MDSAP Affiliate Program

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MDSAP Members

The current participating regulatory authorities (RAs):

厚生労働省
Ministry of Health, Labour and Welfare

pmda
独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Health Canada
Santé Canada

Australian Government
Department of Health
Therapeutic Goods Administration

Agência Nacional de Vigilância Sanitária

FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP Observers:

World Health Organization

Prequalification of In Vitro Diagnostics Programme

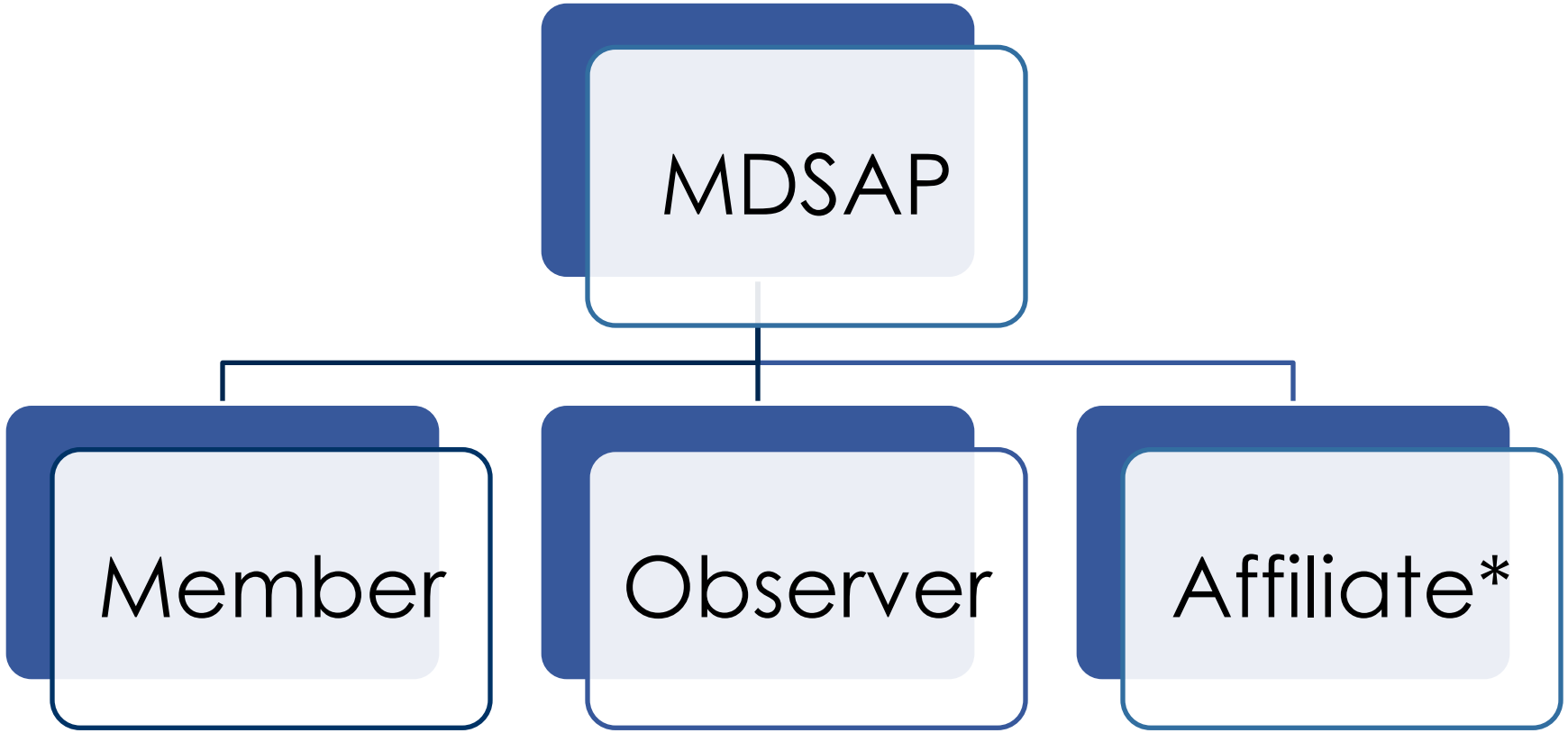
European Union

- The EU and WHO:
  - Joined as observers since program establishment in 2014.
  - Participated in the original IMDRF MDSAP working group and contributed to the foundational MDSAP documents.
  - Participated in RAC meetings and witness audits since program inception.
- EU did not become a full MDSAP member due to funding and resource constraints, but remain committed to becoming a full member.
- WHO is not a regulator and will maintain Observer status.

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



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 MDSAP audit/site information (MDSAP Affiliate Report)
  - Listed on MDSAP website as an Affiliate Member
  - Participate in yearly MDSAP Forum meetings

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 Affiliate Members

- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Republic of Korea's Ministry of Food and Drug Safety
- Singapore's Health Sciences Authority (HSA)

https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

References

- 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

Any Questions?

MDSAP

MEDICAL DEVICE SINGLE AUDIT PROGRAM