MDSAP

MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP Program Introduction

Pretoria, 16 November 2023

What is MDSAP?

The Medical Device Single Audit Program (MDSAP) is a regulatory audit program that was initially jointly developed by four jurisdictions (Japan joined in 2015).

It allows a medical device manufacturer to have a single quality management system audit to satisfy the requirements of all participating regulatory authorities.

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What is MDSAP?

As currently implemented, MDSAP allows any medical device manufacturer to contract with an MDSAP recognized Auditing Organization (AO) to have a single regulatory quality management system audit that meets the requirements of all participating Regulatory Authorities.

Each country defines how MDSAP outcomes are used within its jurisdiction in accordance with its legislation and regulatory framework.

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Autoridades Regulatórias Participantes

Programa de Avaliação

Organismos Auditores

Programa de Auditoria

Fabricantes de produtos

Resultados de Auditorias

MDSAP Development

The MDSAP objectives are:

- To operate a single audit program that provides confidence in program outcomes
- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry

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MDSAP Development

The MDSAP objectives are (*continued*):

- To promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each authority

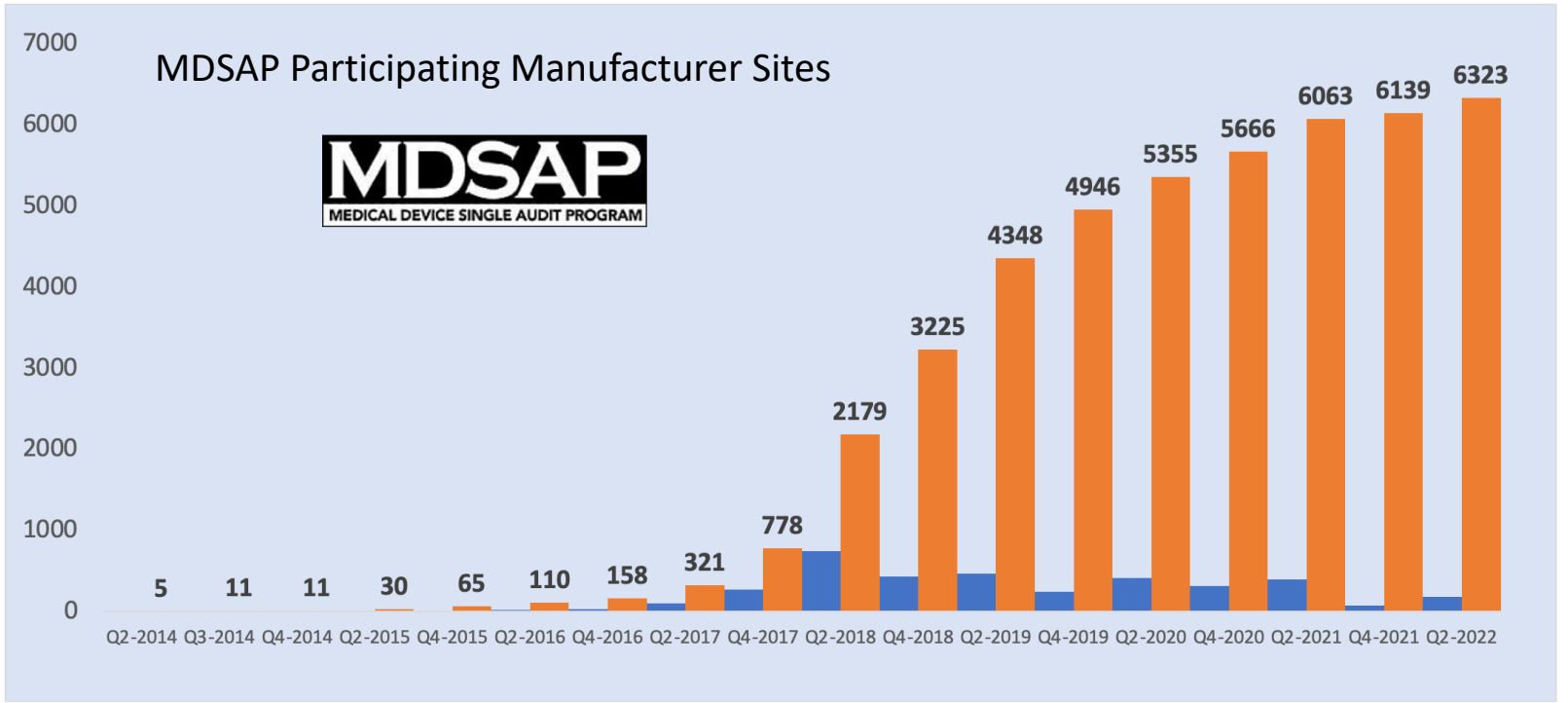
- To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices

MDSAP Members

MDSAP Official Members

MDSAP Official Observers

MDSAP Affiliate Members



ANVISA's Certificates Issued Based on MDSAP Reports

Year	# GMP Certificates Issued Based on MDSAP Reports (% of total)
2017	38 (4.7%)
2018	107 (19,3%)
2019	374 (48,7%)
2020	544 (49,1%)
2021	529 (51,4%)
2022	621 (59,7%)
2023	412 (62,6%)

Until 31 August

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Auditing Organizations Assessment Program Assessment Criteria

- IMDRF/MDSAP-WG/N3
- IMDRF/MDSAP-WG/N4
- IMDRF/MDSAP-WG/N5
- IMDRF/MDSAP-WG/N11

- ISO 17021:2015

Available at https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-documents

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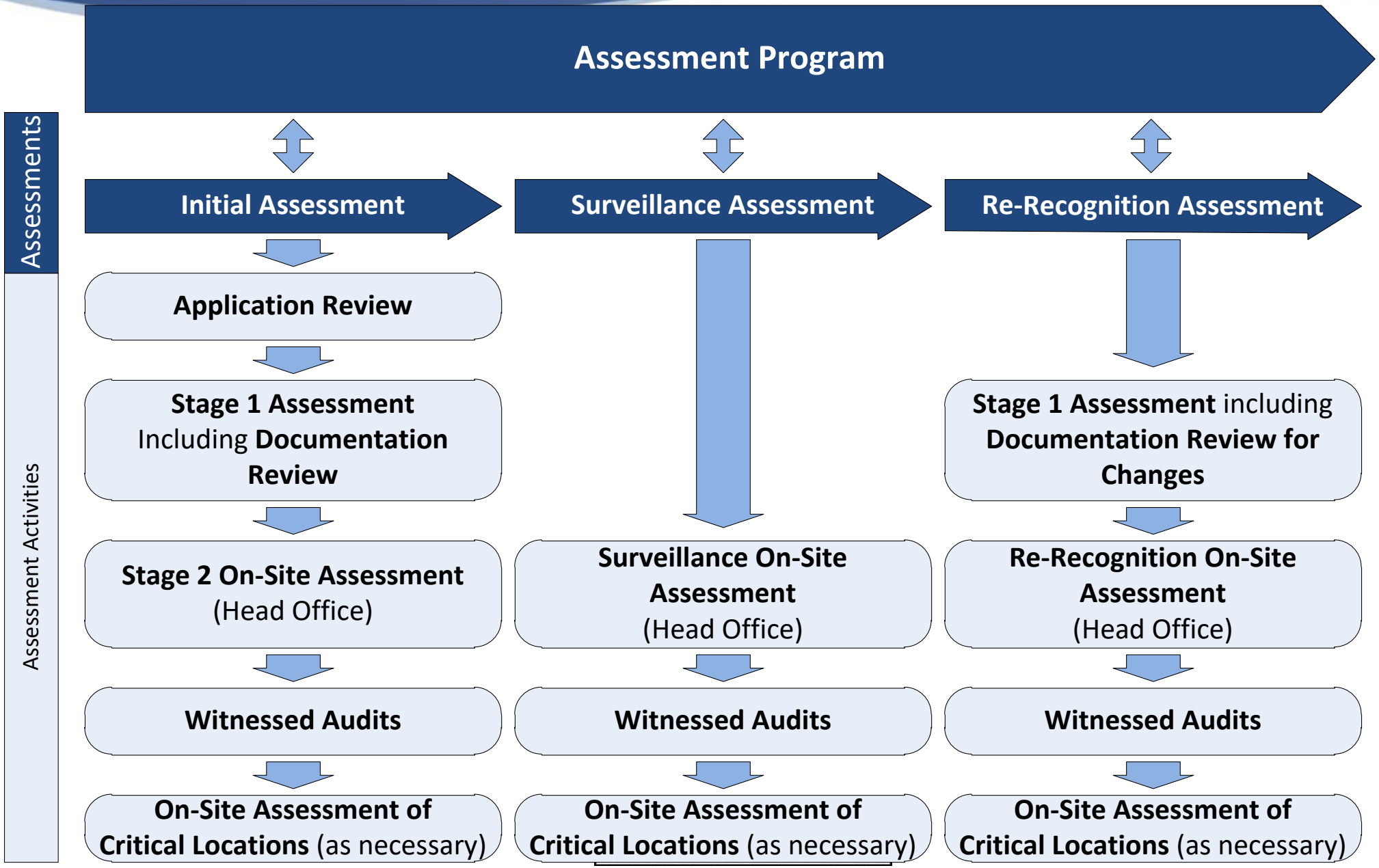
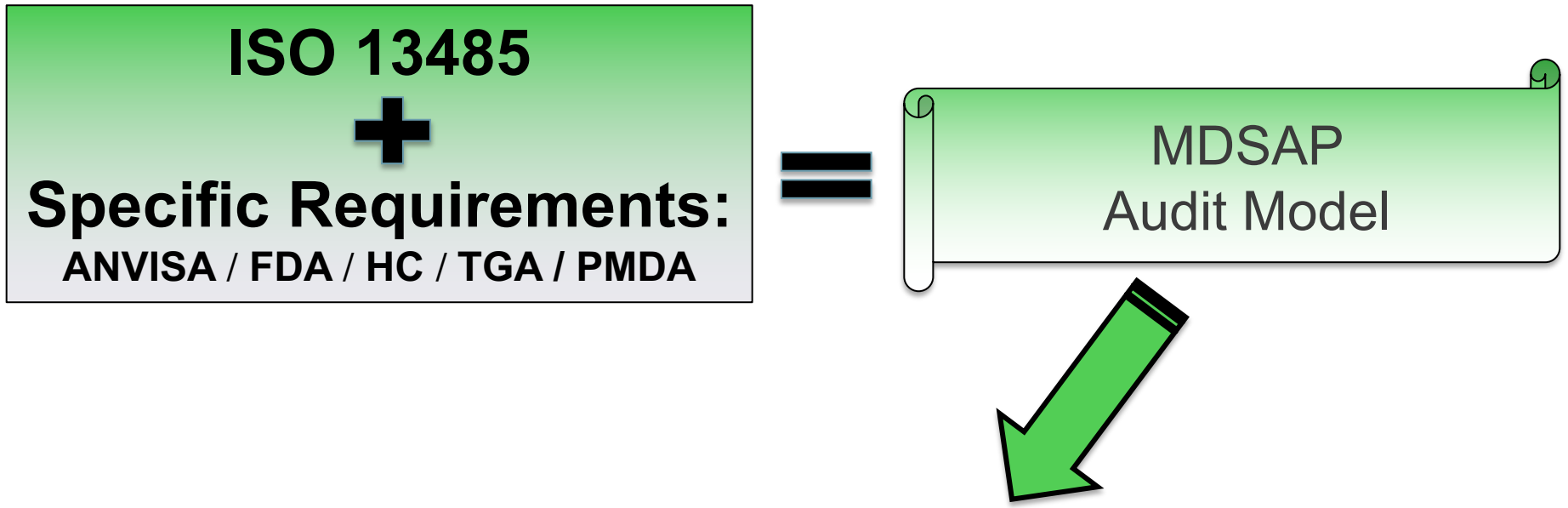

Assessment Program
Assessments
Assessment Activities
Initial Assessment
Surveillance Assessment
Re-Recognition Assessment
Application Review
Stage 1 Assessment Including Documentation Review
Stage 2 On-Site Assessment (Head Office)
Witnessed Audits
On-Site Assessment of Critical Locations (as necessary)
Surveillance On-Site Assessment (Head Office)
Witnessed Audits
On-Site Assessment of Critical Locations (as necessary)
Stage 1 Assessment including Documentation Review for Changes
Re-Recognition On-Site Assessment (Head Office)
Witnessed Audits
On-Site Assessment of Critical Locations (as necessary)

Auditing Organizations	Status
BSI Group America	Recognized
TUV SUD America Inc.	Recognized
Intertek Testing Services	Recognized
UL Medical and regulatory Services of UL, LLC	Recognized
SGS UK Ltd.	Recognized
DEKRA Certification B.V.	Recognized
TUV Rheinland N.A. Inc.	Recognized
LNE G-MED	Recognized
TUV USA Inc.	Recognized
NSAI	Recognized
DQS Med	Recognized
NCC Certificacoes do Brasil Ltd.	Authorized
DNV Presafe	Authorized
DNV Medcert	Authorized

Audit Criteria in Manufacturers



MDSAP AU P0002: Audit Approach
MDSAP AU G0002: Audit Process Companion Document

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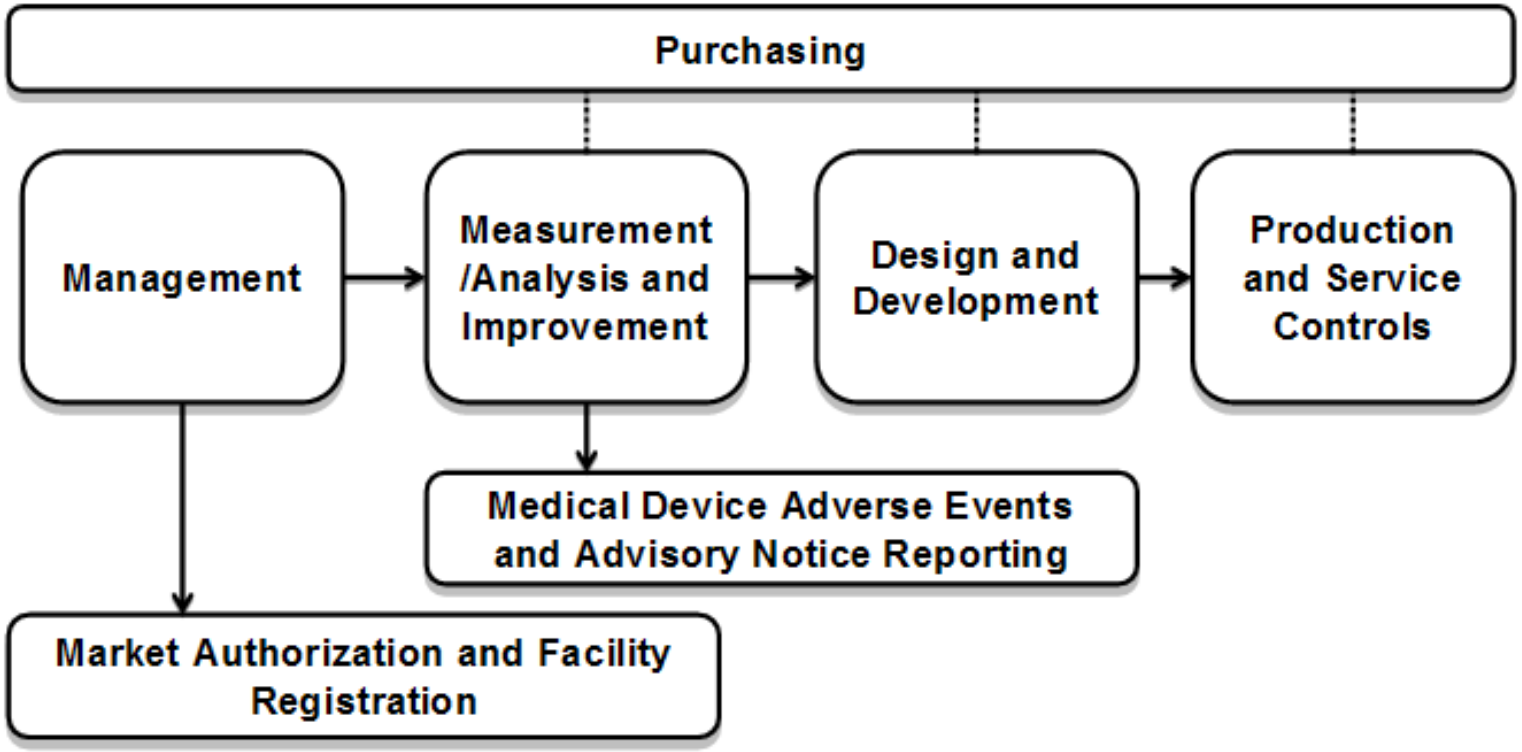
MDSAP Audit Sequence

- The MDSAP Audit Approach was designed for the audit of the MDSAP processes in the following sequence:



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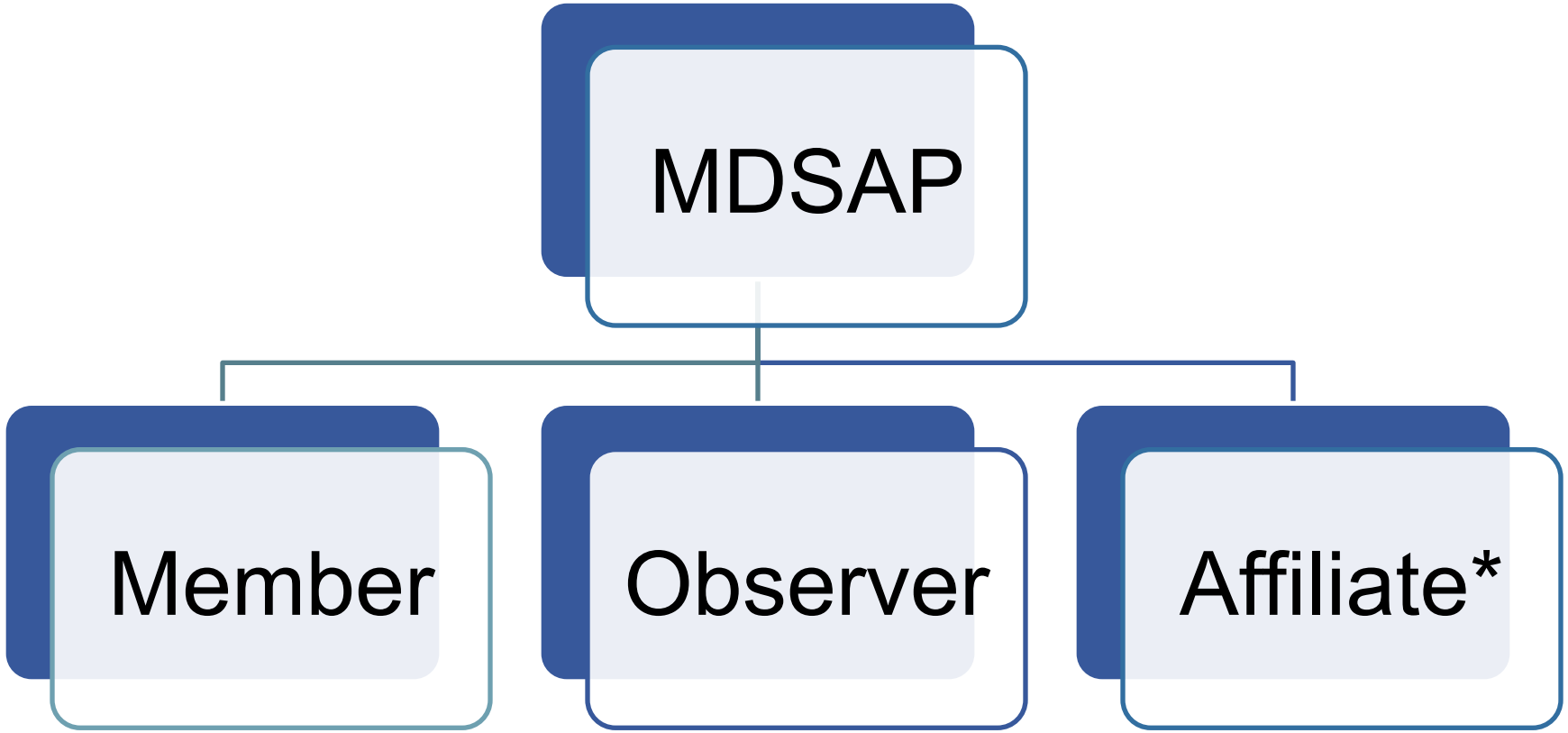
Expansion of MDSAP

- MDSAP is currently not accepting additional regulatory authorities as full Members or Observers
  - 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



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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 the new jurisdiction
  - Receive a routine list of MDSAP audits conducted, dates, location, and AO's
  - Listed on MDSAP website as an Affiliate Member
  - Participate in yearly MDSAP Forum meetings

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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 / Country
  - Initial Audit Start Date
  - Initial Audit End Date
  - Next Target Audit 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

mdsap.atendimento@anvisa.gov.br

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