Medical Device Single Audit Program (MDSAP)

The 24th AHWP Annual Meeting
14 November 2019
The Crystal Ballroom, Grand Millennium
Muscat, Oman

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Objectives

- MDSAP Introduction
- MDSAP Assessments and Audits
- Potential Benefits
- How to Participate
- 2019 Program Updates

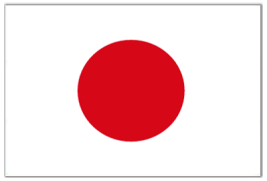
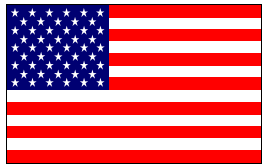
MDSAP

- Started in 2012 by the International Medical Device Regulators Forum (IMDRF)
- Allows recognized Auditing Organizations (AOs) to conduct a “single audit” of a medical device manufacturer (MDM) that will satisfy the relevant requirements of participating Regulatory Authorities (RAs)
- Pilot – (January 2014 – December 2016)
- **January 2017** – Full implementation!

Regulatory Authorities

- Therapeutic Goods Administration of Australia (TGA)
- Brazil's Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada
- Japan
  - Ministry of Health, Labour and Welfare (MHLW)
  - Pharmaceuticals and Medical Devices Agency (PMDA)
- U.S. Food and Drug Administration (FDA)



MDSAP Participants

- The current MDSAP Observers are:

World Health Organization

European Union

Union(WHO)

MDSAP Mission

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

MDSAP Objectives

- Appropriate regulatory oversight while minimizing regulatory burden on industry
- Efficient and flexible use of regulatory resources
- Promote a greater global alignment of regulatory approaches and technical requirements
- Promote consistency, predictability, and transparency

MDM Audit vs. AO Assessment

MDM Audit

- Of Device Manufacturers By Auditing Organization
- Of compliance to ISO 13485 + specific quality system requirements from PRAs' regulations
- 3-year cycle
- MDSAP Audit Model

AO Assessment

- Of Auditing Organization By Regulatory Authorities
- Of compliance to the IMDRF Recognition Criteria (including ISO/IEC 17021, GHTF SG3/N19, etc.)
- 4-year cycle
- MDSAP Assessment Program

MDSAP Language

- Audits may be conducted in multi languages.
- All MDSAP “documentation” of assessments or audits should be written in English.
- MDSAP AU P0019 (Audit Report Policy)

Potential Benefits

- Reduced Number of Audits
- Use of some MDSAP Audit Reports for Medical Device Marketing Authorization
- Improvement in Predictability of Audit Outcomes
- As MDSAP Grows, So Will RA Participation
- Choice of MDSAP Auditing Organization
- Further Commitment to Quality

How to Participate

- Any medical device manufacturer is eligible
- Contact an Auditing Organization authorized to conduct audits by MDSAP RAs
- Participation is not initiated through RAs

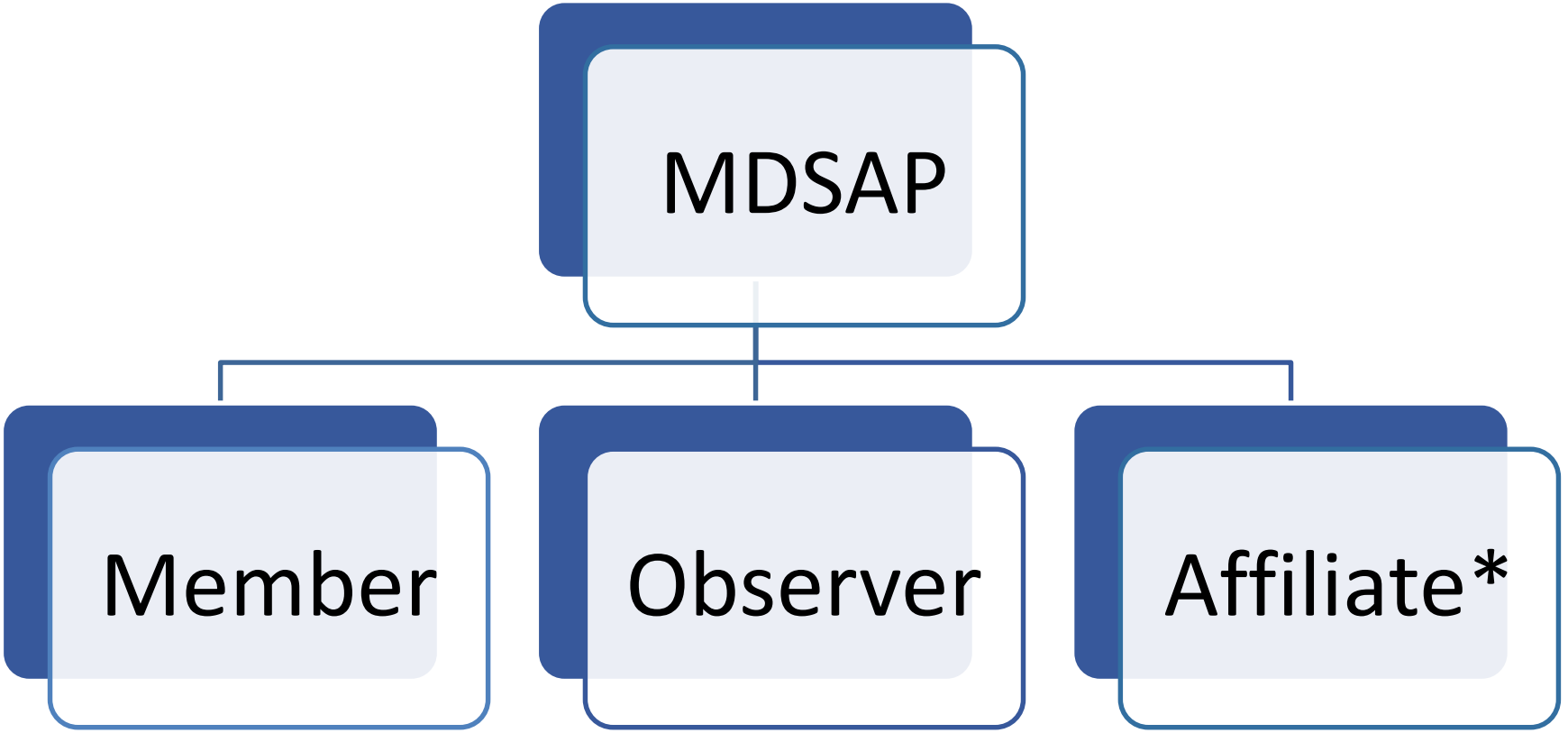
2019 Program Updates

- 13 Auditing Organizations Recognized
- Launch of MDSAP IT Portal, Regulatory Exchange Platform – secure (REPs)
- MDSAP participation required for Canada
- Regulatory Authority Affiliate Membership

Expansion of MDSAP

- MDSAP is currently not accepting additional regulatory authorities as full Members or Observers of MDSAP
  - Program needs more time to settle and stabilize in the 5 jurisdictions and with manufacturers due to complexity of incorporating the regulatory requirements of 5 regulatory authorities into one audit program.
  - Auditing Organizations are either still at various stages of gaining recognition or gaining experience executing the MDSAP audit model and processes.

New MDSAP Membership Category: Affiliate Membership



New MDSAP Membership Category: Affiliate Membership

- Regulatory requirements of the Affiliate Member are not included in the audit model
- Reports will need to be requested from the medical device manufacturer
- Benefits:
  - Training on MDSAP
  - Ability to utilize MDSAP reports in jurisdiction
  - Receive a routine list of MDSAP audits conducted, dates, location, and auditing organization
  - Listed on MDSAP website as an Affiliate Member
  - Participate in yearly MDSAP Forum meetings

Contents of the Report

- Routine reports will be sent to Affiliate Members and will include the following information:
  - Facility Name
  - Facility Street Address
  - Facility City State / Province Zip, Country
  - Initial Audit Start Date
  - Initial Audit End Date
  - Responsible AO

Affiliate Membership Criteria

- Membership for Regulatory Authorities
- Criteria includes:
  - Laws and regulations in place for evaluating a medical device manufacturer's QMS based on GHTF and IMDRF foundations and principles
  - Other laws and regulations that build on GHTF and IMDRF foundations and principles (ex: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance)
  - Completion of MDSAP on-line training modules
  - Objectives for becoming an Affiliate Member
  - Contributions to MDSAP
  - Implementation of MDSAP documents

Affiliate Membership Application Form

MDSAP AFFILIATE MEMBERSHIP APPLICATION FORM

Applications or questions must be submitted to the Chair of the MDSAP Regulatory Authority Council Secretariat (RAC): hc.rac-secretariat.sc@canada.ca For additional information, please refer to the MDSAP web page:
https://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/

The RAC will officially recognize MDSAP Affiliate Member applicants after they have adequately demonstrated understanding and utilization of the program. To maintain membership, MDSAP Affiliate Members shall report annually the utilization of MDSAP report and/or MDSAP certificates to the RAC.

Contact Details for Applicant:
Name of Applicant Organization:
Contact Person(s):
Title:
Address:
Phone:
Email:

1. Are you a Regulatory Authority?

   ☐ Yes ☐ No

2. Do you have any laws and regulations in place for evaluating a medical device manufacturer's QMS based on GHTF and IMDRF foundations and principles?

   ☐ Yes ☐ No

   If yes, please provide the relevant law or regulation, a comprehensive description of its contents and a description of related enforcement activities. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on this topic.

Affiliate Membership Application Form

3. Do you have any other laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles? For example: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance.

   ☐ Yes ☐ No

   If yes, please provide the relevant law or regulation, a comprehensive description of its contents and a description of related enforcement activities. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on these topics.

4. Have you successfully completed the MDSAP on-line training modules?

   ☐ Yes ☐ No

   If yes, please list names of personnel that have successfully completed the on-line training modules. Please also include contact information and dates of completion:

5. Please describe your organization's objective for becoming an MDSAP Affiliate Member and how you will benefit from participating in the program as an Affiliate Member:

Contribution to MDSAP

6. Describe how your organization contributes or can contribute resources and expertise to the objectives of MDSAP and how its membership would be a benefit to MDSAP:

Implementation of MDSAP Guidelines

7. Describe your policy/strategy regarding the implementation of MDSAP guidelines:

8. Please indicate which MDSAP documents you intend to implement or have implemented and provide relevant documentation to support evidence of implementation:

MDSAP Forum

- Yearly forum with Regulatory Authorities and Auditing Organizations to learn about the program.

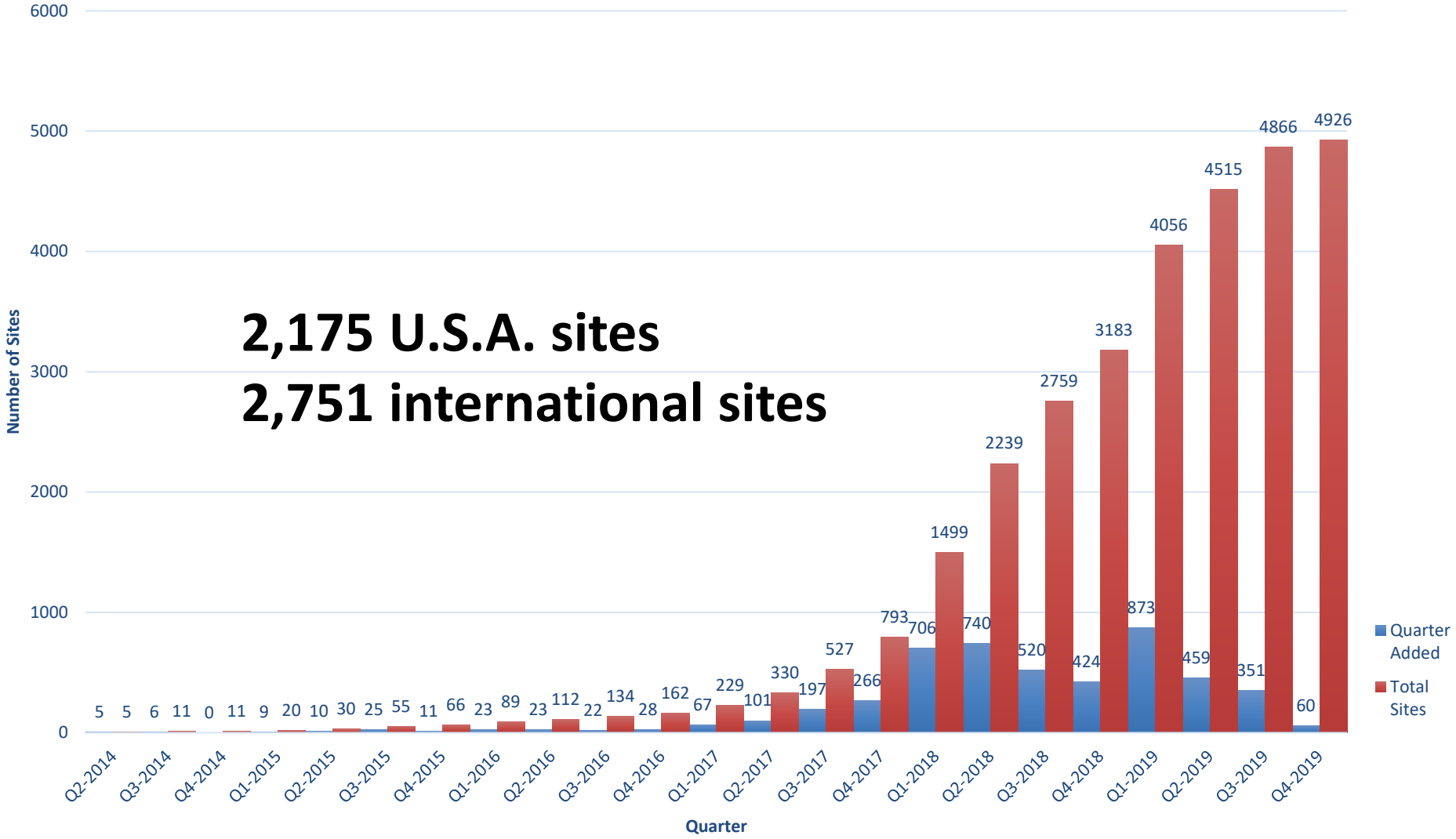
- Date: December 5 - 6, 2019
- Time: 0900 to 1700 EST
- Location: Pan American Health Organization (PAHO) Headquarters, 525 23rd Street Northwest, Room A, Washington, District of Columbia USA 20037

- RSVP: Ms. Anita Epps, Anita.Epps@fda.hhs.gov
- Questions: Neil Mafnas at Neil.Mafnas@fda.hhs.gov or
- Marc-Henri Winter at Marc-Henri.Winter@fda.hhs.gov

References

- Auditing Organization Availability to Conduct MDSAP Audits
  - https://www.fda.gov/media/131149/download
- MDSAP Affiliate Membership Document
  - https://www.fda.gov/media/127697/download
- MDSAP Affiliate Membership Application
  - https://www.fda.gov/media/127700/download
- MDSAP Website
  - https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap
- MDSAP Training
  - https://www.fda.gov/training-and-continuing-education/cdrh-learn

MDSAP Participating Manufacturing Sites



MDSAP Participation by Top 5 Countries

1. United States 2,175
2. Canada 399
3. Germany 390
4. China 249
5. Japan 222

We Accept Industry Feedback

- IMDRF Consultations
- MDSAP Participation Surveys
- Email:
  - MDSAP@tga.gov.au
  - MDSAP.ATENDIMENTO@anvisa.gov.br
  - QS_MDB_HC@hc-sc.gc.ca
  - MDSAP@pmda.go.jp
  - MDSAP@fda.hhs.gov

Resources

- **MDSAP Website**

  http://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/default.htm

- **MDSAP Question and Answer Document**

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

- **Canadian Medical Device Conformity Assessment System (CMDCAS)-Recognized Certification Bodies**

  http://www.scc.ca/accreditation/management-systems/cmdcas/cmdcas-recognized-certification-bodies

- **IMDRF Consultations**

  http://www.imdrf.org/consultations/consultations.asp#current

Contact Information

- FDA MDSAP Team
  - mdsap@fda.hhs.gov
- CDR Neil A. Mafnas
  - neil.mafnas@fda.hhs.gov

Thank you!

William (Bill) Sutton

萨盾

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