Medical Device Single Audit Program (MDSAP)

Marc-Henri Winter

Staff Fellow

Division of International Compliance Operations

Office of Compliance

Center for Devices and Radiological Health

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

Pilot International Consortium

- The international consortium of countries for the MDSAP Pilot are:
  - Therapeutics Goods Administration (TGA) of Australia,
  - Brazil's Agência Nacional de Vigilância Sanitária (ANVISA),
  - Health Canada,
  - Japanese MHLW and PMDA, and
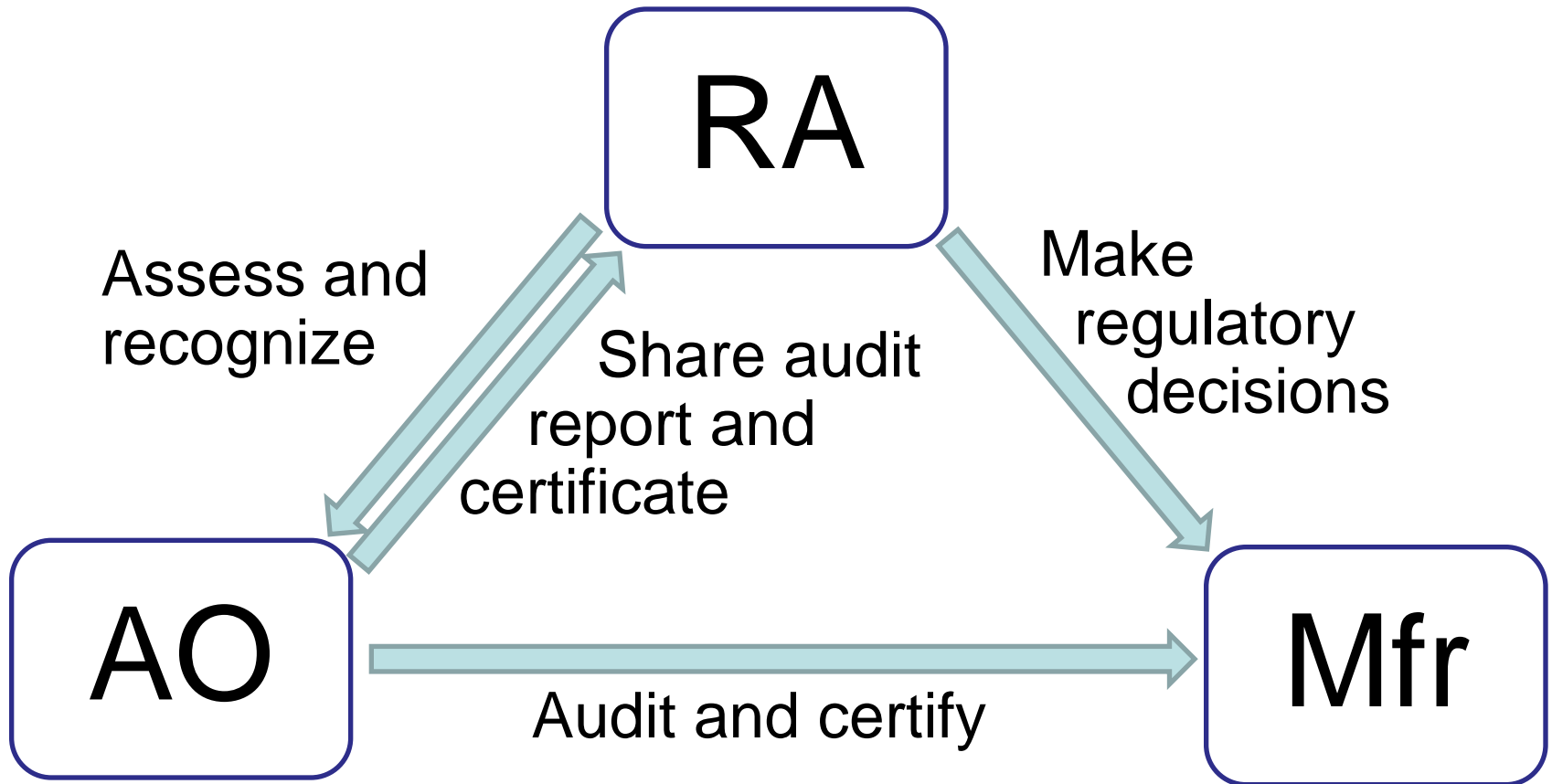 - U.S. Food and Drug Administration

- Observers
  - World Health Organization (WHO) Diagnostic Prequalification Program
  - European Union

Mission

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Concept

RA

AO

Mfr

Assess and recognize

Share audit report and certificate

Make regulatory decisions

Audit and certify

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

RA Operational Organization

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

Regulatory Authority Council (RAC)

- The MDSAP governing body is the RAC which is comprised of two senior managers from each participating jurisdiction, as well as representation from observing jurisdictions

- 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

International Subject Matter Expert (SME) Working Groups

- Regulatory Exchange Platform secure (REPs) SME Working Group
  - Developed IT requirements and specifications for REPs
  - Oversee the Cooperative Agreements with the Host Organization

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Audit-Related Documents

- Audit Model

- Audit Model Companion Guidance

- Web based Audit Model Training

- Audit Report Fillable Form

- Audit Time Calculations

- MDSAP Certificate Procedures

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 Criteria

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

- Registration of manufacturer sites
- Licensing of medical device
- Reporting adverse event and advisory notices
- Device tracking

Assessment Process
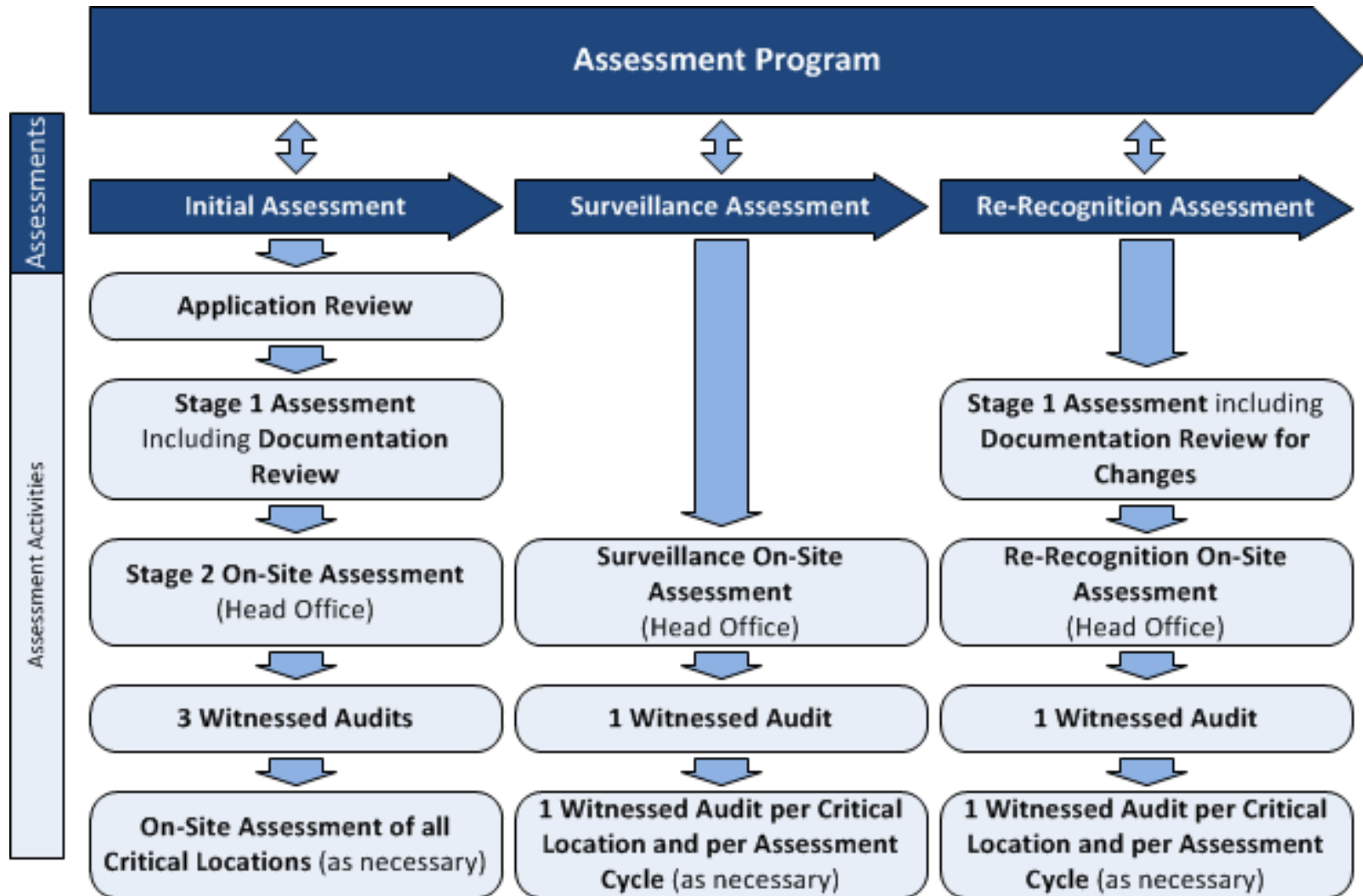
IMDRF Documents

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

www.imdrf.org

U.S. Food and Drug Administration
Protecting and Promoting Public Health

IMDRF MDSAP Documents

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

- IMDRF/MDSAP WG/N3FINAL:2013 – "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/N24 – "MDSAP Audit Report Guidance"

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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

Oversight of 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
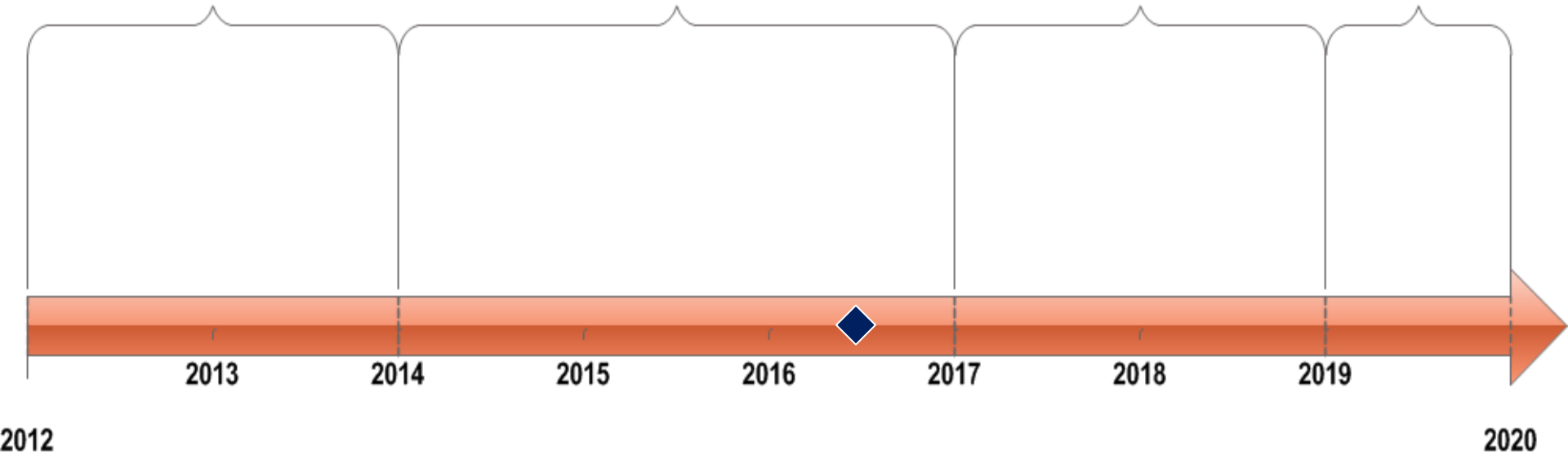
Timeline

2012 - 2013
Pre-Pilot

2014 - 2016
MDSAP Pilot

2017 - 2018
Transition

2019 - 2020
Full MDSAP

2012 · 2013 · 2014 · 2015 · 2016 · 2017 · 2018 · 2019 · 2020

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health

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
- Feb.: ISO 13485:2016
- Jun.: 2nd MDSAP Forum
- ~ Dec.: Review of MDSAP Pilot, using Proof of Concept criteria

21

Transition Milestone

2017
- Jan.:   Auditing Organizations other than CMDCAS registrars can apply

2019
- Jan. 1: MDSAP replaces CMDCAS

What Auditing Organizations can apply to the MDSAP Pilot?

During the Pilot, only the Auditing Organizations recognized under the Canadian CMDCAS program are allowed to participate

The list of Registrars Recognized by Health Canada can be found on the MDSAP website

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Auditing Organization Applications

AO Applications
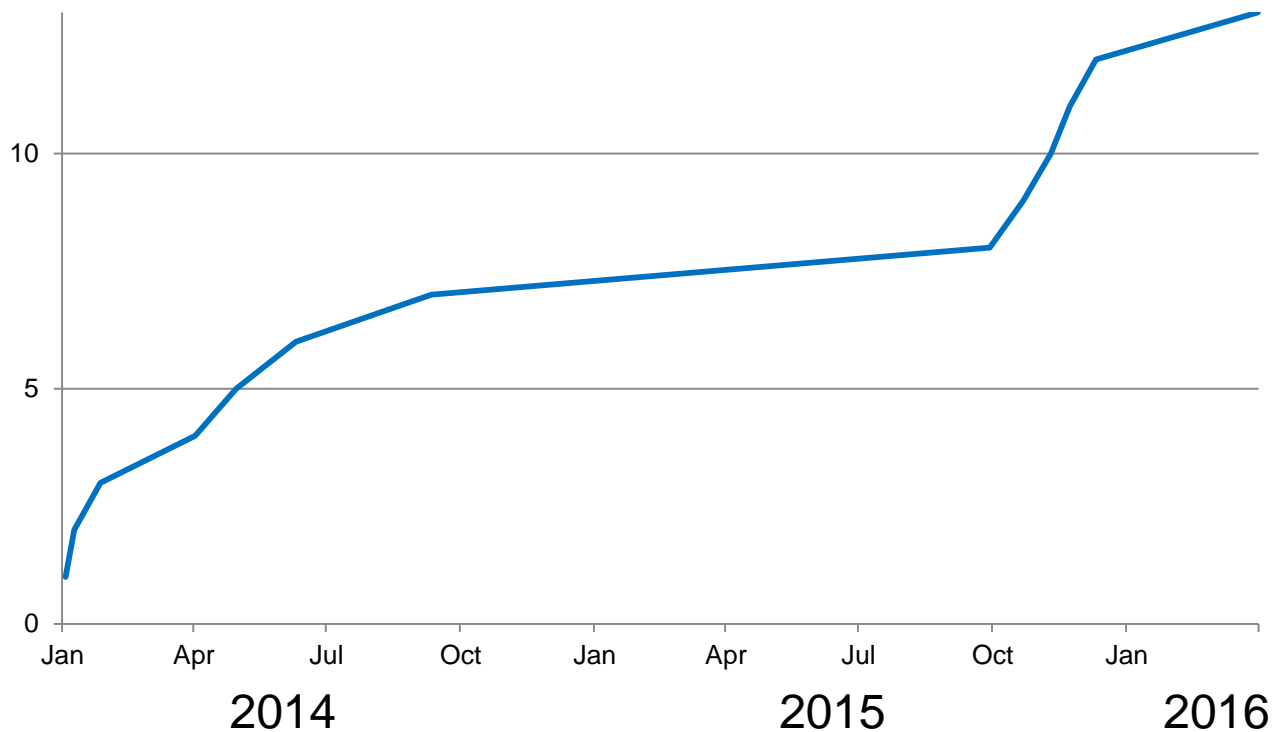
Facts: Assessment Activities

- Application Review: 13
- Stage 1 Assessment: 10
- Stage 2 Assessment: 10
- Critical Locations: 5
- Witnessed Audit: 11
- Surveillance Assessment: 7
- Special Assessment: 1

Authorization During MDSAP Pilot

- Authorized to conduct MDSAP Audits:
  - BSI Group America**
  - Intertek Testing Services**
  - LNE/G-MED*
  - QMI – SAI Global
  - TUV SUD America**
  - TUV USA

Completed at least 1 Witnessed Audit
*** Completed 3 Witnessed Audits*

Why Should Manufacturers Participate?

- Limit the number of medical device regulatory audits
- Facilitate the application for marketing authorization in countries where a quality management system audit is a prerequisite
- Anticipate the transition towards the mandatory application of MDSAP in Canada
- Be a part of the process during the pilot to help shape the policies and procedures for the operational program scheduled to begin in 2017
- Encourage the Auditing Organization to get authorized/ recognized

# *How can medical device manufacturers participate?*

- The CMDCAS registrars were allowed to start submitting their application for MDSAP recognition starting January 2014. Almost all of the CMDCAS Auditing organizations have submitted their application for MDSAP recognition.

- Some Auditing Organizations have successfully passed their assessments and are ready to audit medical device manufacturers and grant certification. See the website for current listing:

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

Participating Manufacturers (June 2016)

MDSAP Participating Manufacturer Sites - Calendar Year
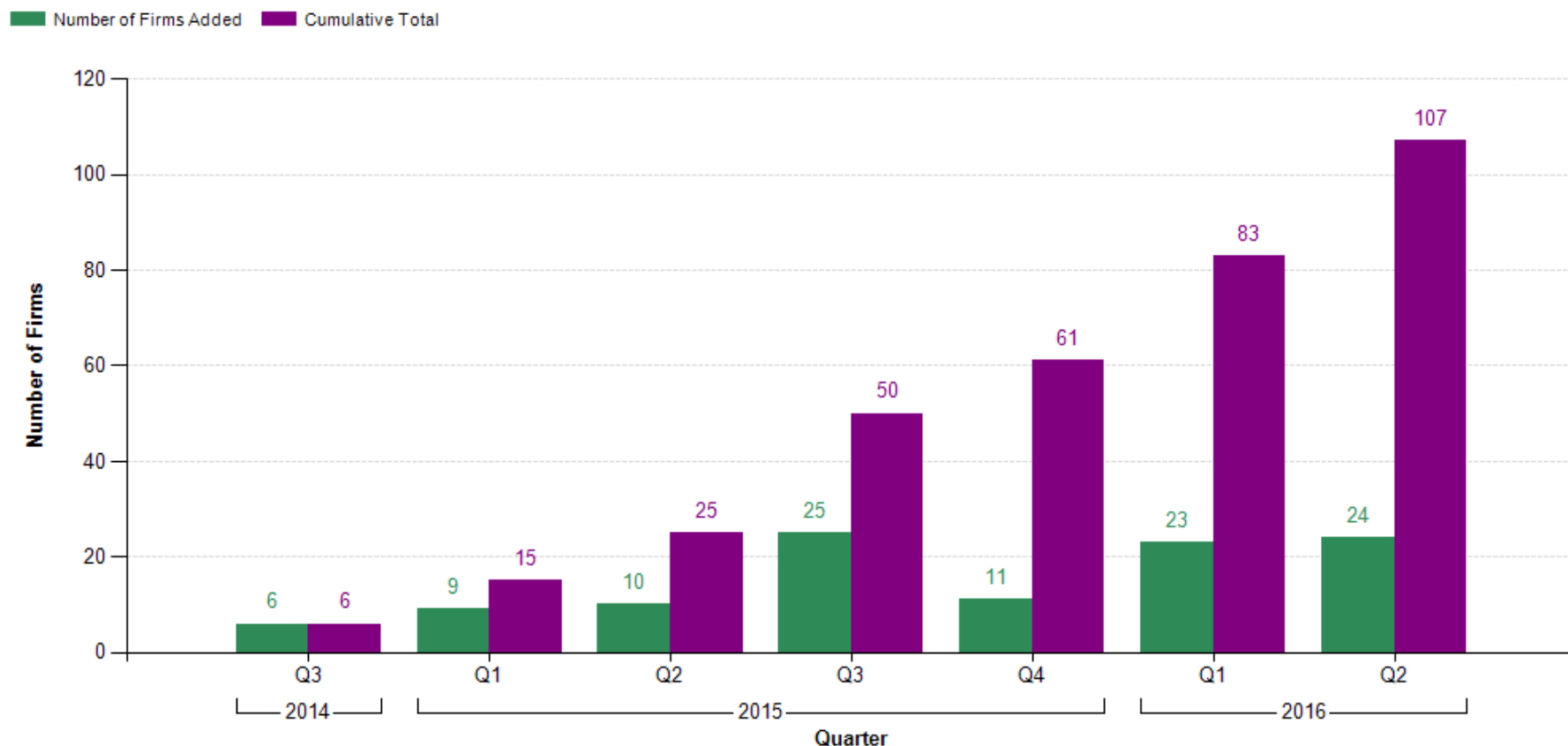
Profile of Manufacturers
Most Benefitting from MDSAP

- Organization selling in Canada and internationally
- Manufacturing site of finished medical devices
- Relatively large organization (~ 70 people and more)
- Manufacturer of combination products selling in Australia
- Organization intending to sell in Brazil
- Manufacturer of high risk medical devices
- Organization participating in WHO *Prequalification of In Vitro Diagnostics (IVDs) Programme*

- In the future: Organization intending to sell in countries requiring premarket QMS audit, and accepting MDSAP certificates as evidence of compliance.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Resources

<u>CDRH Learn</u>:

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

<u>MDSAP Documents</u>:

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

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

<u>IMDRF Final Documents</u>:

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