MDSAP Program Introduction

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What is MDSAP?

The Medical Device Single Audit Program (MDSAP) is a regulatory audit program that allows a manufacturer to have a single quality management system audit to satisfy the requirements of all participating regulatory authorities.

Regulatory Authorities

Auditing Organizations

Medical Devices Manufacturers

Assessment Program

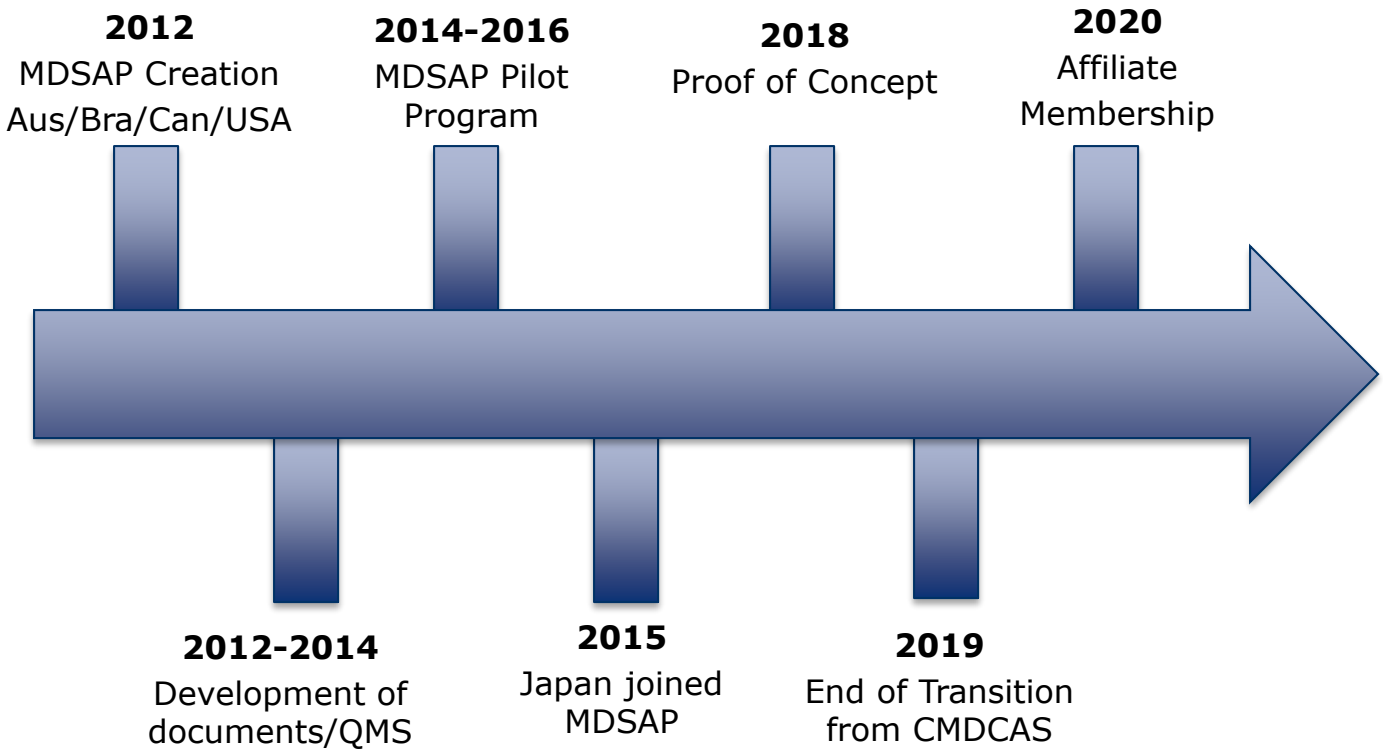
Audit Program

Audit Reports

MDSAP Objectives

- **To run a unified audit program that ensures reliable outcomes.;**
- **To ensure effective regulatory oversight of manufacturers' quality systems while reducing industry burden.;**
- **To enhance regulatory efficiency through collaboration and mutual acceptance, respecting each authority's autonomy;**
- **To foster global alignment of regulatory approaches and technical standards, following best practices.**

MDSAP Timeline



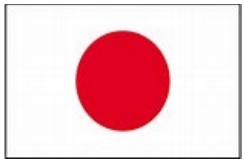
MDSAP Members

Official Members

Australia Therapeutic Goods Administration (TGA)

Brazil Agência Nacional de Vigilância Sanitária (ANVISA)

Canada Health Canada (HC)



Japan (MHLW/PMDA)

US Food and Drug Administration (FDA)

MDSAP Members

Official Observers

World Health Organization (WHO)

European Union (EU)

Medicines and Healthcare Regulatory Agency (MHRA)

Singapore's Health Sciences Authority (HSA)

MDSAP Members

Affiliate Members

Federal Commission for Protection from Sanitary Risks (COFEPRIS) of Mexico

Korea's Ministry of Food and Drug Safety (MFDS)

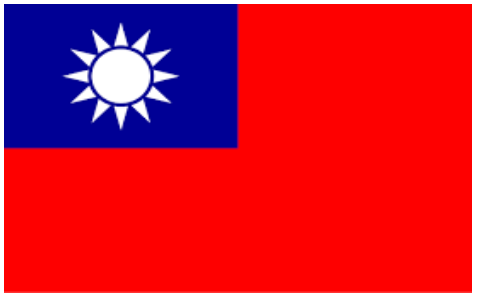
Ministry of Health of Israel

Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)

MDSAP Members

Afilliate Members

Kenya's Pharmacy and Poisons Board



TFDA - Taiwan Food and Drug Administration

South African Health Products Regulatory Authority (SAHPRA)

How the Auditing Organizations are evaluated and recognized under MDSAP?

Assessment Criteria

ISO/IEC 17021-1:2015 Conformity assessment Requirements for bodies providing audit and certification of management systems

IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2) *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*

IMDRF/MDSAP WG/N4 FINAL:2021 (Edition 2) *Competence and Training Requirements for Auditing Organizations*

What are the requirements verified in the MDSAP Audit?

MDSAP Audit Criteria

ISO 13485

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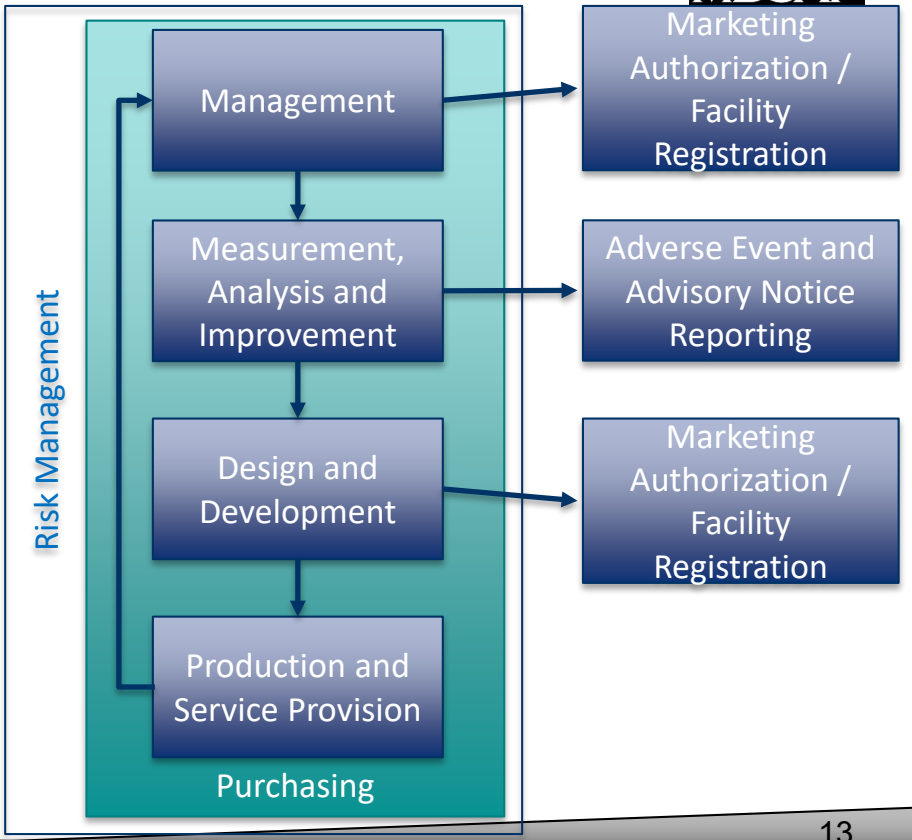
Specific Requirements:

MDSAP AUDIT APPROACH



The use of MDSAP

Manufacturers:
MDSAP allows any medical device manufacturer to contract with an MDSAP AO to have a single audit that meets the requirements of the participating Regulatory Authorities.

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

The MDSAP promotes global regulatory harmonization, increasing efficiency and quality in managing medical devices while building mutual trust and easing the regulatory workload.


¡Muchas
Gracias!


OBRIGADO
THANK YOU
Thank You
Obrigado
Asante
Merci
Grazie
Kiitos
Juspaxar
Chokrane
Mochchakkeram
Terima Kasih
Spasibo
Arigato
Welalin
Multumesc
Vinaka
Salamat
Dank Je
Motondo
Matur Nuwun
Cam on ban
Maake