HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 1 IMDRF Industry Joint Workshop| 09 March 2026

Using MDSAP in reliance

Kenichi Ishibashi

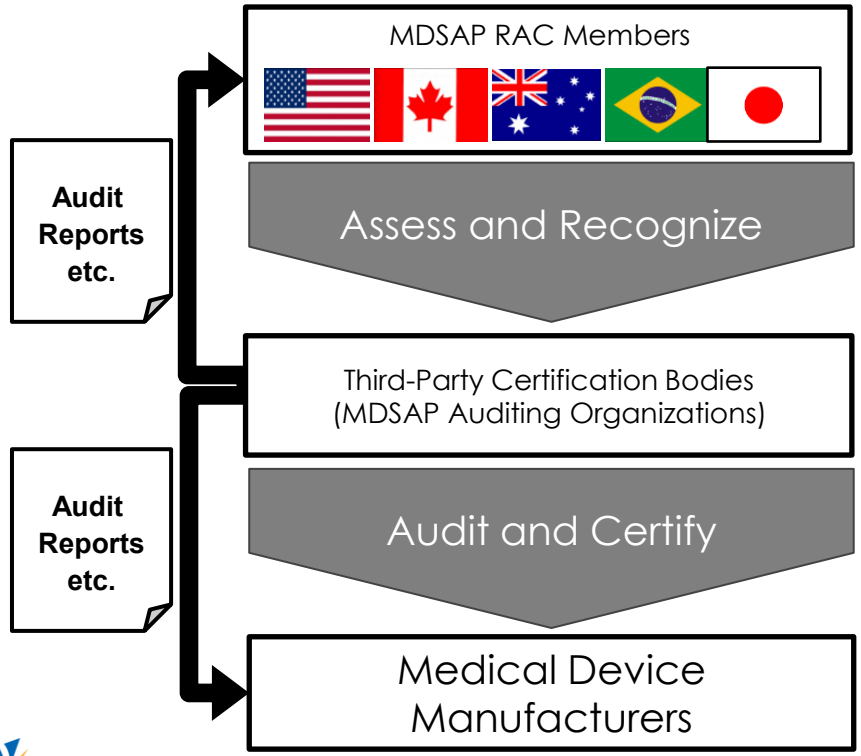
Senior Scientist

PMDA, Japan

Today's Topic

- MDSAP Overview
- MDSAP: Experience in Japan
- Japan's Outreach Initiatives on MDSAP

What is MDSAP?



1. The regulatory authorities (RAs) jointly assess third-party certification bodies, known as MDSAP Auditing Organizations. Through this work-sharing arrangement, RAs can effectively utilize regulatory resources.

2. MDSAP Auditing Organizations conduct audits on manufacturers instead of RAs. The outcome of these audits are then shared with RAs, which utilize them for regulatory purposes.

3. Manufacturers can circumvent frequent audits by RAs, thus alleviating their operational burden.

MDSAP Members

MDSAP RAC Members

Australia, Brazil, Canada, Japan, US

Official Observers

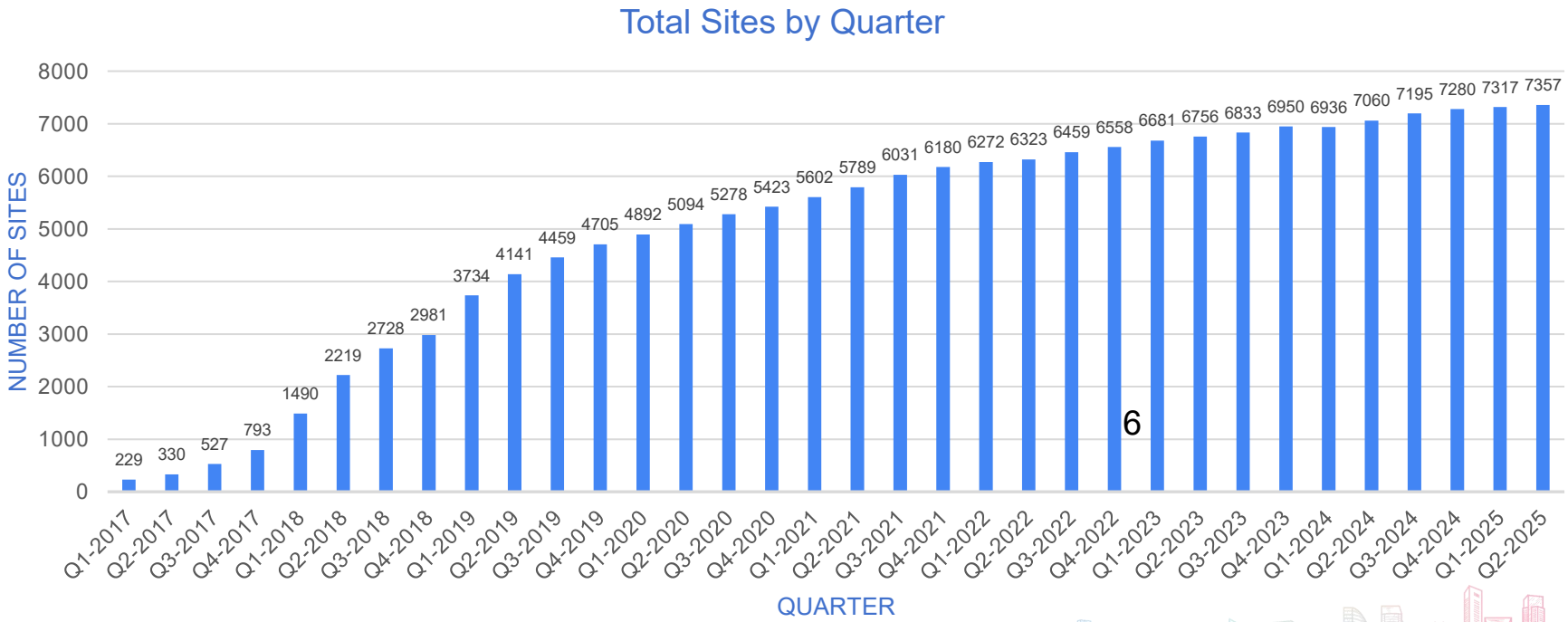
EU, Singapore, UK, WHO

Affiliate Members

New!

Argentine, Israel, Kenya, Mexico, South Korea, South Africa, Chinese Taipei, Malaysia

MDSAP Participating Facilities



MDSAP Today

31,426

Number of MDSAP Audits Conducted
(January 2018-May 2025)

15

Number of Auditing Organizations able to conduct MDSAP audits

82

Number of Countries where MDSAP Audits occurred

7,357

Number of Active Facilities Participating with MDSAP

Today's Topic

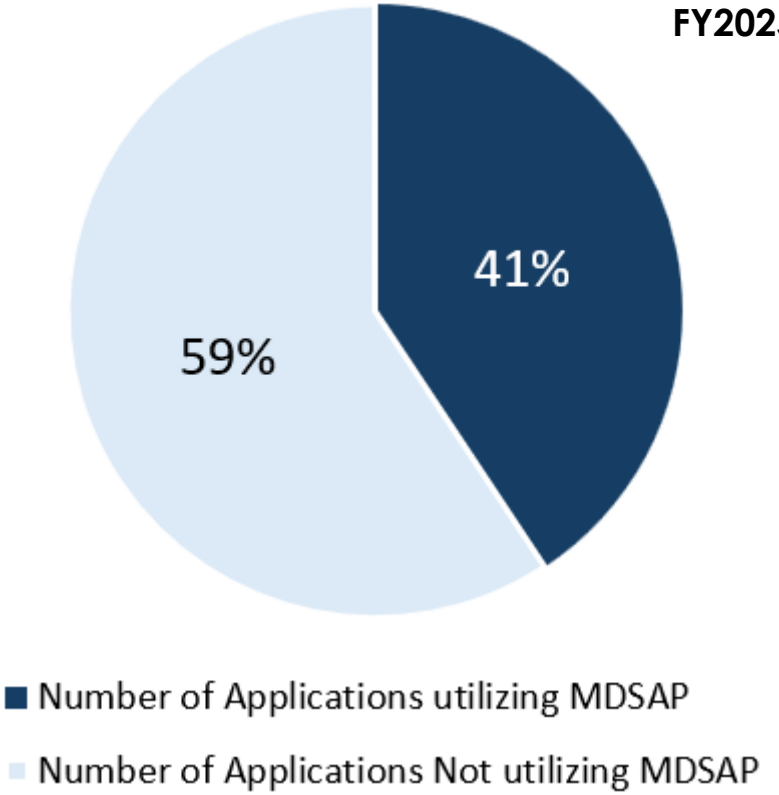
MDSAP Overview

MDSAP: Experience in Japan

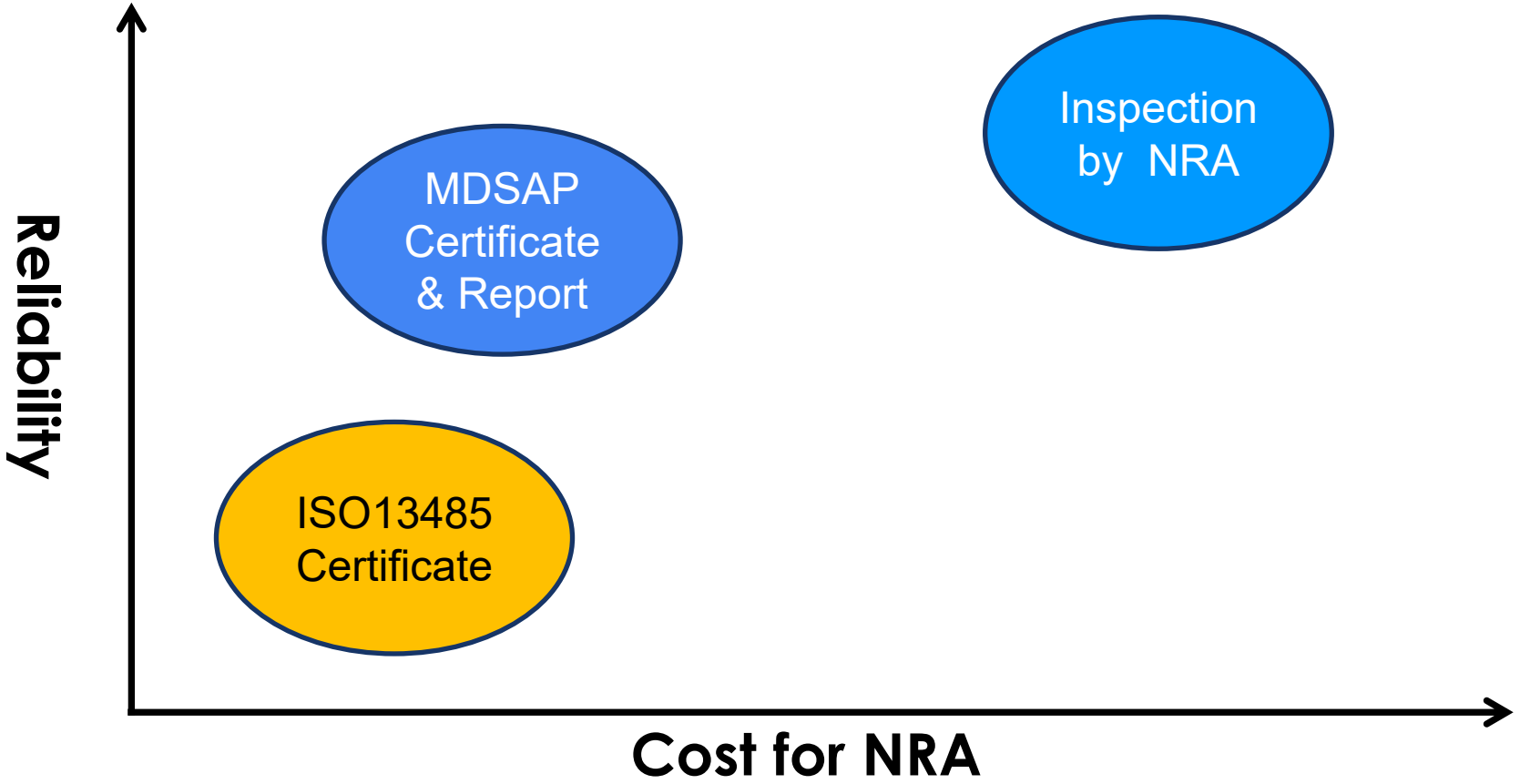
Japan's Outreach Initiatives on MDSAP

FY2025* Use of MDSAP in Japan

FY2025*: April 2025 to January 2026

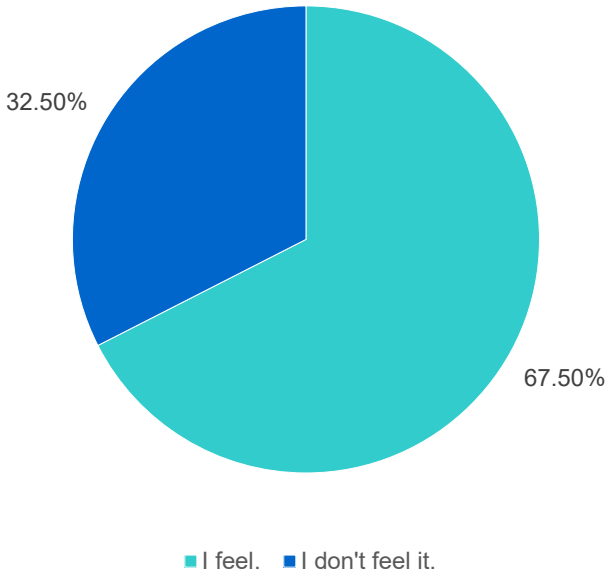


Characteristics of MDSAP from a RA Perspective

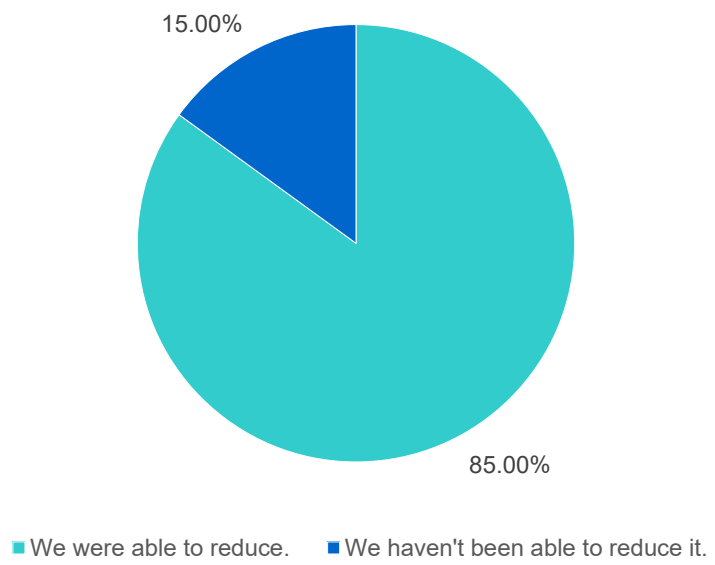


MDSAP Survey Results in Japan (2024)

Did the organization see a cost benefit from the MDSAP audit?



Has the organization been able to reduce on-site audits through MDSAP audits?




Regulatory Authority
Manufacturer

Today's Topic

MDSAP Overview

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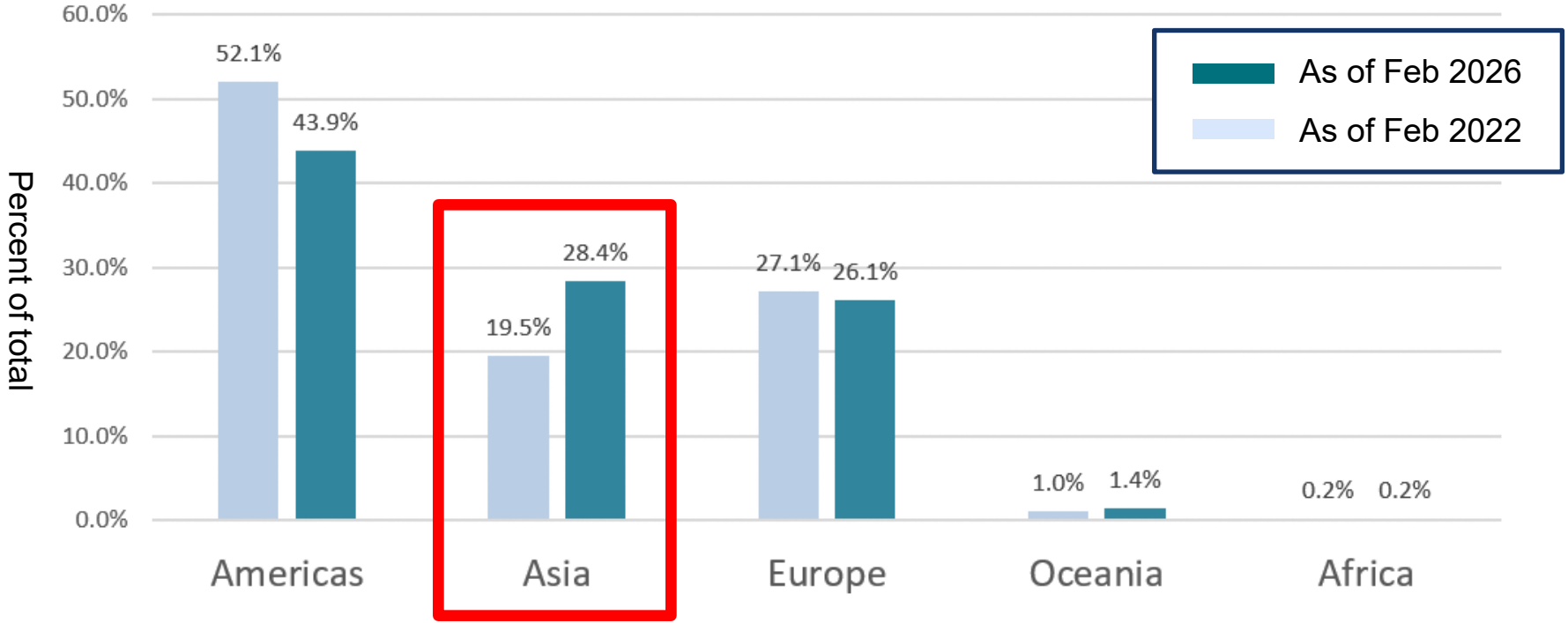
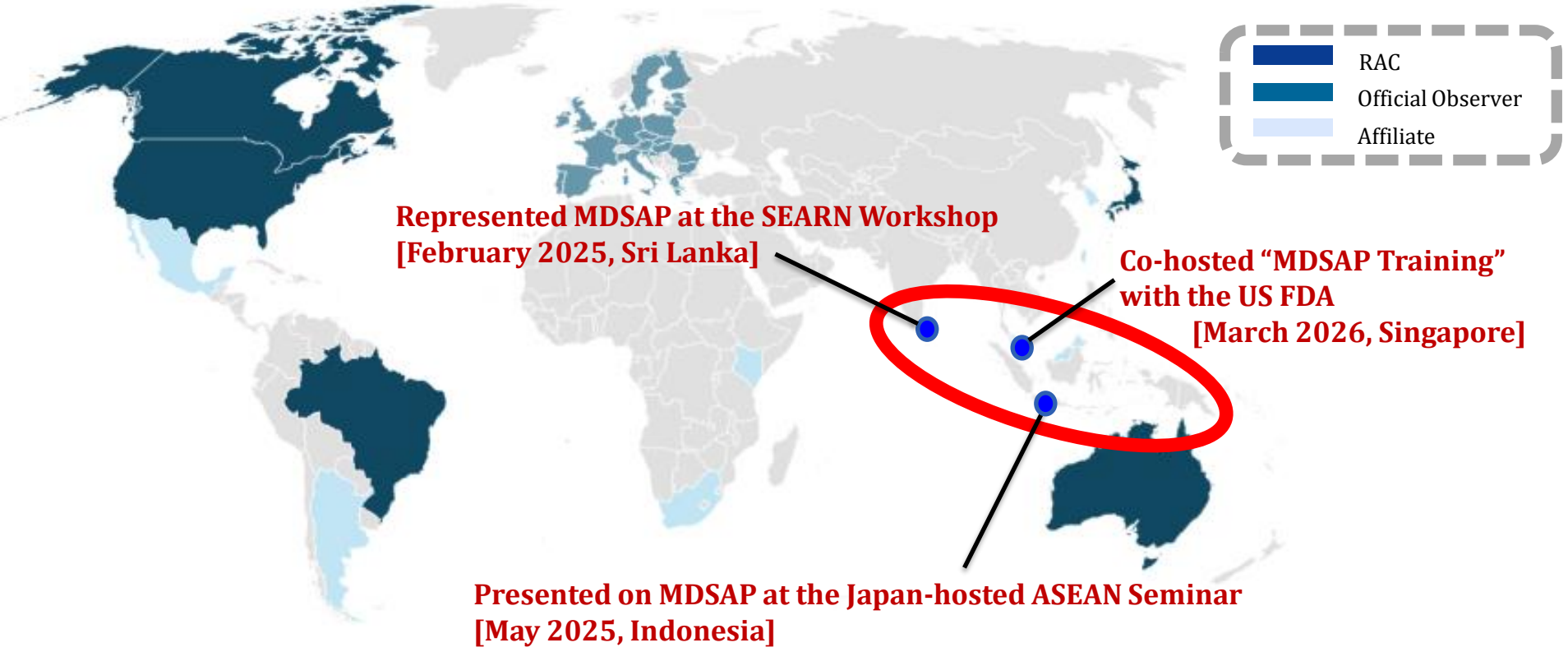
MDSAP Sites by Continent



Japan's Outreach Initiatives on MDSAP



Since 2025, Japan has been conducting outreach activities on MDSAP in the Asian region.

2026 MDSAP Forum
Kyoto, Japan

June 15–19, 2026

International Conference Center Kyoto (ICC Kyoto)

Register: https://2026mdsapforum.omcst.org/registration/

Contact: mdsapforum2026_secretariat@pmda.go.jp

Venue Website

Event Website

Thank You!

Contact: ishibashi-kenichi@pmda.go.jp

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What makes an MDSAP audit output suitable for regulatory reliance?

Thiago Rezende Pereira Cunha

International Affairs / MDSAP Vice-Chair

ANVISA - Brazil

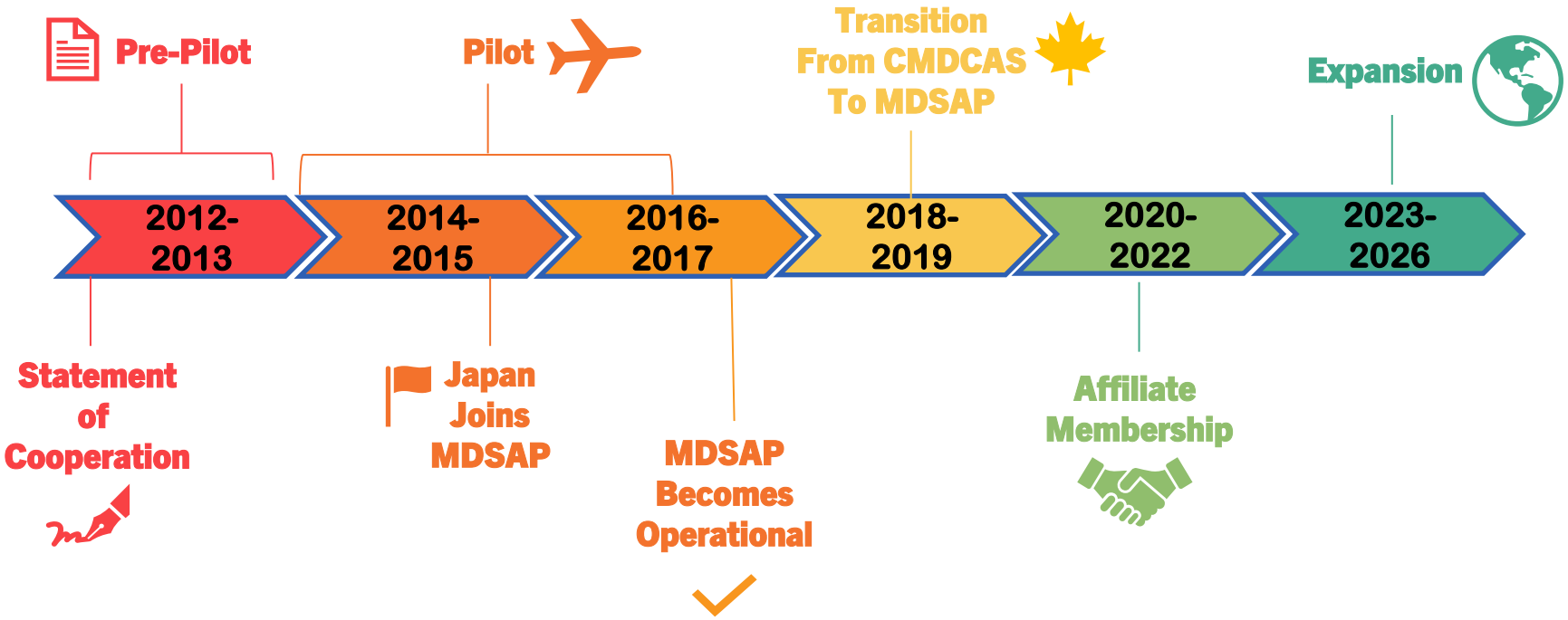
What makes an MDSAP audit output suitable for regulatory reliance?

1. Development Process
2. MDSAP Audit Criteria
3. Assessment Program
4. Reliable Outputs

MDSAP
Medical Device Single Audit Program


Regulatory Authorities
Auditing Organizations
Medical Devices Manufacturers
Assessment Program
Audit Program
Audit Reports

1. Development Process



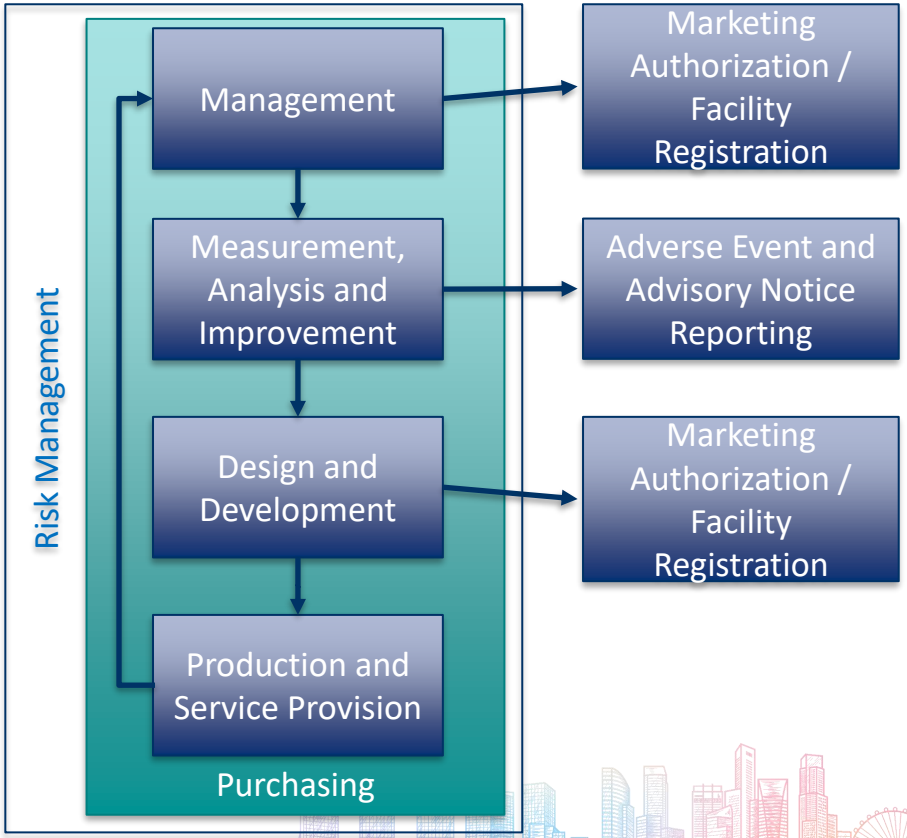
2. MDSAP Audit Criteria

ISO 13485

+

Specific Requirements:

MDSAP AUDIT APPROACH



3 - Assessment Program

ISO 17021:2015

+

IMDRF/MDSAP/N3

+

IMDRF/MDSAP/N4

Assessment Activities

- Management
- Use of external resources
- Measurement, Analysis & Improvement
- Competence Management
- Audit and certification decision
- Information Management

Assessment Program

Initial

- Application Review
- Stage 1 Documentation Review
- Stage 2 On-Site Assessment

AUTHORIZATION

- 3 Witnessed Audits
- On-Site Critical Location Assessment (as needed)

RECOGNIZE

Surveillance

1	2	3
Stage 2 On-Site Assessment	1 Witnessed Audit	1 Witnessed Audit Per Critical Location

Re-Recognition

- Stage 1 On-Site Assessment
- On-Site Re-recognition Assessment
- 1 Witnessed Audit
- 1 Witnessed Audit Per Critical Location

Re-Recognize

MDSAP Witnessed Audits

4 – Reliable Outputs

MDSAP Certificates

- Must allow authenticity check

MDSAP Reports

- Download direct from REPs

Use of MDSAP by Anvisa – Pre Market

Brazilian GMP Certificate

- Compulsory for market authorization of devices Risk Class III and IV

MDSAP Reports

- Used for granting Anvisa GMP certifications

MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

*Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, o Decreto nº 3.029, de 16 de abril de 1999 e a publicação no Diário Oficial da União por meio da Resolução RE nº **1.843** na data de 29/05/2023certifico que a empresa, a seguir descrita, cumpre com a legislação sanitária vigente, quanto às Boas Práticas de Fabricação de produtos para saúde exigidas pela autoridade sanitária brasileira, estando sujeita a inspeções periódicas.*

Empresa: Labtest Diagnóstica S/A CNPJ: 16.516.296/0001-38

Endereço: Avenida Paulo Ferreira da Costa, nº 600, Distrito Industrial Vista Alegre, Lagoa Santa, Minas Gerais CEP: 33400-000

Autorização: 1000901 Expediente: 4873435/22-6

Certificado de Boas Práticas de Fabricação de Produtos para Saúde:

Produtos para diagnóstico de uso in vitro das classes III e IV.

Motivo: Publicado deferimento, subsidiado por critérios renovação automática

Validade até: 29/05/2025

Documento assinado eletronicamente por **Marcus Aurelio Miranda de Araujo, Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 01/06/2023, às 14:55, conforme horário oficial de Brasília, com fundamento no § 3º do art. 4º do Decreto nº 10.543, de 13 de novembro de 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.

A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **2408225** e o código CRC **B6385209**.

Use of MDSAP by Anvisa – Postmarket

MDSAP 5-Day Notices

- Open investigation / Risk Evaluation
  - ➢ Product suspension
  - ➢ Anvisa Onsite inspection

Thank You!

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Using MDSAP in reliance

Graeme Tunbridge

SVP, Global Regulatory and Quality

BSI

The role of an Auditing Organisation

Regulatory Authorities (RA)

- Manage the program
- Assess and recognise AOs
- Utilise outputs within their marketing authorisation or apply other regulatory easement

Auditing Organisations (AO)

- Conduct QMS audit of MF
- Share audit reports with RAs
- Issue MDSAP certification
- Act upon instructions from RAs

Manufacturers (MF)

- Receive a single QMS audit from AO instead of multiple inspections from various RAs
- Apply for marketing authorisation and/or regulatory easement to RAs

Being an Auditing Organisation

BS EN ISO/IEC 17021-1:2015

BSI Standards Publication

Conformity assessment - Requirements for bodies providing audit and certification of management systems

Part 1: Requirements

IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2)

IMDRF International Medical Device Regulators Forum

Final Document

International Medical Device Regulators Forum

Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

g Group: IMDRF MDSAP Working Group

24 March 2016

Fabio Pereira Quintino, IMDRF Chair

IMDRF/MDSAP WG/N4FINAL:2021 (Edition 2)

IMDRF International Medical Device Regulators Forum

Final Document

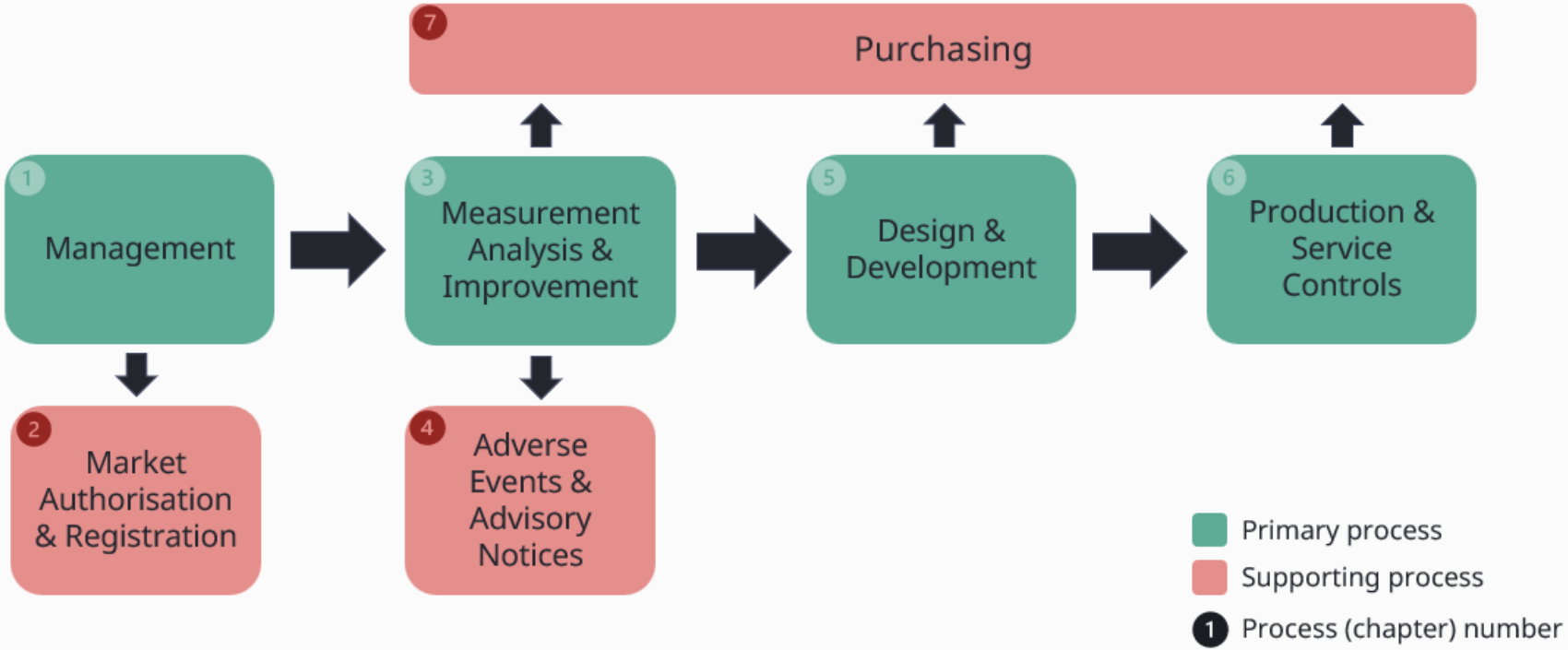
Competence and Training Requirements for Auditing Organizations

ıg Group: IMDRF MDSAP Working Group

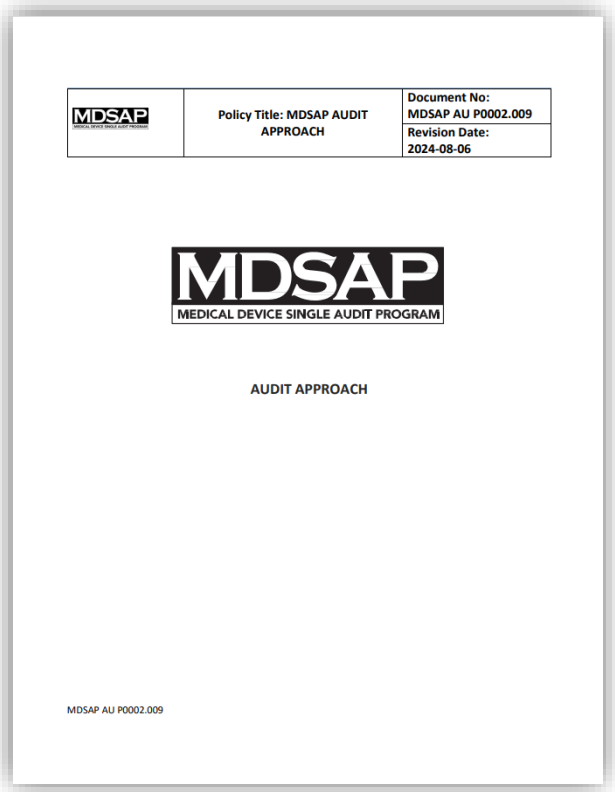
16 September 2021

Oh-Sang Kwon, IMDRF Chair

The audit approach



The audit approach



MDSAP	Policy Title: MDSAP AUDIT APPROACH	Document No: MDSAP AU P0002.009
		Revision Date: 2024-08-06

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

AUDIT APPROACH

MDSAP AU P0002.009

- A manual for conducting MDSAP audits – publicly available
- Comprises a set of tasks for each process
- Tasks linked to ISO 13485 clauses and country-specific requirements
- Facilitates consistency, predictability and transparency

The audit process

Task 6 – Personnel Competency and Training

Confirm the medical device organisation has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives.

Ensure records of training and competencies are maintained.

Clause and Regulation

ISO: ISO 13485:2016: 4.2.1, 6.2

ANVISA: RDC ANVISA 665/2022: Art. 8°, Art. 13, Art. 14, Art. 15

MHLW/PMDA: MO169: 6, 22, 23

FDA: 21 CFR 820.20(b)(2), 820.25

Additional country-specific requirements

Brazil (ANVISA):

Confirm that the manufacturer ensures that any consultant who gives advice regarding design, purchasing, manufacturing, packaging, labeling, storage, installation, or servicing of medical devices has proper qualification to perform such tasks. Those consultants shall be contracted as a formal service supplier, according to purchasing controls defined by the manufacturer [RDC ANVISA 665/2022: Art. 16, Art. 17].

Audit outputs

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

Facility ID Number: F000334

Holds Certificate No: **MDSAP 680668**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-15 Effective Date: 2022-04-01 Expiry Date: 2024-04-05

Page: 1 of 5

MDSAP

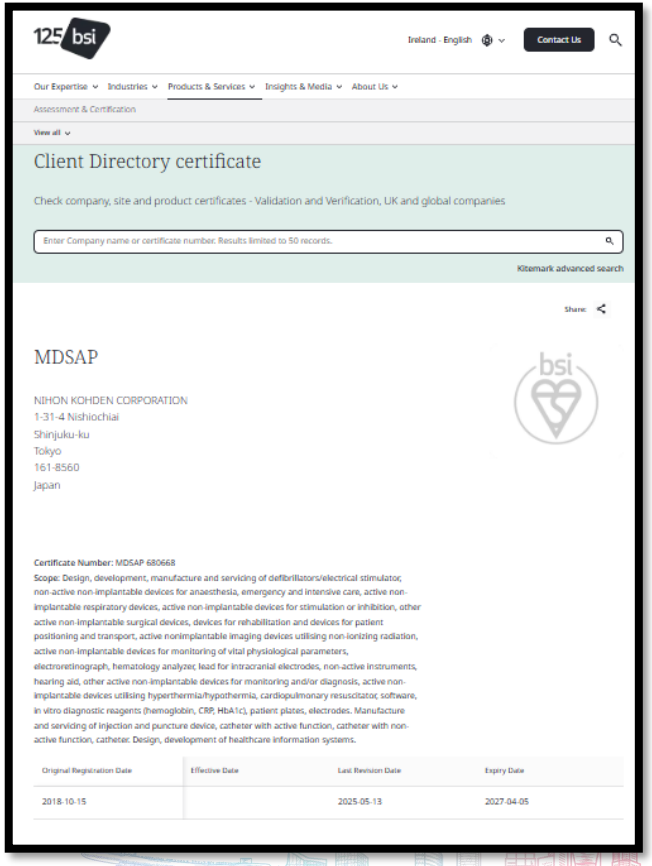
...making excellence a habit.

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

COPY

Verification



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Assessment & Certification

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Enter Company name or certificate number. Results limited to 50 records.

Kitemark advanced search

Share

MDSAP

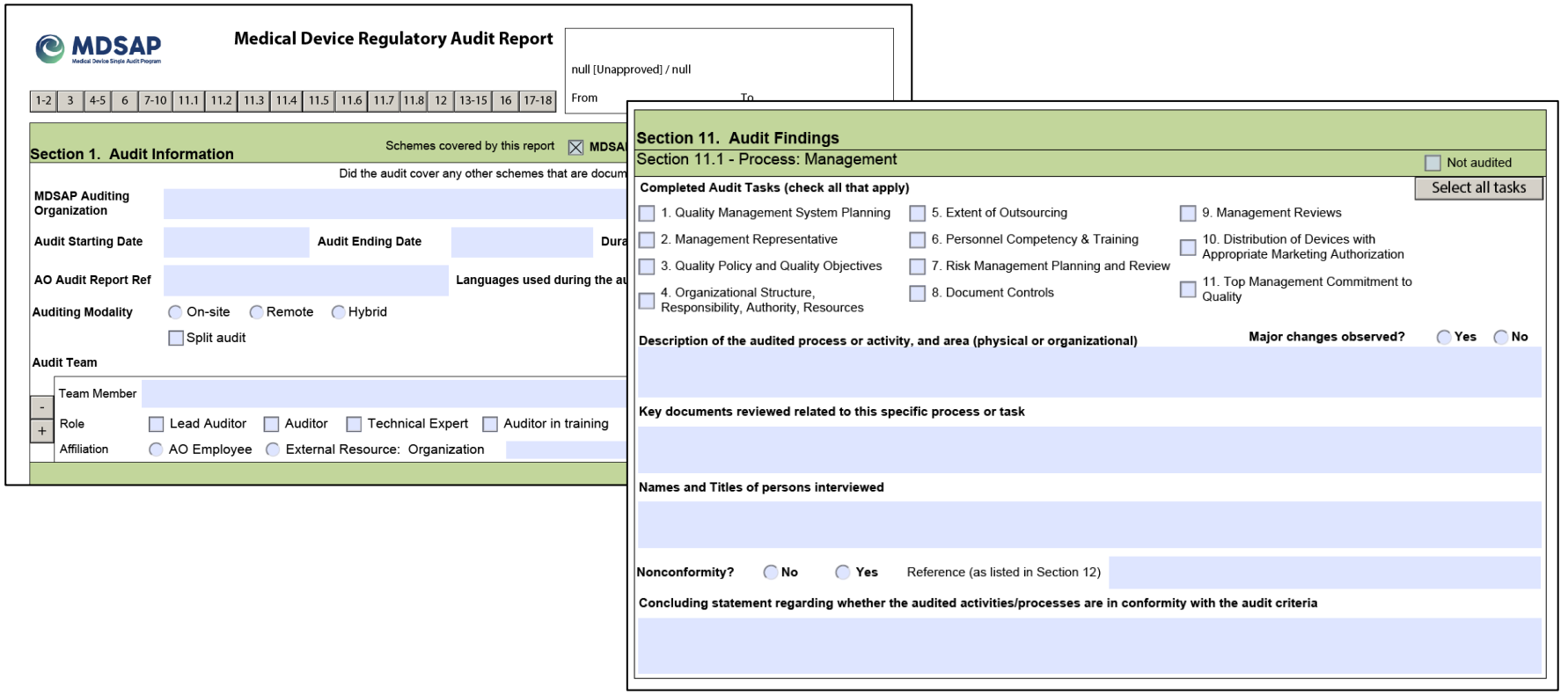
NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

Certificate Number: MDSAP 680668

Scope: Design, development, manufacture and servicing of defibrillators/electrical stimulator, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, devices for rehabilitation and devices for patient positioning and transport, active nonimplantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, electroretinograph, hematology analyzer, lead for intracranial electrodes, non-active instruments, hearing aid, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices utilising hyperthermia/hypothermia, cardiopulmonary resuscitator, software, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), patient plates, electrodes. Manufacture and servicing of injection and puncture device, catheter with active function, catheter with non-active function, catheter. Design, development of healthcare information systems.

Original Registration Date	Effective Date	Last Revision Date	Expiry Date
2018-10-15		2025-05-13	2027-04-05

Audit outputs



MDSAP
Medical Device Single Audit Program

Medical Device Regulatory Audit Report

null [Unapproved] / null

From To

1-2 | 3 | 4-5 | 6 | 7-10 | 11.1 | 11.2 | 11.3 | 11.4 | 11.5 | 11.6 | 11.7 | 11.8 | 12 | 13-15 | 16 | 17-18

Section 1. Audit Information

Schemes covered by this report ☒ MDSAP

Did the audit cover any other schemes that are docum

MDSAP Auditing Organization

Audit Starting Date **Audit Ending Date** **Dura**

AO Audit Report Ref **Languages used during the au**

Auditing Modality ○ On-site ○ Remote ○ Hybrid

☐ Split audit

Audit Team

Team Member

Role ☐ Lead Auditor ☐ Auditor ☐ Technical Expert ☐ Auditor in training

Affiliation ○ AO Employee ○ External Resource: Organization

Section 11. Audit Findings

Section 11.1 - Process: Management

☐ Not audited

Completed Audit Tasks (check all that apply)

Select all tasks

☐ 1. Quality Management System Planning
☐ 2. Management Representative
☐ 3. Quality Policy and Quality Objectives
☐ 4. Organizational Structure, Responsibility, Authority, Resources
☐ 5. Extent of Outsourcing
☐ 6. Personnel Competency & Training
☐ 7. Risk Management Planning and Review
☐ 8. Document Controls
☐ 9. Management Reviews
☐ 10. Distribution of Devices with Appropriate Marketing Authorization
☐ 11. Top Management Commitment to Quality

Description of the audited process or activity, and area (physical or organizational)

Major changes observed? ○ Yes ○ No

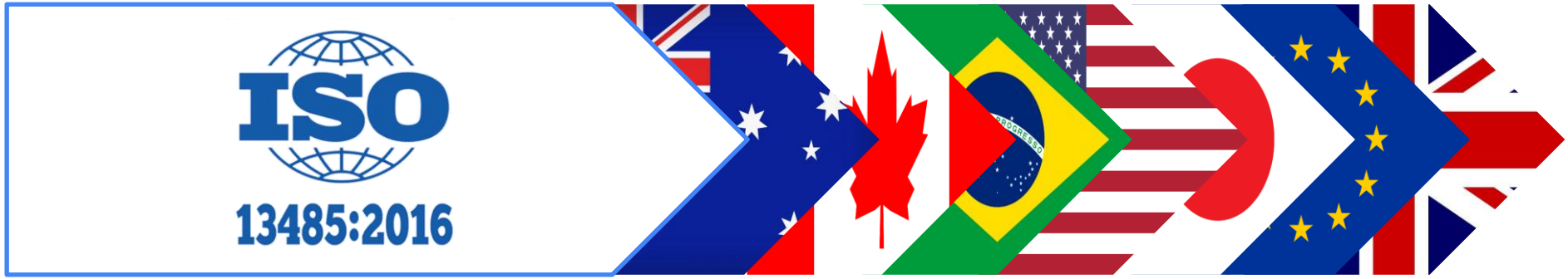
Key documents reviewed related to this specific process or task

Names and Titles of persons interviewed

Nonconformity? ○ No ○ Yes Reference (as listed in Section 12)

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

Managing multiple audit schemes



Bringing MDSAP audits to life

Professional Background

- 30+ years in manufacturing, design engineering, and operations
- Worked with Zuellig Pharma, Siemens Medical Instruments, Volume Interactions, Western Digital, EPI, Reka
- Collaborations with A*STAR, ITE West, Nanyang Polytechnic
- Former VP Operations managing 250+ staff across functions

Audit Experience

- Role: Lead Auditor & Tutor – Medical Devices / QMS
- Standards: ISO 13485, MDSAP, GDPMDS/SS 620, MDR, MDD
- BSI Tenure:
  - **9 years and 1 month**
  - **Over 1,125 medical device audit days**
  - **120 MDSAP audit days (holding MDSAP codes since 2018)**
- To relax, enjoys streaming dramas such as The Night Manager and Steal

Thank You!

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MDSAP Postmarket Utilization at U.S. Food and Drug Administration

Kimberly Lewandowski-Walker

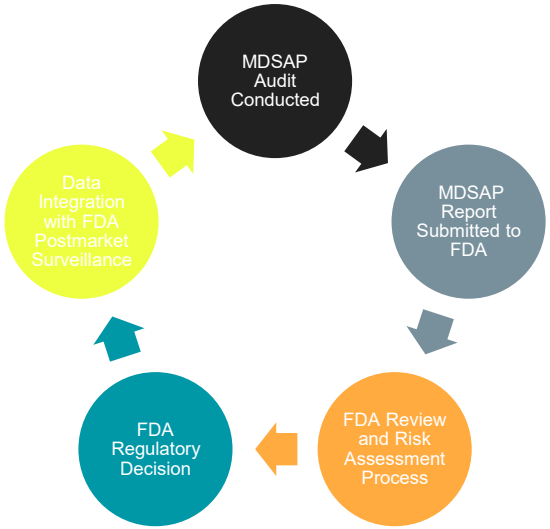
Regulatory Officer

U.S. Food and Drug Administration

Overview

- MDSAP provides regulatory intelligence for FDA for participating medical device manufacturers

- Benefits of participating in MDSAP
  - For FDA
  - For regulated industry



How does FDA Utilize MDSAP?

- Participating MDSAP organizations can be removed from the routine surveillance workplan for FDA inspections
- Provides regulatory intelligence for further FDA evaluation and review of the MDSAP Audit Report
- Follow-up on allegations of regulatory misconduct (complaints)
- Resolve import alerts for certain types of issues
- Follow-up on advisory actions (Warning Letters) in limited instances
- Preparation for marketing in the United States

Manufacturer Site Participation

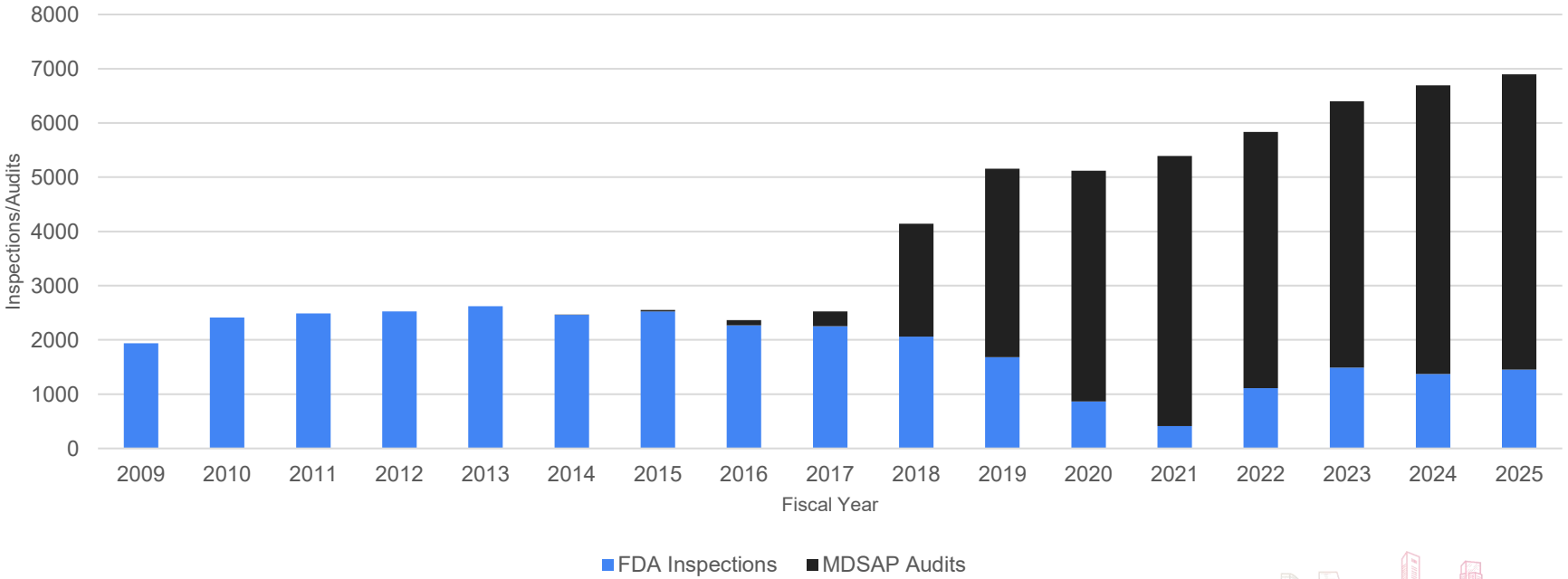
- 7,646 active MDSAP sites
- 4,033 (53%) are registered with FDA
- 6,409 unique FEIs
  - 2,155 domestic
  - 4,264 foreign

Regulatory Intelligence

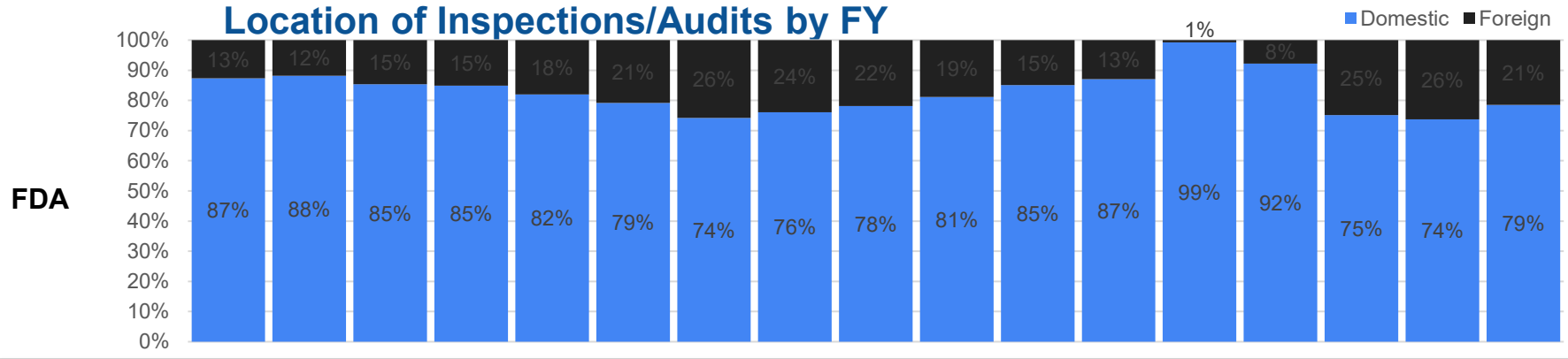
- MDSAP provides information to FDA as to the potential regulatory conformity of the audited organization

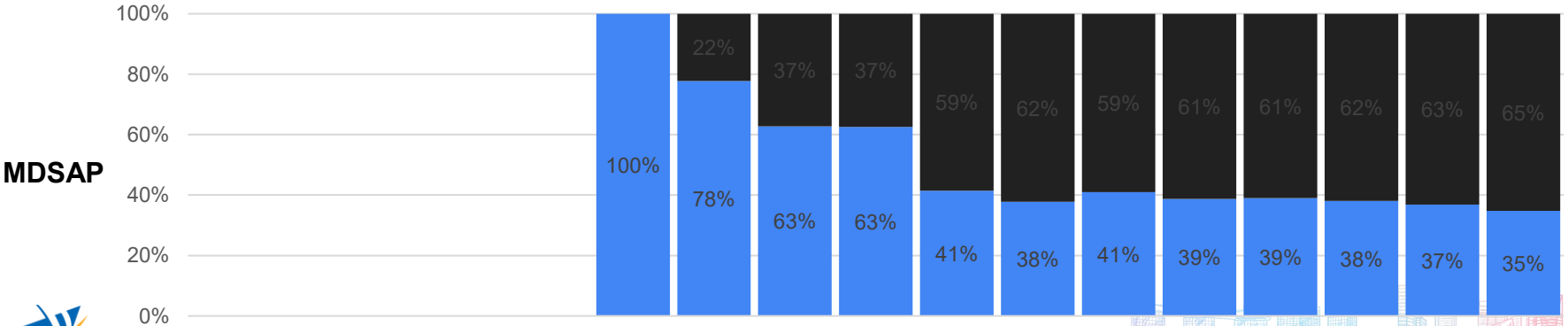
- Review of the MDSAP audit report by FDA can lead to regulatory meetings, directed inspections by FDA investigators, or advisory actions

MDSAP + FDA Inspections/Audits by FY



Location of Inspections/Audits by FY





Utilization of MDSAP Audits in Regulatory Decision Making

- Advisory Actions
- Allegation Follow-up
- Compliance meetings
- Preparation to enter US market
  - PMA approval considerations
  - Ensuring Quality System in place prior to marketing

Advisory Actions

- For some Warning Letters for general good manufacturing practice deficiencies (ex – no procedure for complaint handling), FDA can utilize an MDSAP audit report to close-out the Warning Letter if the MDSAP audit shows that the deficiencies that are the subject of the Warning Letter have been corrected.

Imports Data (CY25)

Device Class	Imported Device Lines	MDSAP Lines	% MDSAP
1	13,027,216	3,635,289	28%
2	12,673,462	5,750,988	45%
3	385,558	229,130	59%
Total	**26,086,236**	**9,615,407**	**37%**

- 9.6 million device lines were imported from 3,654 MDSAP-certified firms in 2025
- 37% of all imported device lines come from from MDSAP participants

Import Alerts

FDA has the option to use MDSAP audit reports:

- to support a decision to place a manufacturer on import alert for general good manufacturing practice violations.
- remove a manufacturer from import alert if the import alert was imposed based on general good manufacturing practice violations and the MDSAP audit report shows the violations have been corrected

Follow-up to Allegations

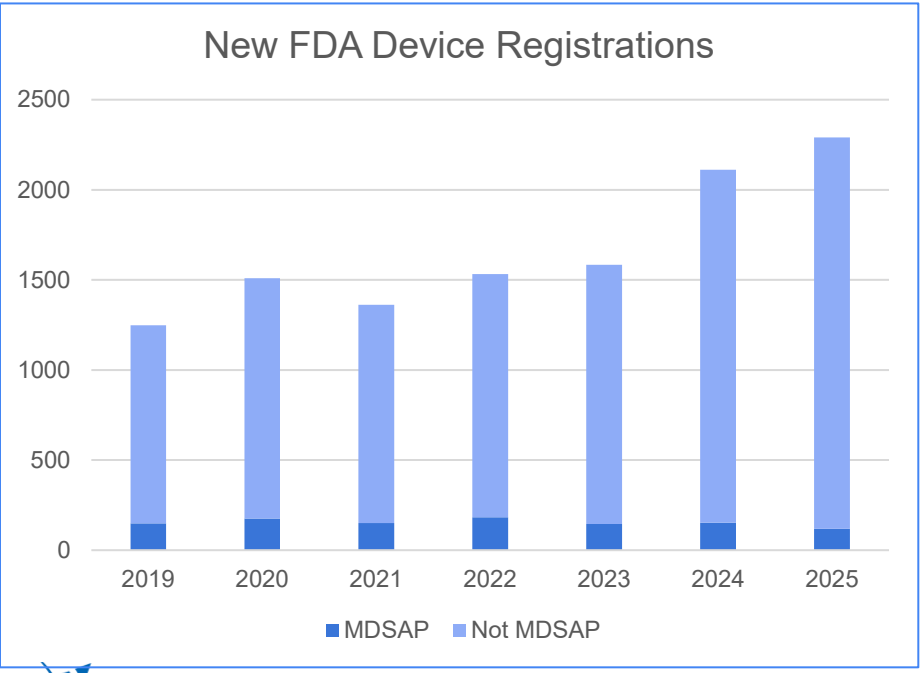
- In the case of allegations of regulatory misconduct (ex – whistleblower complaint) against a manufacturer participating in MDSAP, FDA can request that the MDSAP auditing organization follow-up on specific items that were communicated to FDA in the complaint

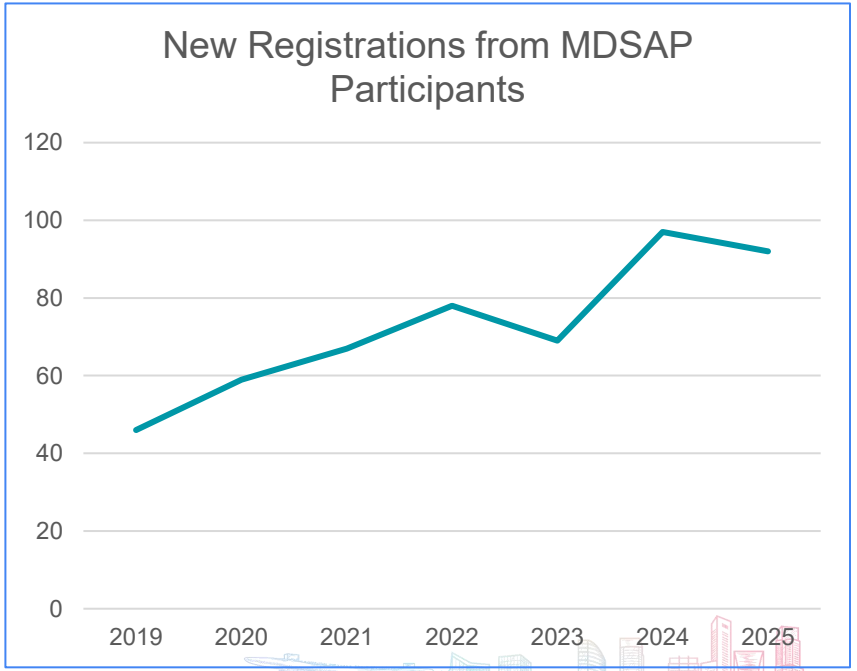
Preparation for Marketing

- Some medical device manufacturers have chosen to include the United States in their scope of certification prior to obtaining marketing authorization in the United States

- Can be helpful for the manufacturer in achieving compliance with FDA regulations in advance of marketing

New Device Registrations and MDSAP





Thank You!

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Using MDSAP and ISO 13485 to Strengthen Reliance in the Post-Market Phase of the TPLC

Kang-hyun KIM

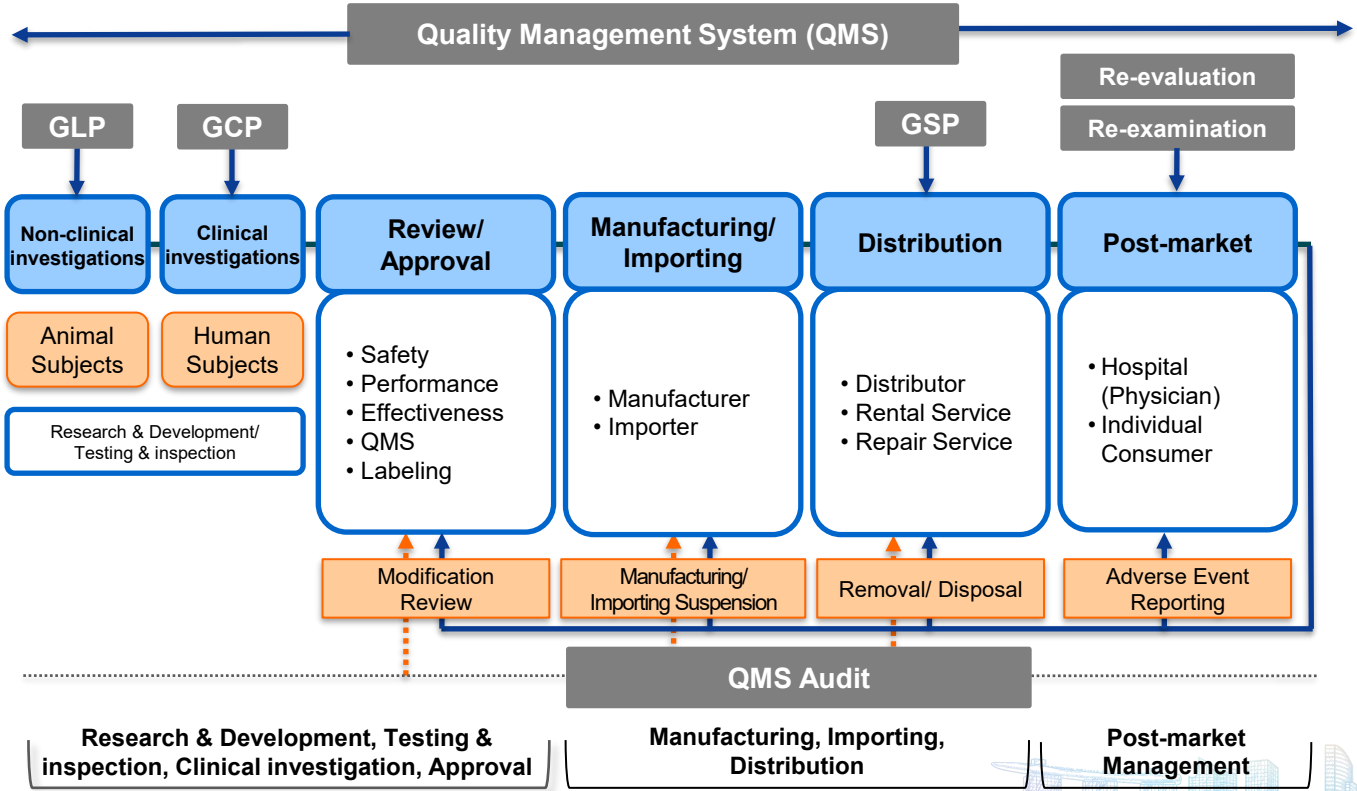
Deputy Director of Medical Device Management Division

Ministry of Food and Drug Safety(MFDS), Republic of Korea

Overview

1. Medical Device Regulatory Framework in Korea
2. Use of MDSAP in QMS Audit
3. KGMP-MDSAP Combined Audit Program
4. Use of MDSAP and ISO 13485 in Post-Market
5. Future Challenges

Safety Management System for Medical Devices (MFDS)



Quality Management System Regulation in Korea

- Must obtain a **Good Manufacturing Practices (GMP) certificate** prior to product approval and market entry
    - Exemptions apply to **Class I** and **export-only** medical devices
- Manufacturing sites are subject to an **initial audit** of QMS implementation, followed by **periodic audits** every **three** years to ensure ongoing compliance
    - **Document** review and **on-site** inspections are conducted by **product group**
- The **audit criteria** are based on the Standards of Medical Device Good Manufacturing Practices (MFDS Notification) [Annex 2], which are equivalent to **ISO 13485:2016**
- **Audit authorities** vary by medical device classification
    - (Class IV) **Joint** audits by Regional MFDS Offices and QMS Certification Bodies
    - (Class II & III) **Independent** audits conducted solely by QMS Certification Bodies

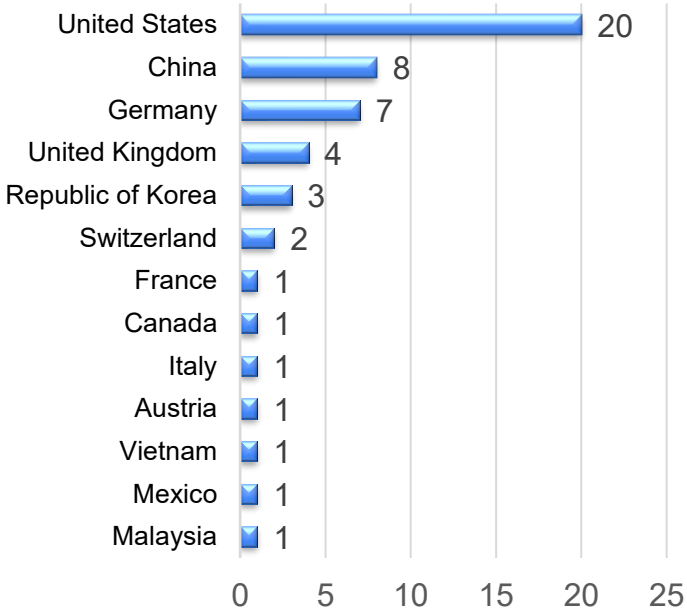
Use of MDSAP Results for QMS Audit

- When an MDSAP audit report is submitted, the **on-site** QMS audit may be **waived** and **replaced** by a **document** review
    - Applicable to manufacturing sites certified through **MDSAP on-site audits**
    - Submission: **MDSAP Audit Report** (Form F0019.1) and QMS audit application form
    - Audit Method: **document** review only
    - Expiry Date: **aligned** with the expiry date of the MDSAP certificate
- Requirements under Korean medical device regulations are **assessed separately**
- However, an on-site inspection is conducted if **one Grade 5** nonconformity, or **two or more Grade 4** nonconformities are identified in the **MDSAP audit results**

2025 Use of MDSAP Statistics

- A total of **54** MDSAP audit reports or certificates were submitted
  - **40 cases: exemption from on-site inspection for initial audits**
    - GMP on-site inspections were waived based on MDSAP audit reports (document review only)
  - **14 cases: confirmation of audit history during periodic audits**
    - MDSAP and EN ISO 13485 certificates are mandatory submission documents for GMP audit applications

MDSAP Use Cases by Country



Introduction of the Combined Audit Program

- Allows manufacturers to apply for KGMP and MDSAP audits simultaneously, enabling assessment of all applicable requirements within the same audit period
    - Common requirements under **ISO 13485** are audited together
    - Korean requirements are audited separately using **additional man-days**
    - Audit reports are prepared and submitted separately according to respective formats and procedures
- Audit conducted by: **TÜV SÜD** Korea, **TÜV Rheinland** Korea
    - MFDS-designated QMS certification bodies and MDSAP Auditing Organizations
- **Reduced duplicate** audit preparation and documentation burden for manufacturers
- More **efficient allocation** of audit resources (auditors, reports) for auditing organizations

Promoting the Combined Audit Program

- **Aligning MDSAP and KGMP audit cycles**
  - **(As-is)** The **validity periods** of **MDSAP recertification audits** and **KGMP periodic audits** are **not aligned**, which **limits** manufacturers to apply for combined audits.
  - **(To-be)** KGMP periodic audits can now be **combined with MDSAP surveillance audits** (annual cycle) to **align validity periods** and **encourage participation**.
    - When combined with a surveillance audit, MFDS reviews the full scope audit reports from the previous initial or recertification MDSAP audit.
- **Improvement of audit report submission timelines**
  - **(As-is)** The KGMP audit report submission deadline (7 days) is shorter than that of MDSAP (45 days), **increasing auditor workload**.
  - **(To-be)** Nonconformities are first communicated to the applicant within 7 days for prompt corrective action, while the full audit report submission deadline is aligned with MDSAP (45 days).

Use of MDSAP and ISO 13485 in Scope of Post-Market

Assessment of QMS reliability when safety information arises

- When **adverse event** reports or overseas **safety alerts** are identified,
    - MFDS conducts an **integrated internal review** of the manufacturer's ISO 13485-based QMS performance and MDSAP audit results.
- Rather than focusing on a single incident, MFDS considers the **overall maturity of the QMS** to:
    - decide whether additional oversight measures, such as **unannounced inspections**, are needed, and
    - determine the **appropriate** level of regulatory action.

Future Challenges

- Demonstrate the importance and effectiveness of regulatory reliance by accumulating practical cases on how MDSAP and ISO 13485 audit results can be linked to post-market regulatory decision-making
    - **Reducing** regulatory **burden** for manufacturers
    - **Establishing** an **efficient post-market oversight system** that allows regulatory resources to focus on **high-risk** areas
- Enhance understanding of MDSAP and confidence in its outcomes
    - **Improving** clarity of MDSAP audit method and results to **strengthen** their **credibility** as regulatory evidence
    - **Promoting** training and outreach to **encourage broader use of MDSAP** and reduce duplicate audits across more jurisdictions

Thank You!

For any question, please contact:

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HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 1 IMDRF Industry Joint Workshop| 09 March 2026

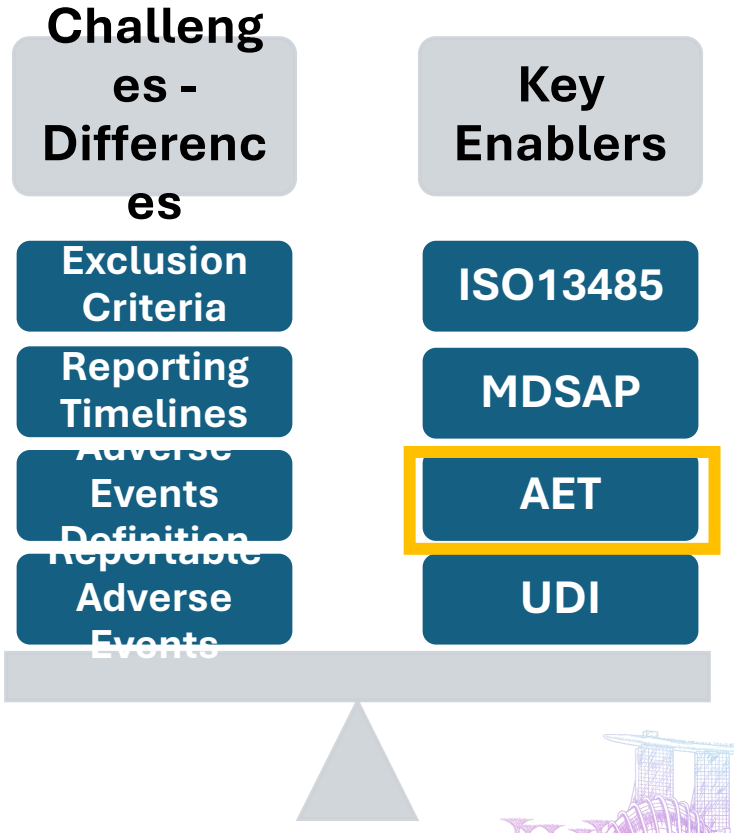
IMDRF Adverse Event Terminology: A Reliance Enabler

Lailing LIEW
Deputy Director, Diagnostic Devices Branch
Health Sciences Authority, Singapore
Former IMDRF AETWG Maintenance Chair (2021-2022)

The Path to Post-Market Reliance

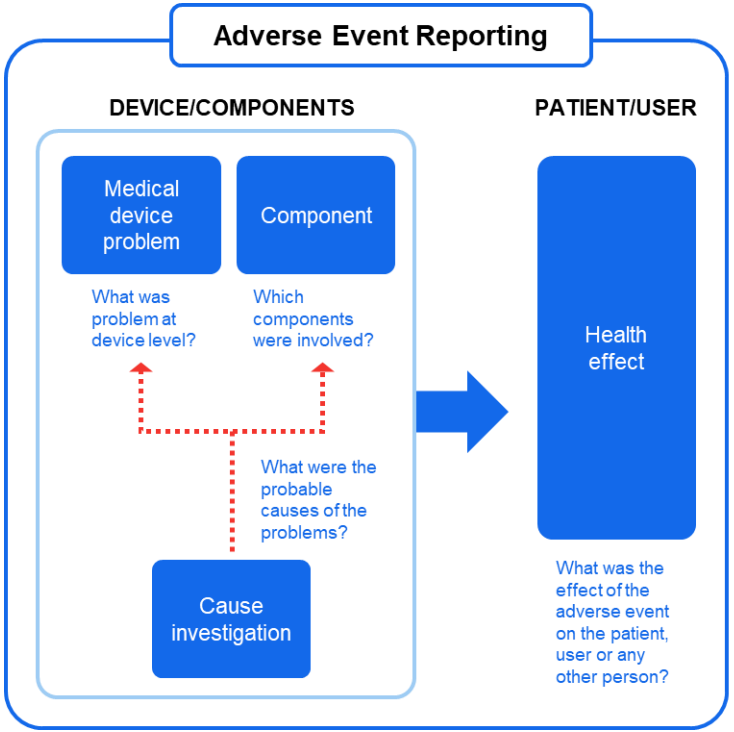
Legislative changes require time to implement across jurisdictions

✓ **Opportunity:** Countries developing new medical device laws can draw reference from IMDRF documents to facilitate convergence



Facilitates **post-market reliance**

The Complete AE Terminology Package



Seven annexes within **four different sets of terminologies** and their associated alphanumeric codes.

Facilitates reporting of:

- observations at the level of the medical device;
- its components, including accessories;
- observations (typically adverse effects on health) at the level of subjects (patients, users, other persons) -- *mapped to MedDRA;*
- investigations into possible causes of the event, and causal links between use of the device (independent of whether malfunctioning or not) and adverse health effects.

***Complete causal chain**: Device Problem → Investigation → Health Impact → Component*

***Hierarchical structure** enables granular yet consistent reporting*

Common Language Foundation: IMDRF AE Terminology

Enables Global Regulatory Reliance

- **Universal Understanding**: A|01|01|01 means the same worldwide
- **Automated Analysis**: Standardised codes enable AI-powered safety detection
- **Trusted Assessments**: Harmonised definitions let regulators rely on each other's findings
- **Faster Response**: Common language accelerates cross-border safety communications

Common Terminology = Trusted Data = Faster Global Responses to Safety Signals

AET Maintenance and Continuous Improvement

Living Terminology

- Annual update cycle (by September 1)
- Stakeholder-driven changes through formal change request process (both industry and regulators)
- Only national competent authorities or stakeholder organisations may submit a change request. Proposals from individuals will not be accepted.
- Transparent maintenance with published change logs and response to reviewed change requests

Continuous improvement ensures global relevance and trust

✓ ***380 change requests reviewed, 128 implemented in 2025***

Accelerating Global Adoption
Next Steps for Post-Market Reliance

Immediate Actions

- Adopt IMDRF AET into national reporting systems
- Leverage XLSX or JSON formats for system integration
- Ensure common understanding of the AET for consistency in code selection
- Use common data set for adverse event reporting

Wider adoption of a **IMDRF AE Terminology** – a common technical language -facilitates *reliance, trust, communication, clarity, and transparency* which *are essential to successful implementation of a reliance model in the postmarket setting*

Thank You!

Current IMDRF AET Working Group Chair(s):

- Andrea Hanson, Health Products Regulatory Authority (HPRA), Ireland European Union
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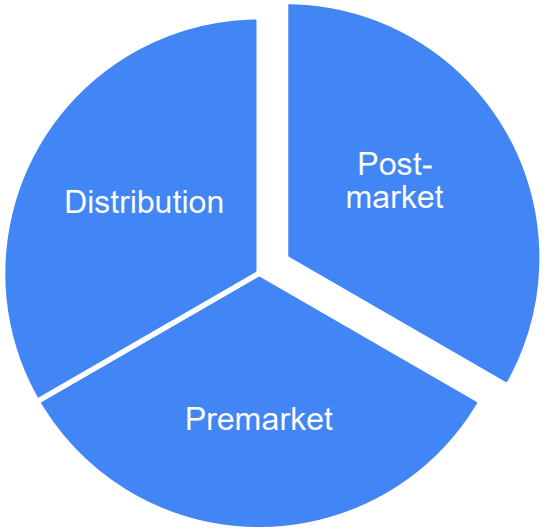
Advancing Adverse Event Reliance

April Veoukas

Director Regulatory, Abbott

GMTA/DITTA

Reliance Across the Total Product Lifecycle



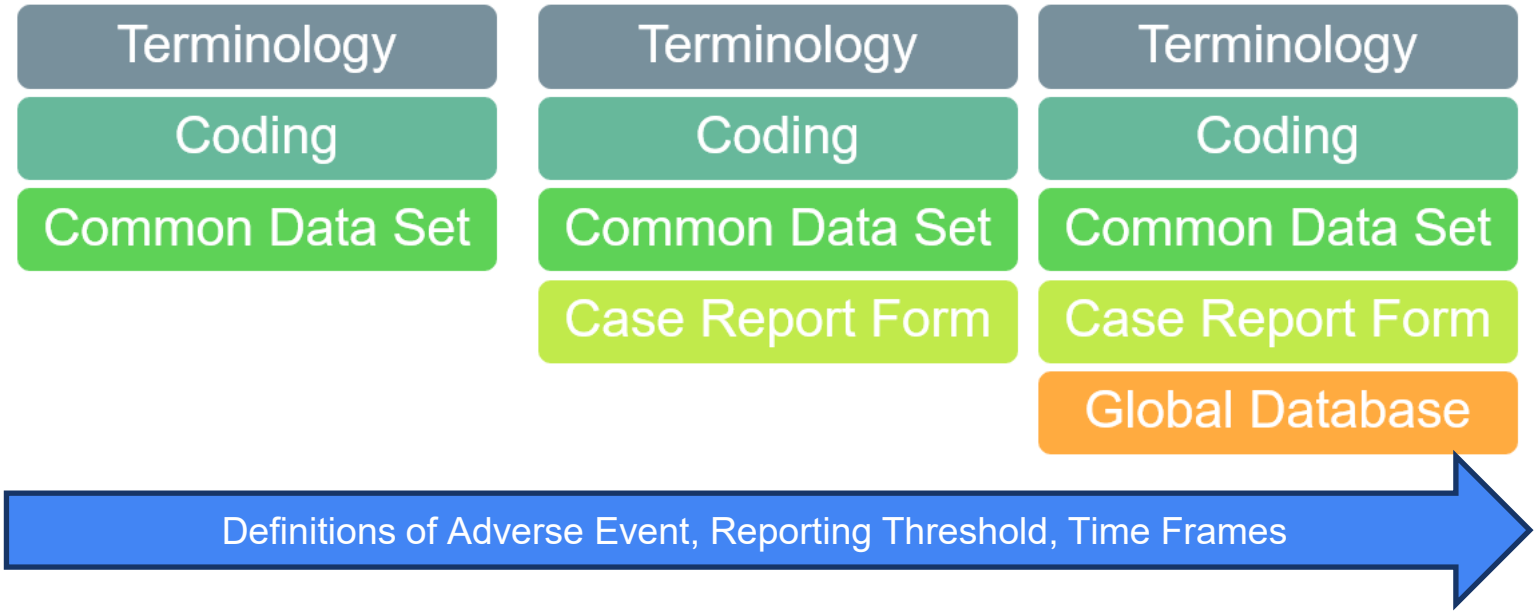
"the principles discussed can be applied to any phase of the product lifecycle (e.g., technical documentation…**post-market activities**…"

"identify the specific regulatory activities to be included in your program (e.g., inspections, audits…**market surveillance**, enforcement actions, such as recalls)"

"Consider your approach for **managing lifecycles in your reliance program"**

Source: IMDRF Playbook for Medical Device Regulatory Reliance

Adverse Event Global Convergence Models



Opportunities for Adverse Event Reliance

DEFINITIONS

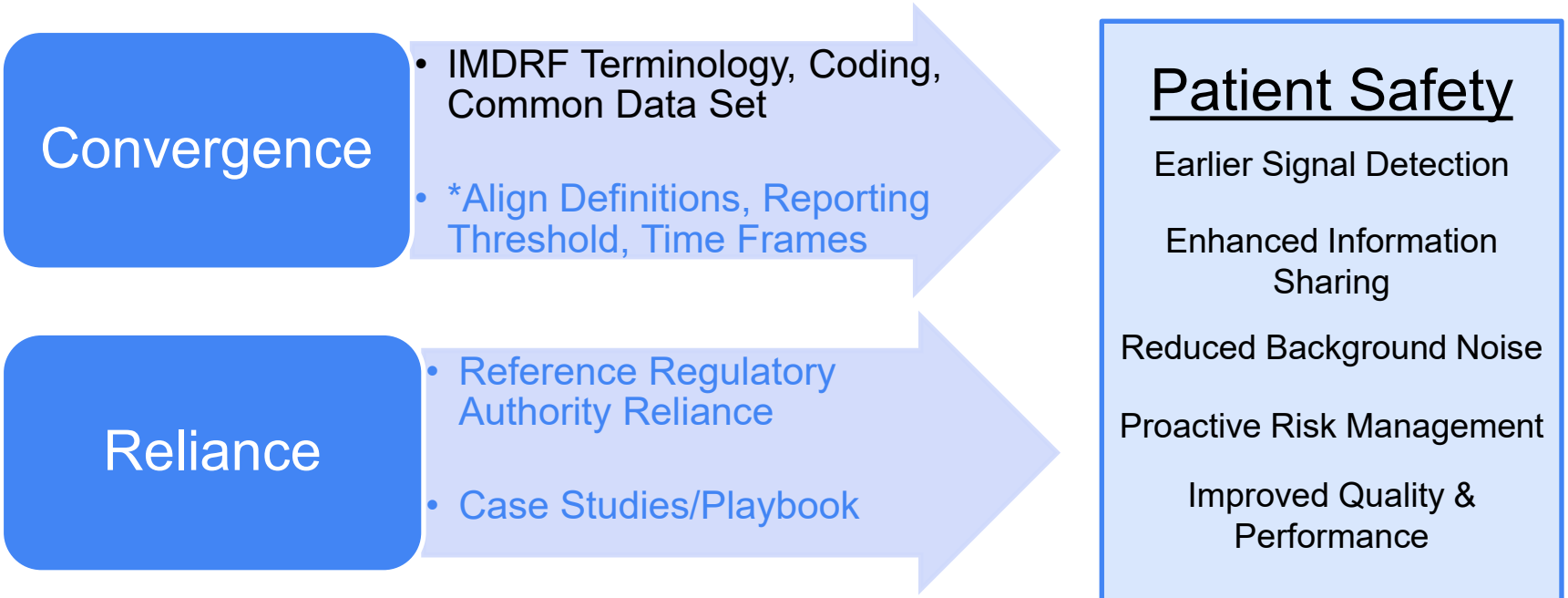
REPORTING

TIME FRAMES

Applying Playbook Principles To AE Reliance

Process
Identify specific regulatory activity: Adverse event reporting
Assess for legal restrictions
Identify reference Regulatory Authority
Compare Adverse Event definition, scope, and timeframes
Select type of reliance: (1) work sharing, (2) abridged pathway, or (3) recognition
Align within legal framework
Establish processes and procedures
Relying Regulatory Authority remains independent, responsible and accountable

Reliance Drives Patient Safety



*GHTF SG2 Guidance for Adverse Event Reporting for Medical Devices

Thank You!