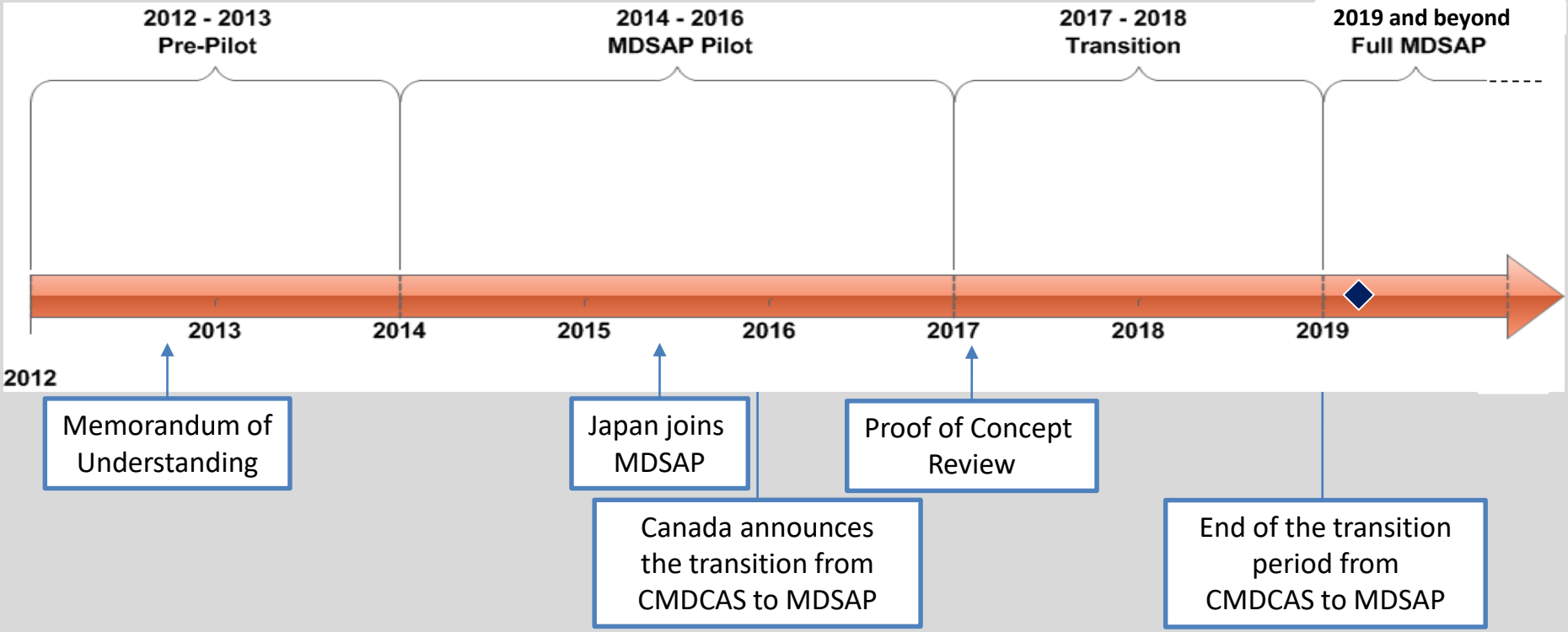
MDSAP Acronyms 101

- Medical Device Single Audit Program (MDSAP)
- Regulatory Authority (RA)
- International Medical Device Regulators Forum (IMDRF)
- Auditing Organizations (AO)

Background

- Started in 2012 by the IMDRF
- Allows recognized AOs to conduct a single audit of a medical device manufacturer
- Pilot: January 2014 – December 2016
- MDSAP Fully Operational – January 01, 2017

Timeline


2012 - 2013
Pre-Pilot
2014 - 2016
MDSAP Pilot
2017 - 2018
Transition
2019 and beyond
Full MDSAP
2012
2013
2014
2015
2016
2017
2018
2019
Memorandum of Understanding
Japan joins MDSAP
Canada announces the transition from CMDCAS to MDSAP
Proof of Concept Review
End of the transition period from CMDCAS to MDSAP

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

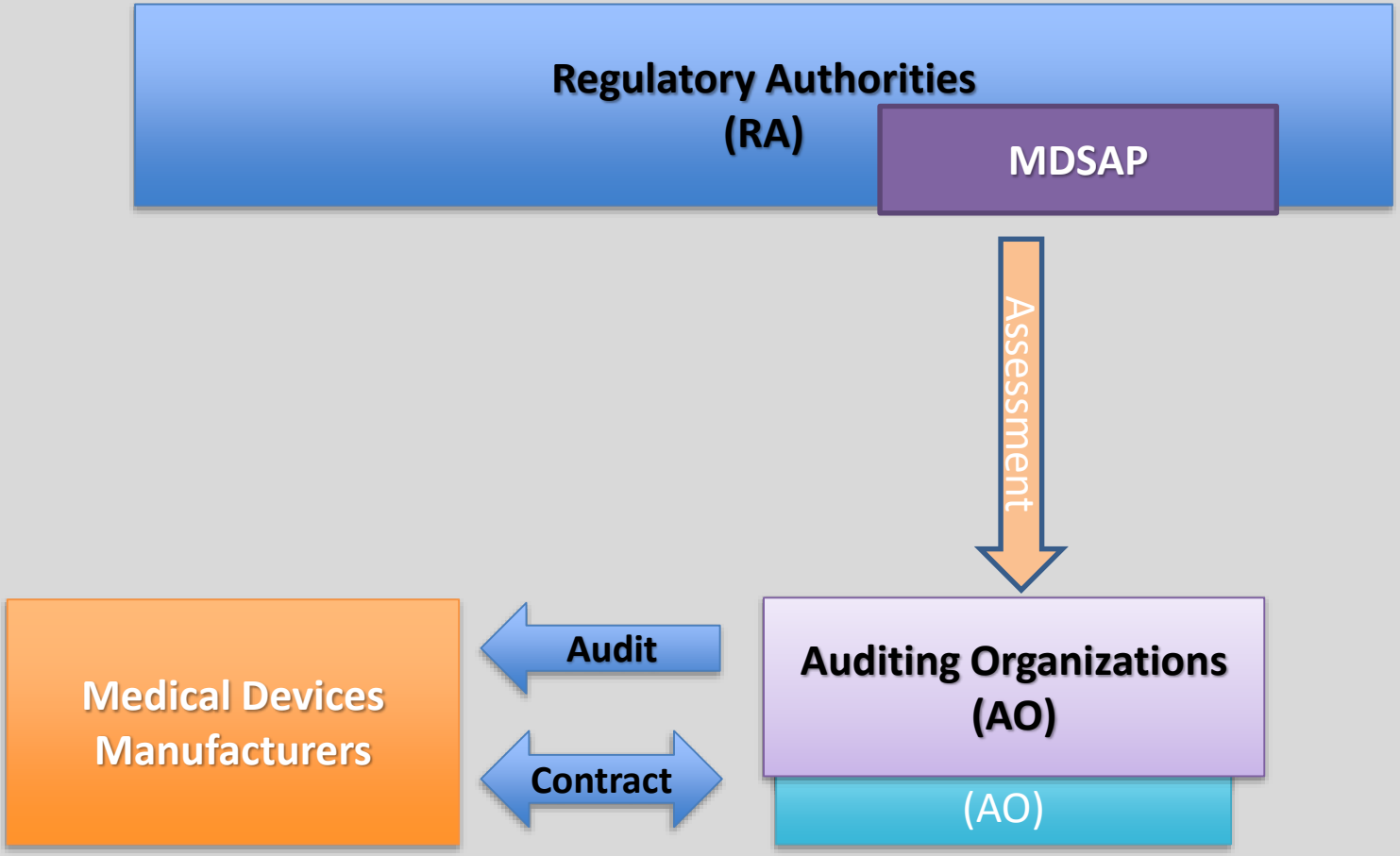

World Health Organization (WHO)


European Union

** Ministry of Health, Labor and Welfare*
*** Pharmaceuticals and Medical Device Agency*

Auditing Organizations

Authorized	Recognized
QMI SAI GLOBAL Lloyd's Register LRQA	TÜV USA Member of TÜV NORD Group bsi. DEKRA DQS MED TÜVRheinland LNE G MED intertek Total Quality. Assured. SGS TÜV SÜD UL NSAI National Standards Authority of Ireland Údarás Um Chaighdeáin Náisiúnta na hÉireann


Regulatory Authorities
(RA)
MDSAP
Assessment
Medical Devices
Manufacturers
Audit
Contract
Auditing Organizations
(AO)
(AO)

MDSAP Audit Model

- The MDSAP audit sequence follows a process approach and has four primary processes:

  (1) Management

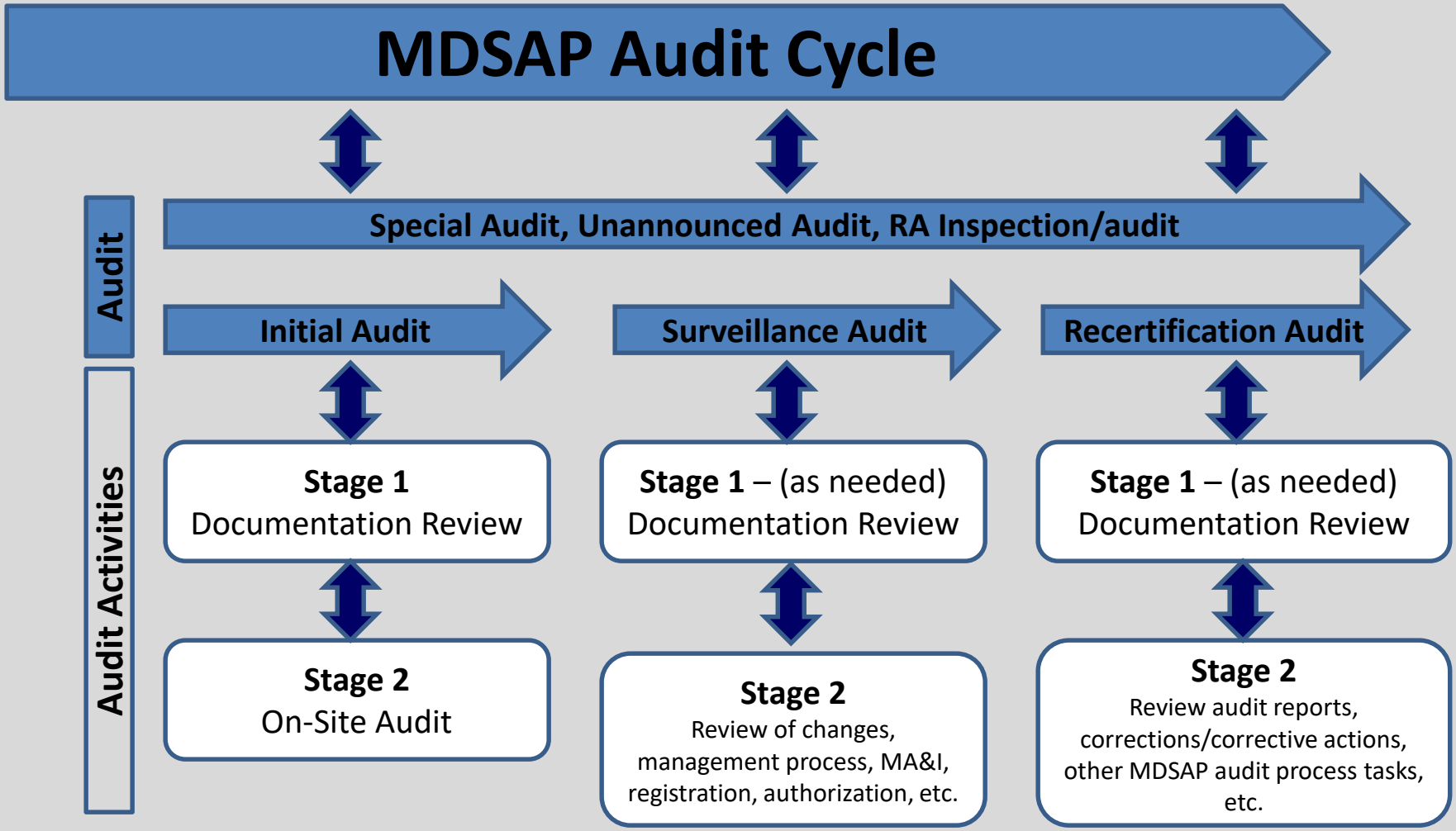
  (2) Measurement, Analysis and Improvement

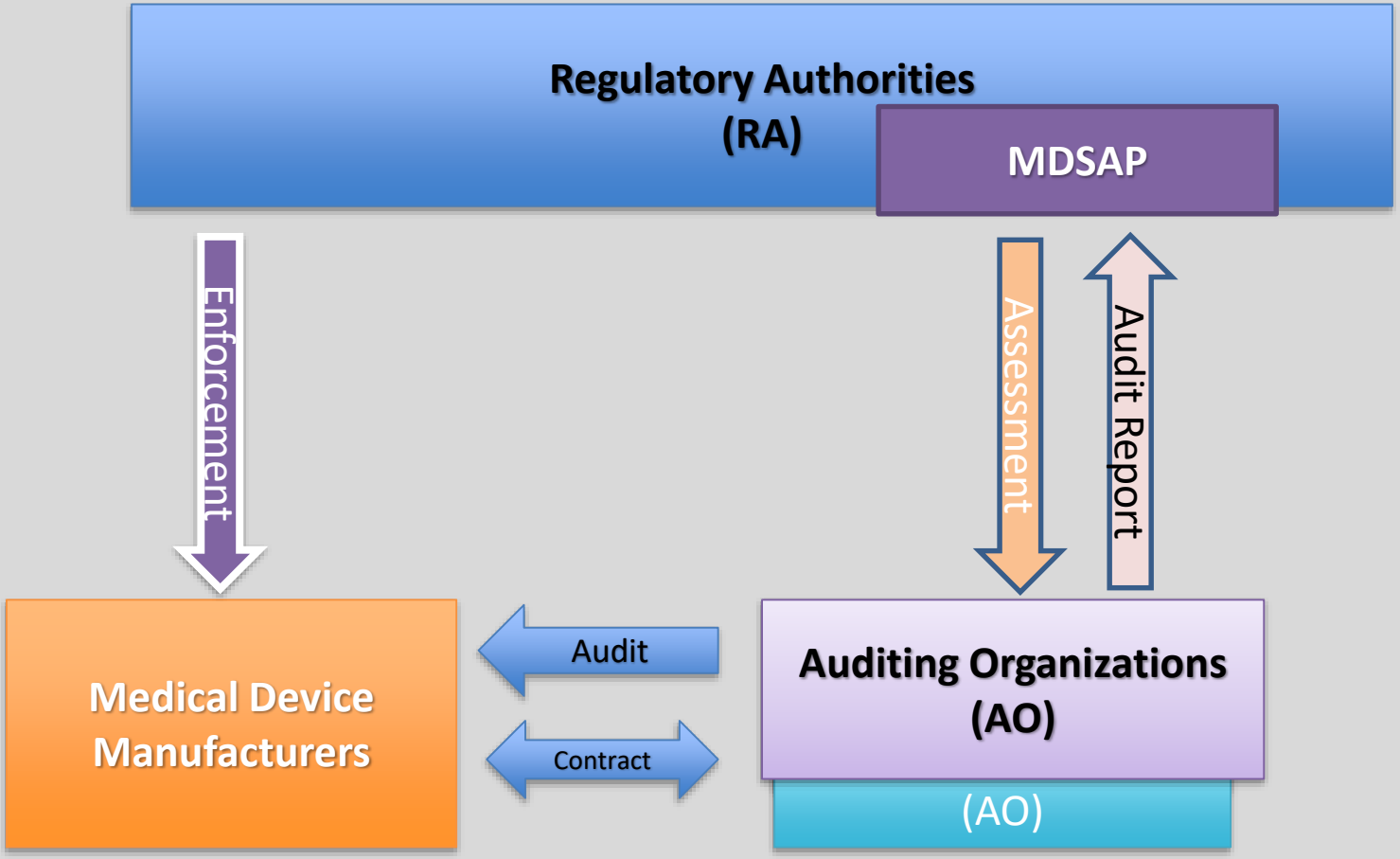
  (3) Design and Development

  (4) Production and Service Controls

- And a supporting process:

  (5) Purchasing


MDSAP Audit Cycle
Audit
Special Audit, Unannounced Audit, RA Inspection/audit
Initial Audit
Surveillance Audit
Recertification Audit
Audit Activities
Stage 1
Documentation Review
Stage 1 – (as needed)
Documentation Review
Stage 1 – (as needed)
Documentation Review
Stage 2
On-Site Audit
Stage 2
Review of changes, management process, MA&I, registration, authorization, etc.
Stage 2
Review audit reports, corrections/corrective actions, other MDSAP audit process tasks, etc.


Regulatory Authorities
(RA)
MDSAP
Enforcement
Assessment
Audit Report
Medical Device
Manufacturers
Audit
Contract
Auditing Organizations
(AO)
(AO)

Program Development

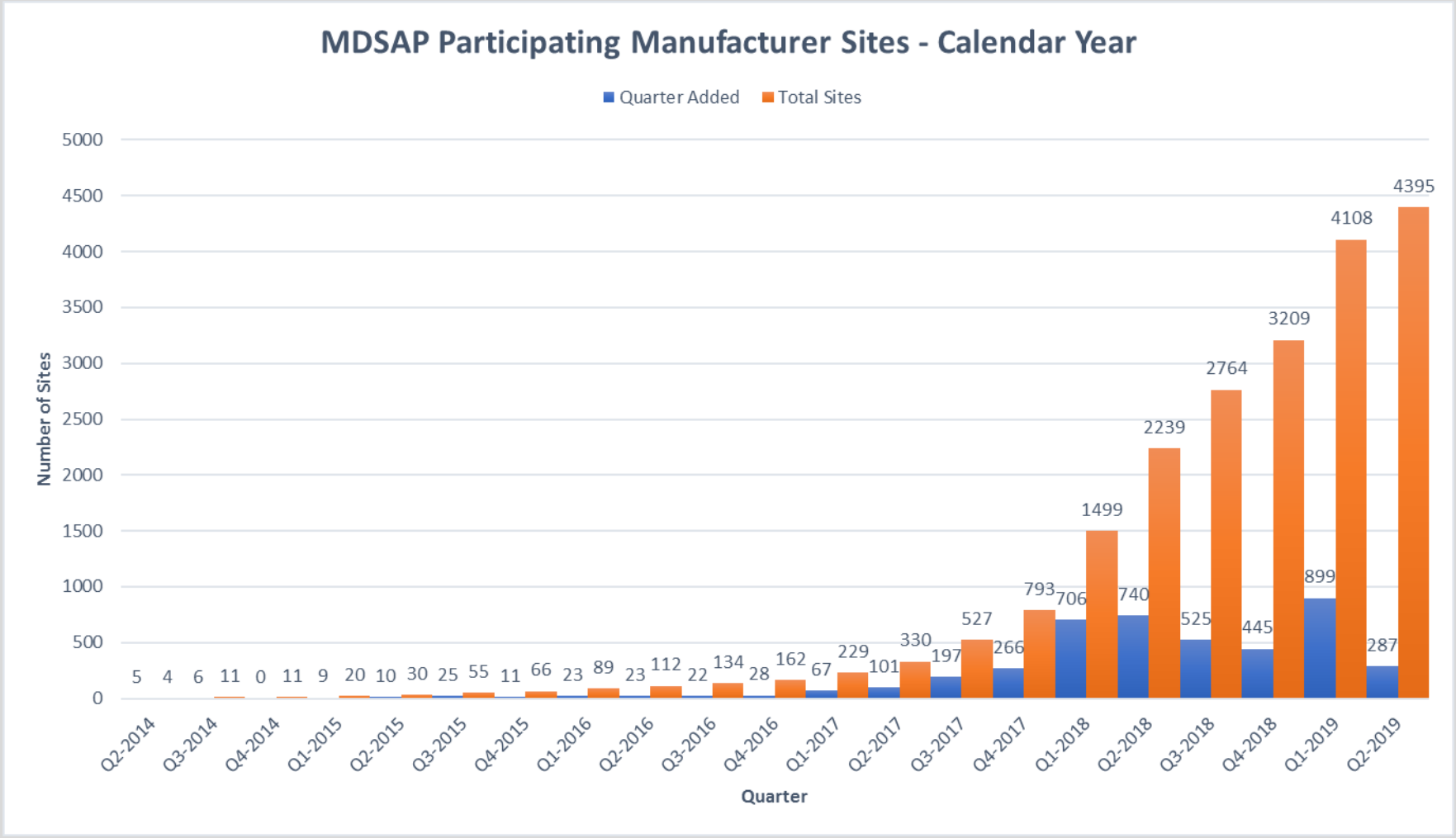
Challenges

- Completely new concept
- Multiple regulatory authorities
- Manufacturer buy-in
- Audit time/cost
- Resource limitations
- Mandatory transition in Canada
- Changes in ISO 13485 standard

Successes

- Development of manufacturer audit cycle and Auditing Organization assessment programs
- Engagement with Auditing Organizations and partner countries
- Program implementation and maintenance
- IT Portal (Pan American Health Organization)

Updates



*As of May 8, 2019

Audit Reports

- **2,274 Audit Reports Received**
- **Classifications**
  - No Action Indicated (NAI): 752
  - Voluntary Action Indicated (VAI): 1,518
  - Official Action Indicated (OAI): 1

Resources

- MDSAP Website
- Training
  - CDRH Learn
  - Auditing Organizations, Professional Organizations

Summary

- MDSAP allows a single regulatory audit that satisfies the requirements of multiple regulatory jurisdictions

- Audits are conducted by recognized Auditing Organizations

Questions

Thank you!

Contact Information

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Your Call to Action

- Evaluate whether MDSAP is right for you
- Speak to a MDSAP recognized Auditing Organization


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