Health Canada Santé Canada

Canada

Health Canada Update: MDSAP & IMDRF

Brazil-Canada Chamber of Commerce, Healthcare Forum
December 7th, 2017

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

- Update on MDSAP – Transitioning from Pilot to Implementation
- Utilisation of the audits by Regulatory Authorities
- Manufacturer participation and feedback to-date
- International Medical Devices Regulators Forum (IMDRF)

Medical Device Single Audit Program Pilot

- 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 (Australia, Brazil, Canada, Japan and United States)
- The MDSAP Pilot documents are based on the foundation established by the International Medical Device Regulatory Forum (IMDRF) MDSAP documents

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*

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

Status of Auditing Organizations

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

Outputs of an MDSAP Audit

The participating MDSAP Regulatory Authorities will each use the output of MDSAP audits in accordance with their regulatory programme.

Outputs of an MDSAP Audit

Australia:

Where regulations require a TGA CAC, TGA will take into account MDSAP certificates when deciding to issue or maintain a TGA CAC. Under some circumstances, a manufacturer may avoid routine TGA inspections.

Where regulations do not require a TGA CAC, TGA will accept MDSAP certificates as evidence of compliance with ISO 13485 where the standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Outputs of an MDSAP Audit

Brazil:

ANVISA may use MDSAP audit reports in lieu of premarket inspections by ANVISA to grant ANVISA's GMP Certificates

ANVISA can also use MDSAP audit reports to renew ANVISA GMP Certificates bi-annually as an alternative to an ANVISA comprehensive inspection.

Outputs of an MDSAP Audit

Canada:

Health Canada will accept MDSAP certificates as evidence of conformity in accordance with section 32(2)(f), (3)(j), 4(p), 34, and 43.1

Outputs of an MDSAP Audit

Japan:

MHLW and PMDA can use MDSAP audit reports to:

Exempt a manufacturing site from on-site inspection (restrictions apply)

Substitute considerable part of the documentation to be supplied by the Marketing Authorization Holder for inspection with the MDSAP audit report.

Outputs of an MDSAP Audit

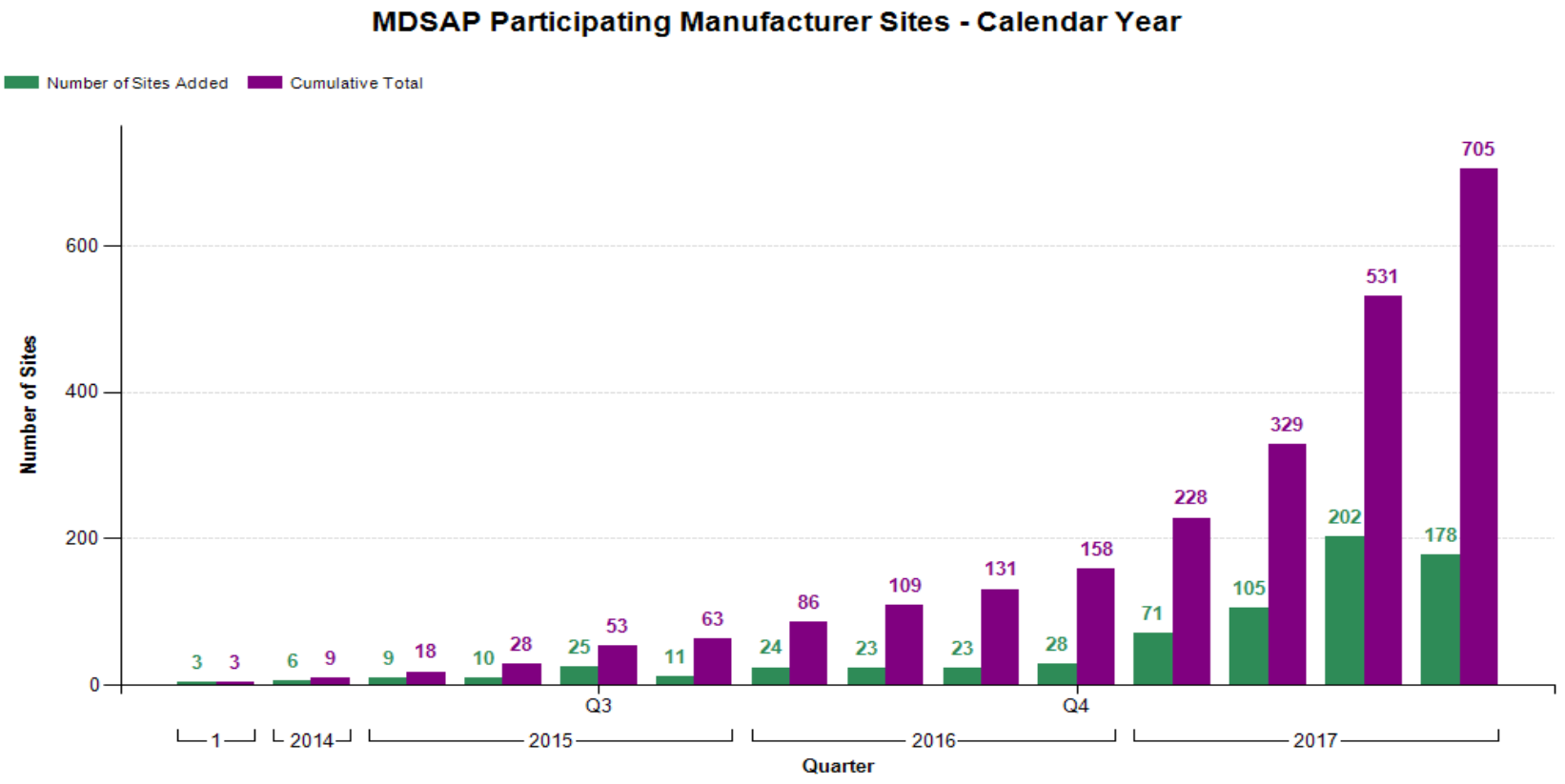
US FDA:

CDRH will accept MDSAP audit reports as a substitute for FDA routine inspections.

MDSAP Transition

- On December 4, 2015, Health Canada published a notice that CMDCAS would be replaced by MDSAP as of January 1st, 2019.
- On April 22nd, 2016, Health Canada published a FAQ document to provide clarification to manufacturers and stakeholders on the upcoming transition from CMDCAS to MDSAP.

Manufacturer Participating Sites



Manufacturer Feedback - 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.

Feedback from Industry Associations

- 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.

International Medical Devices Regulators Forum (IMDRF)

- IMDRF created as successor to GHTF, taking into consideration:
  - Fact that most of work of GHTF completed
  - Limitations of GHTF model in achieving goals of regulatory harmonization
  - Globalization
- Key differences from predecessor:
  - Management Committee (MC) composed only of regulatory authorities
  - Commitment of MC to development and implementation of technical work items of high value to both regulators and stakeholders
  - Broader membership reflecting global regulatory environment

Important Facts

- Launched in February 2012, chair and secretariat rotate on annual basis, beginning with Australia (2012), EU (2013), US (2014), Japan (2015), Brazil (2016), Canada (2017), China (2018)
- Broader membership than GHTF, now including Brazil, China, Russia and Singapore
- AHWP, APEC and PAHO endorsed as Affiliate Organizations: signals importance of close cooperation in achieving common goals
- Two 3 day meetings per year; includes public session

Important Facts

- New Work Items (NWIs) endorsed by MC define technical work of IMDRF and remit of Working Groups (WGs)
- WGs will be disbanded once assigned work completed
- WGs will generally include stakeholders with significant involvement and expertise in topic
- WGs responsible for matters relating to regulatory practices or exchange of confidential information will be comprised of regulators

New Work Items

- Currently 7 NWIs
  - Regulated Product Submission (RPS): Canada
  - Patient Registries: US
  - Adverse Event Terminology: Japan
  - Good Regulatory Review Practices: US
  - Standards – improving the Quality of International Standards for Regulatory Use: EU
  - Unique Device Identification (UDI) Application Guide: EU
  - Patient Specific Devices: TGA

Questions

Questions?