Medical Device Single Audit Program

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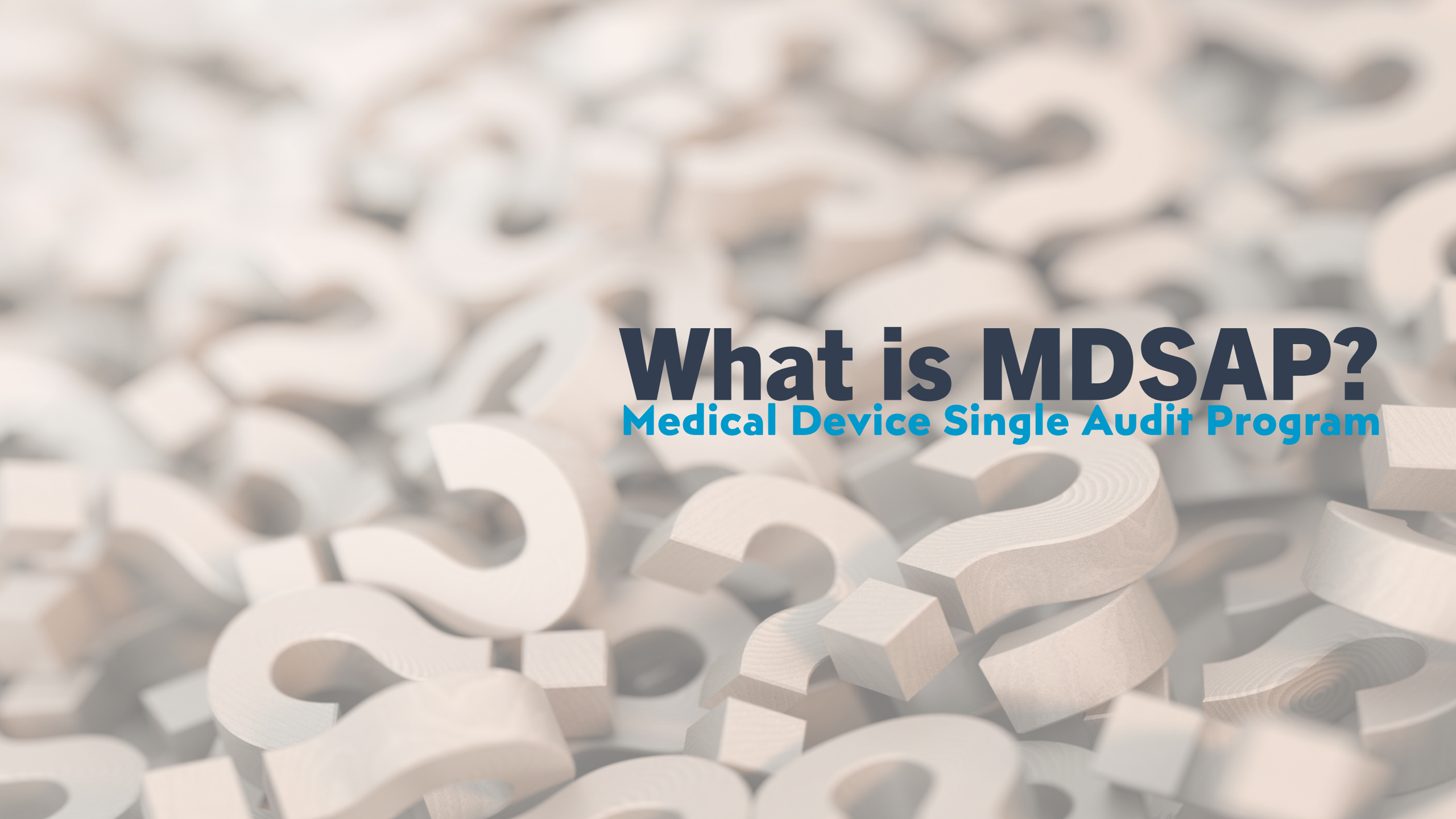
International Affairs
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Objectives

- Overview of MDSAP
- Certificate and Audit Report
- MDSAP Audit Approach
- Assessment Program



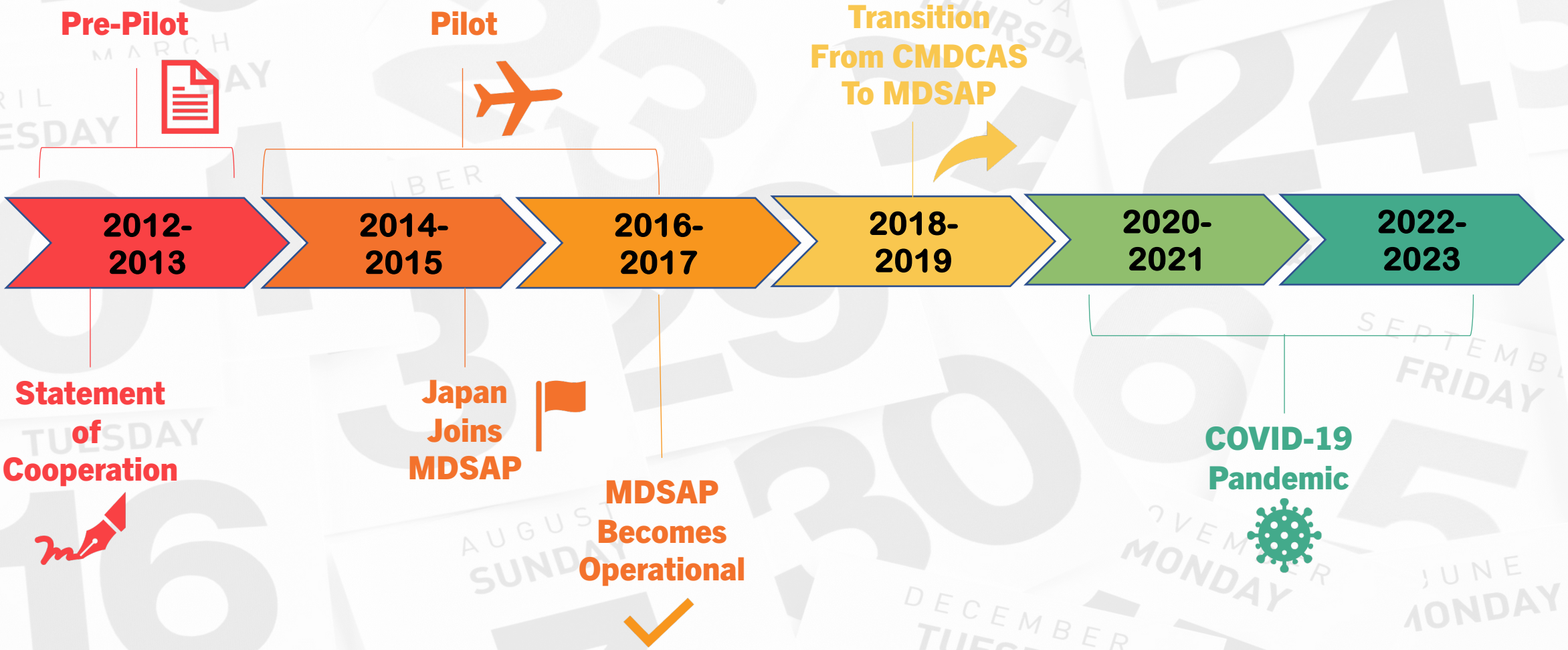
What is MDSAP?

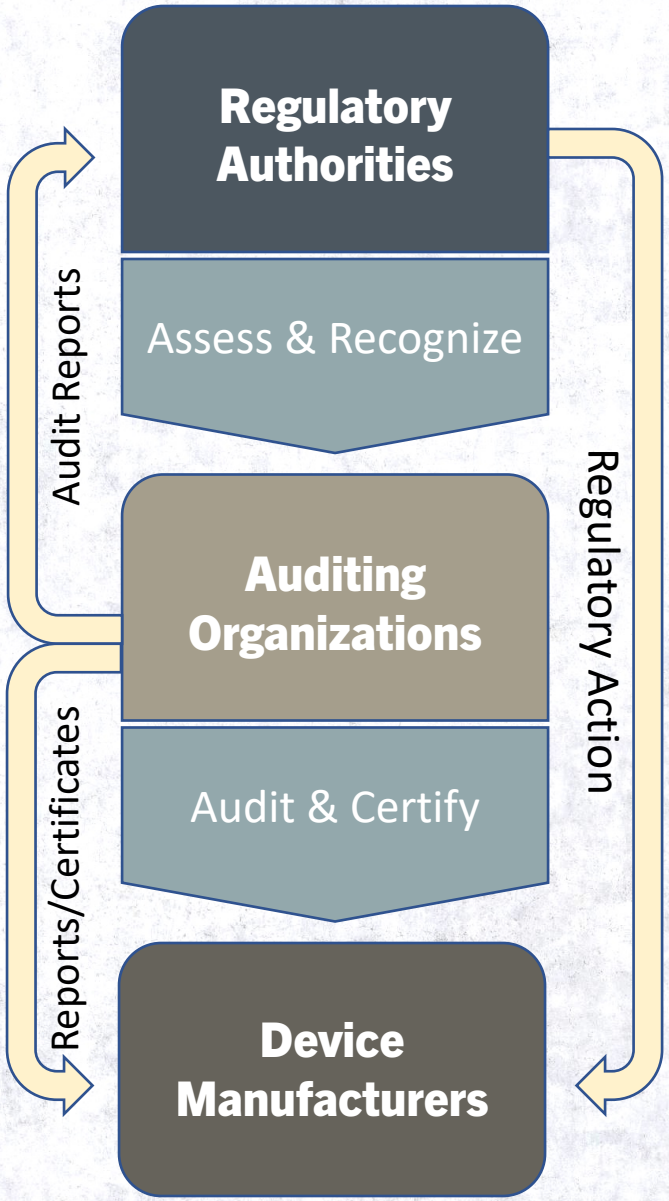
Medical Device Single Audit Program

MDSAP
Summary

Multi-RA Harmonization Effort	MDSAP is managed by regulators from Australia, Brazil, Canada, Japan and the U.S.
Third Party Auditing Organizations	Perform quality management system audits and provide audit reports to regulatory authorities
Single Regulatory Audit	At least one audit annually against ISO 13485:2016 plus country-specific requirements
Mutual Acceptance Independent Reviewed	Regulators accept audit reports that include their jurisdiction. Reports are evaluated independently for possible regulatory action

MDSAP TIMELINE





6,800+
Medical Device Manufacturing Sites
3 Year Certification Program

16 AOs
Audit Manufacturers Annually
Audit Reports Submitted to RAs
4 Year Assessment Program

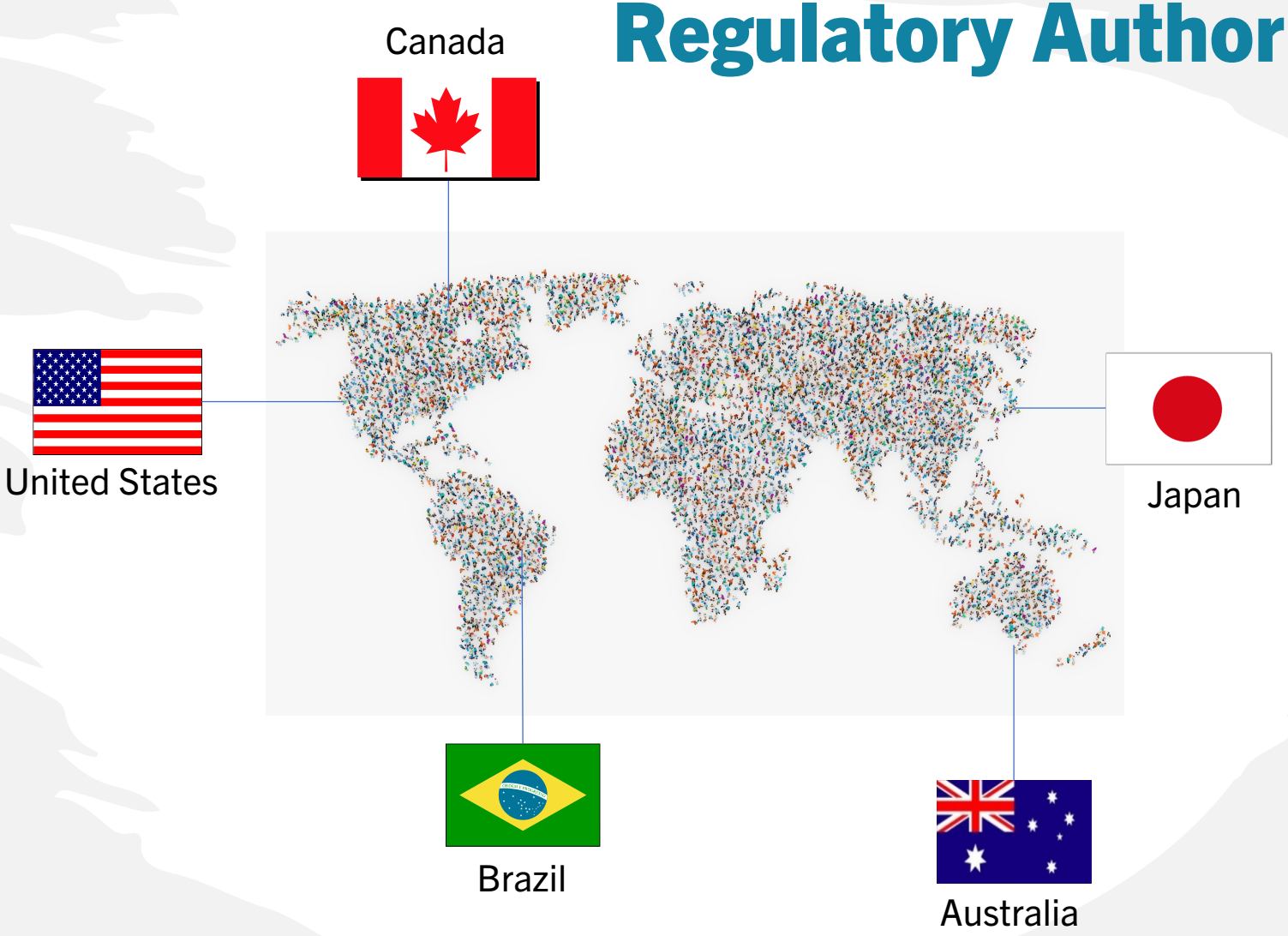
5 RAs
Evaluate AOs Annually
Utilize Reports and/or Certificates
Take Appropriate Regulatory Action

Membership

Regulatory Authority Council

Members

Decision-making and
MDSAP management



World Health Organization

United Kingdom

European Union

Observers

SME Workgroups
Attend open meetings
No decision-making
Confidentiality Commitments

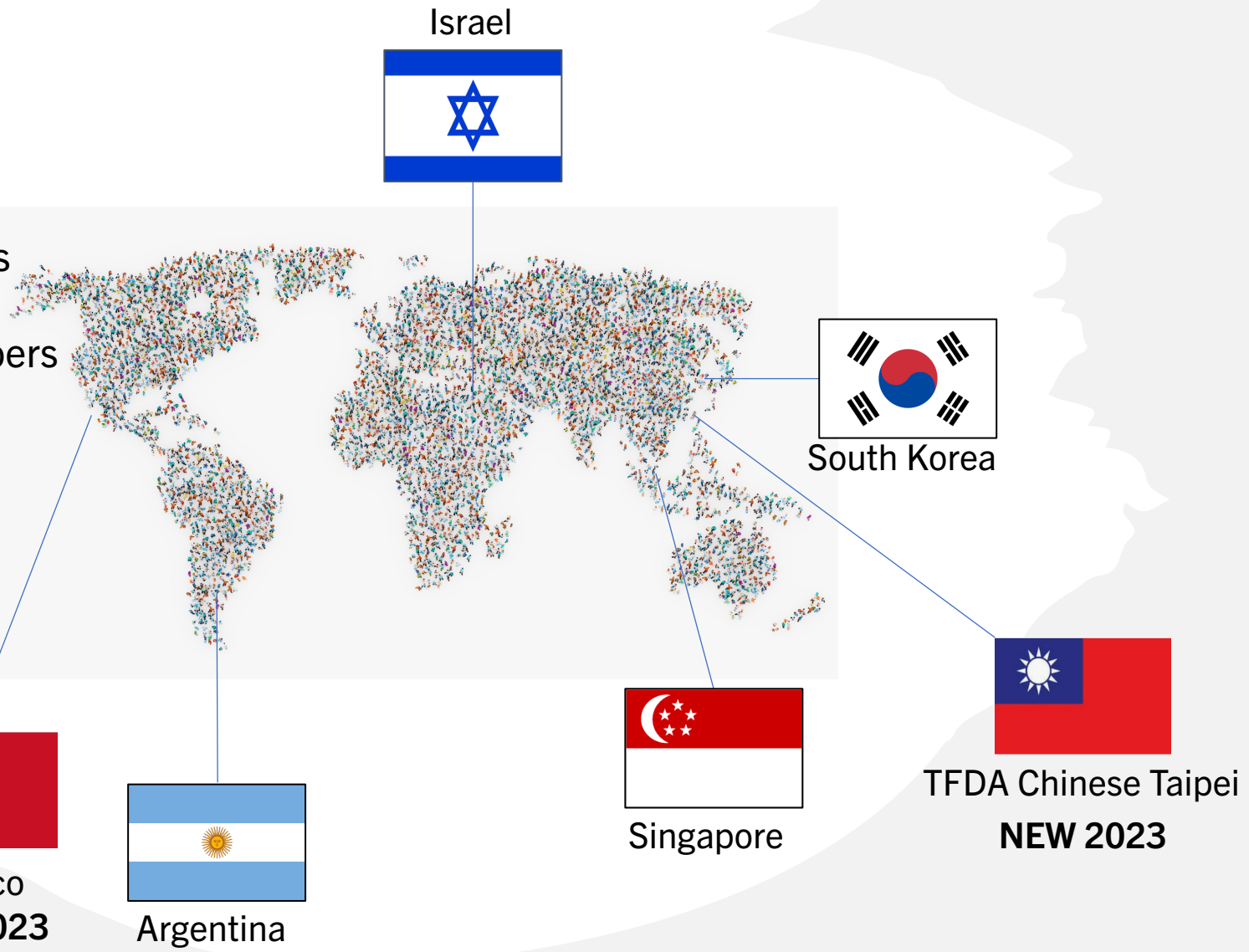
Affiliate

Members

Utilization of MDSAP audit reports
Program promotion
Capacity building with RAC members

Requirements

- Regulatory Authority
- MDSAP Knowledge
- Plan to implement use
- Training & Meeting obligations
- Annual Report on MDSAP Use
- Promote MDSAP



How does an RA apply?

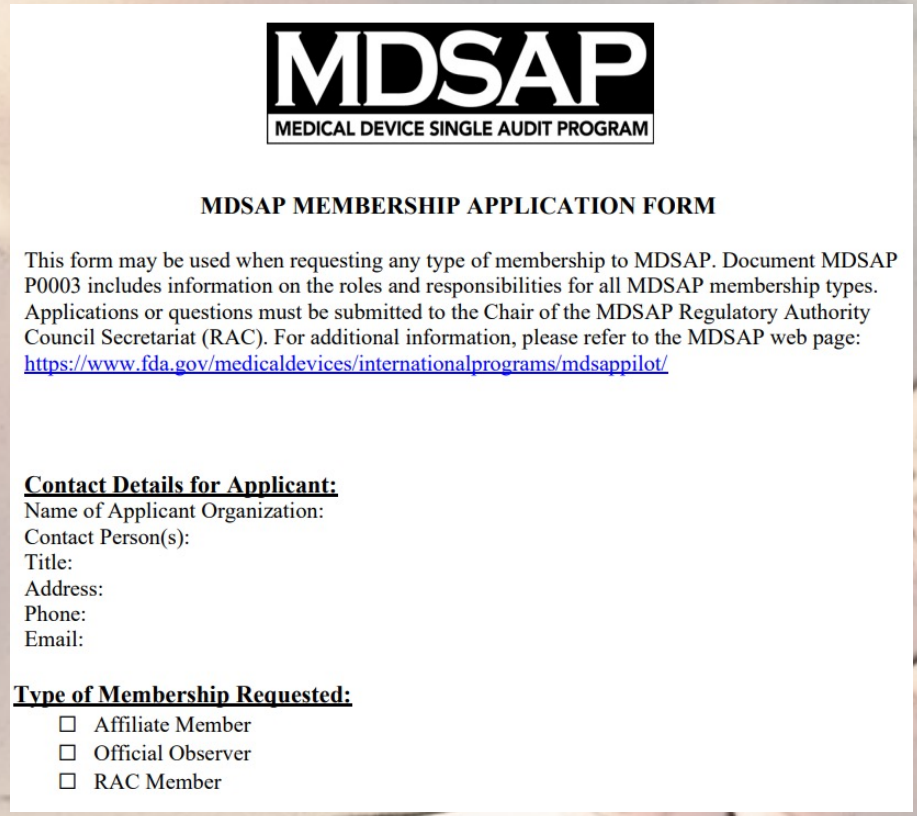
https://www.fda.gov//media/164361/download?attachment

TRAINING - https://www.fda.gov/training-and-continuing-education/cdrh-learn

Single Application

Explanation on how requirements are met

Plan for MDSAP use



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP MEMBERSHIP APPLICATION FORM

This form may be used when requesting any type of membership to MDSAP. Document MDSAP P0003 includes information on the roles and responsibilities for all MDSAP membership types. Applications or questions must be submitted to the Chair of the MDSAP Regulatory Authority Council Secretariat (RAC). For additional information, please refer to the MDSAP web page: https://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/

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

Type of Membership Requested:
- ☐ Affiliate Member
- ☐ Official Observer
- ☐ RAC Member

Auditing Organizations

Recognized

bsi.
DEKRA
TÜVRheinland
SGS
NSAI
DQS MED
TÜV USA
Member of TÜV NORD Group
TÜV SÜD
GMED LNE GROUP
UL

Authorized

DNV
IMQ
SAI GLOBAL

Question

Which country was the last to join MDSAP as a Regulatory Authority Council member?

a. Japan
b. Australia
c. South Korea
d. Brazil

Question

MDSAP Affiliate must have confidentiality commitments with RAC members.

a. True
b. False
c. It depends

Benefits & Regulatory Use

Benefits

1 Audit

13 MDSAP RAs
WHO pre-qual program
Use in other countries

Predictable

Objective NC Grading
Single Audit Approach
ISO 13485:2016

AOs

Choice of AO
Audit other schemes

Reduced Burden

ISO 13485:2016
Limit of country-specific requirements
Streamline RA workload

Transparent

Online documentation
RA-AO Interactions

Reliable

AO Assessments
Audit Approach
Continuous Improvement
Strong Criteria

TGA Australia

MDSAP audit reports and certificates provide evidence of compliance with medical device conformity assessment procedures & marketing authorization requirements

100 TGA audits have been canceled or postponed due to MDSAP

95% of MDSAP manufacturing sites listed on TGA CA certificates no longer scheduled for TGA audits

ANVISA Brazil

MDSAP audit may be used in-lieu of a ANVSIA premarket inspection to grant a class III or IV GMP certificate

Accelerates GMP certification process and MDSAP is considered for bi-annual GMP certificate renewal

2023 Update - PILOT under public consultation to use MDSAP certificates to grant device recertification and to extend the certificate period of validity from 2 to 4 years

HEALTH Canada

MDSAP certification required to maintain or obtain a new Class II, III or IV medical device license

Audit reports and Nonconformity forms are used in post-market analysis

PMDA & MHLW

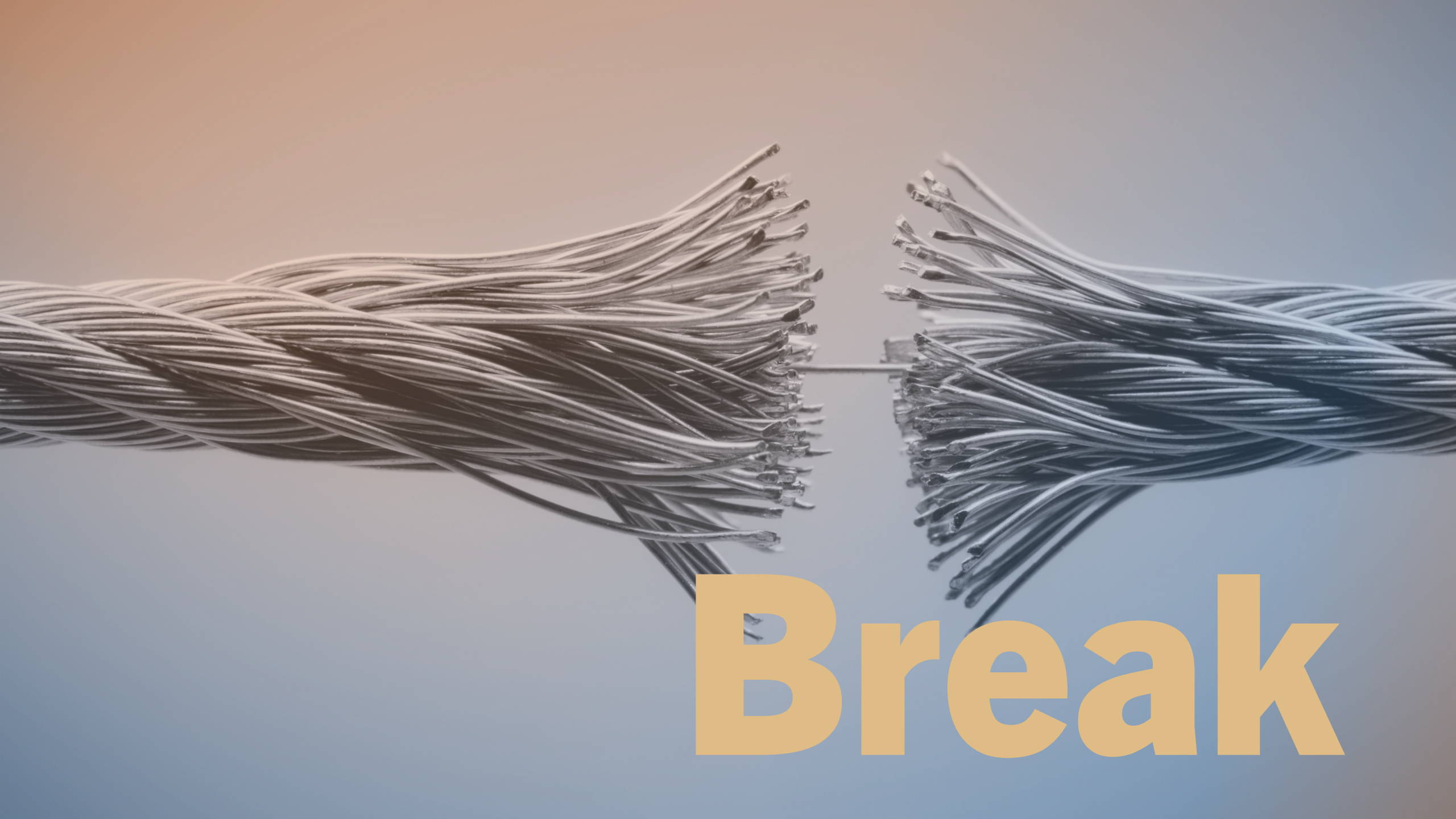
Japan

Streamline premarket and postmarket requirements

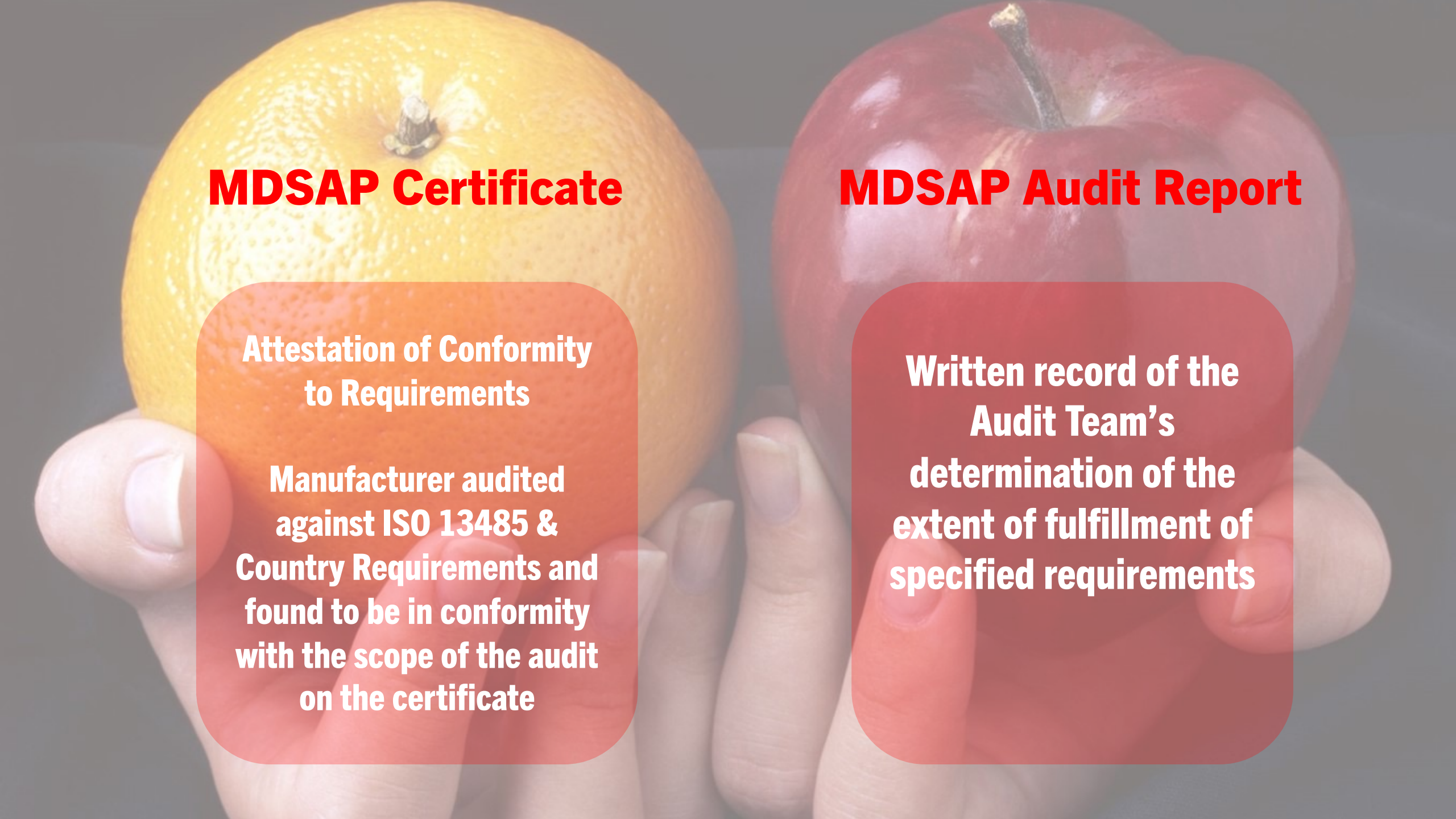
Exempt on-site inspection for some sites

In FY2022, 250 MDSAP audit reports were accepted for review for QMS inspection application


United States
FDA
MDSAP audit reports accepted in-lieu of an FDA surveillance inspection
FDA still conducts For Cause, Compliance Follow-up, premarket and Electronic Product Radiation Controls inspections


Break

Audit Report & Certificate



MDSAP Certificate

Attestation of Conformity to Requirements

Manufacturer audited against ISO 13485 & Country Requirements and found to be in conformity with the scope of the audit on the certificate

MDSAP Audit Report

Written record of the Audit Team's determination of the extent of fulfillment of specified requirements

MDSAP CERTIFICATE REQUIREMENTS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD America

CERTIFICATE

No. QS6 084462 0044 Rev. 02

Certificate Holder: KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: See Page 2 - 3 for Overall Scope Statement.

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 31-573-1430

Effective Date: 2020-09-09

Expiry Date: 2022-05-09

Date of Issue: 2020-11-13

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD America

CERTIFICATE

No. QS6 084462 0044 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Overall Scope Statement:

Design, Development, Production, Servicing, Installation and Distribution Products in Scope: Implants (Non-Active Implants for ENT (S), Non-Active Bone Implants for Arthroscopic Procedures (S), Bioabsorbable Implants for Arthroscopic Procedures (S), Surgical Suture Material for Arthroscopic Procedures (S)), HOPKINS Optics (HOPKINS Telescopes with Channel, HOPKINS Telescopes without Channel), Fiberscopes and Semiflexible Endoscopes (Fiberscopes with Channel, Fiberscopes without Channel, Semiflexible Endoscopes with Channel, Semiflexible Endoscopes without Channel), Videoendoscopes (Rigid Videoscopes with

Date of Issue: 2020-11-13

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

TÜV®

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

Methods

Website

QR code

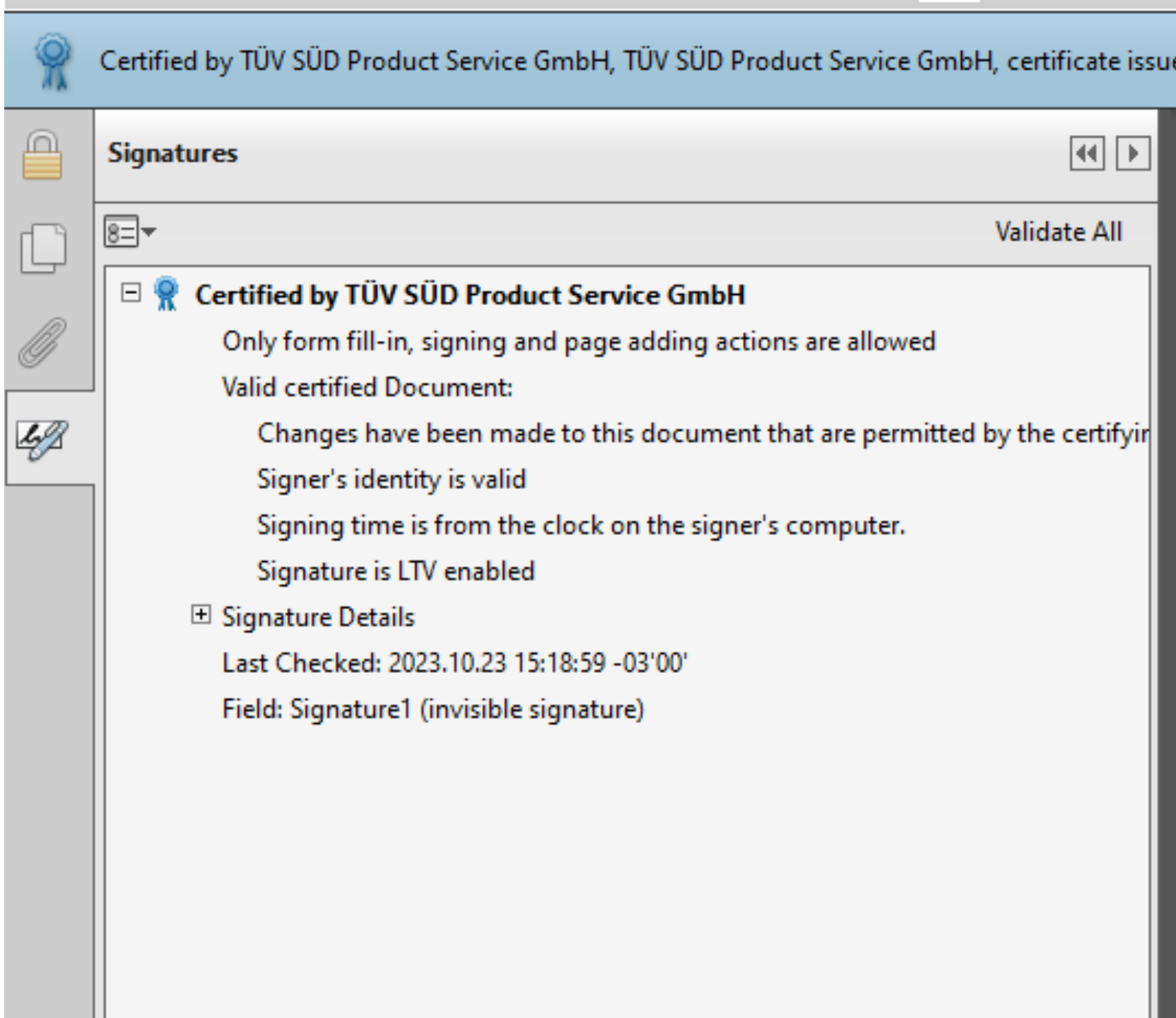
Email Request

AO Methods

BSI Group America Inc	BSI website to validate certificates	https://www.bsigroup.com/en-GB/validate-bsi-issued-certificates/	No
DEKRA Certification BV	website	DEKRA Check.me (dekra-checkme.com)	No
DNV Product Assurance AS	[1] QR code on certificate, [2] DNV website database link embeded posted on the Certificate	DNV - Find a valid certificate	Yes
DNV MEDCERT GmbH	Confirmation must be requested by e-mail	NA	No
DQS Medizinprodukte GmbH	DQS Global website to validate certifcates	https://www.dqsglobal.com/intl/about/certification/certificate-validation	No
IMQ S.p.A	by email, by writing to MDSAP@imq.it	NA	No
Intertek Testing Services NA Inc	By a request form on our website	https://www.intertek.com/business-assurance/certificate-validation/	Yes
G-MED	request through email	NA	No
NCC Certificações Do Brasil	NCC website	https://www.nccgroup.com.br/atuacao/mdsap/certificados-emitidos-mdsap/	
National Standards Authority of Ireland	NSAI Inc website (select approved client listing under the 'Company' heading)	Globally Recognized Management System Certification Services (nsaiinc.com)	
SGS United Kingdom Ltd.	SGS website to validate certificates. Need certificate ID, or company name and location. Currently being upgraded.	https://www.sgsgroup.cz/en/vr/certified-client-directory	No
TÜV Rheinland of North America Inc.	Certipedia Website + telephone number	https://www.certipedia.com/quality_marks	No
TÜV SÜD America, Inc.	QR code on certificate, TUV SUD website database	Certificate Explorer | TÜV SÜD (tuvsud.com)	Yes
TÜV USA, Inc. (TÜV NORD Group)	There is a statement on the Certificate, "The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office."	No Web Link, but in the certificate following information provided: Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com	No
UL Medical and Regulatory Services UL LLC	Go to UL Product IQ search page	https://productiq.ulprospector.com/en/search?term	No

Digital Signature

- Certificate Authentication (traceable to TÜV SÜD LE)
- Signature from EUTL (European Union Trusted List)
- Protection from any Modification (checksum with signature provider)
- Long Term Validation (functionality remains intact even after expiration of the signature)
- Signature registered with CNCA (Certification and Accreditation Administration of the PRC)



Question

Which is not required to be on the MDSAP certificate?

a. Period of Validity
b. Audit Team Members
c. Manufacturer Address
d. Signing Authority

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Medical Device Regulatory Audit Report

null-AUR-null-null / 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

Auditing Organization

Audit Starting Date **Audit Ending Date** **Duration of Audit** (in auditor-days)

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

Audit Team

\- + Team Member

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

Affiliation ○ AO Employee ○ External Resource: Organization

Section 2. Audited Facility

Name of the Audited Facility

MDSAP Facility Identifier

Street Address

Address Details (Building, Appartment, Suite #,...), as applicable

City

Country

State/Province

Zip Code

Contact Person Name

Title

Email

Telephone

Senior Management at the Audited Facility (Name and Title)

Facility Identification Number(s) - if no number or field is not applicable, indicate NA.

Link to RA databases -> Australia | Brazil | Canada | Japan | USA

Australia - TGA

Brazil - ANVISA

Canada - Health Canada

Japan - MHLW/PMDA

USA - FDA

Other Jurisdictions

Section 3. Certification Schemes, Scopes & Criteria, Audit Types

MDSAP Certification Scheme ☐ Not Applicable

Audit type

○ Initial ○ Surveillance #1 ○ Surveillance #2 ○ Recertification ○ Special ○ Unannounced ○ Mock

Specify

Scope of certification

Is any device-drug or device-biologic combination included in the scope of certification? ○ Yes ○ No

☐ Is the scope of of certification revised compared to the currently valid certification (if applicable)

☒ **ISO 13485**	○ 2003 ○ 2016
☐ **Australia**	
☐ **Brazil**	
☐ **Canada**	
☐ **Japan**	
☐ **United States**	

Other reference doc.

CE Marking Certification Scheme ☐ Not Applicable

Audit type
○ Initial ○ Surv. #1 ○ Surv. #2 ○ Surv. #3 ○ Surv. #4 ○ Recertification ○ Special ○ Unannounced

Specify

Scope of certification

☐ New or revised

☒ **Europe**

☐ Medical Device Directive 93/42/EEC (MDD)

☐ Active Implantable Medical Device Directive 90/385/EEC (AIMD)

☐ In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

☐ Other, specify:

Other reference Doc.

Other Certification Schemes ☐ Not Applicable

Certification scheme

Audit type
○ Initial ○ Surveillance #1 ○ Surveillance #2 ○ Recertification ○ Special ○ Unannounced

Specify

Scope of certification

☐ New or revised

Certification criteria

Other reference doc.

Add a Certification Scheme | Remove the Certification Scheme Above

Section 4. Certification Holder and Multi-site Organization

Certification Holder

Is the Audited Facility the certification holder, as identified on the certification documents?	◯ Yes ◯ No

Campus

Is the Audited Facility part of a campus including buildings at different addresses that were also visited during this audit?	◯ Yes ◯ No

Related sites audited as part of the scope of certification (audit outcomes must be documented in separate reports)

Does the scope of certification cover sites other than the Audited Facility?	◯ Yes ◯ No

Corporate Information ☐ See details in Attachment

Section 5. Audit Objectives

Audit objectives shall include as applicable:

Initial Stage 2: evaluation of:
- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;
- product/process related technologies;
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the manufacturer's ability to comply with these requirements.

Surveillance audit: evaluation of:
- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;
- the manufacturer's ability to comply with these requirements;
- new or changed product/process related technologies; and,
- new or amended product technical documentation in relation to relevant regulatory requirements.

Recertification audit: evaluation of:
- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;
- product/process related technologies (e.g. injection molding, sterilization);
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the manufacturer's continued fulfillment of these requirements.

Section 6. Audited Facility Description

Regulatory Roles played by the Audited Facility, considered in the scope of the audit

Europe	☐ Manufacturer	☐ Importer	☐ Distributor	☐ System or Procedure Pack	☐ Authorized Representative
Other					

Activities at the Audited Facility

Audited Facility Address

null - null, null, null, null

☐ Design and Development	☐ Purchasing	☐ Management (regulatory affairs)
☐ Production (finished device)	☐ Production (sterilization)	☐ Servicing
☐ Production (component/sub-assembly)	☐ Production (in-process, other than sterilization)	☐ Installation
☐ Production (device-drug combination)	☐ Production (packaging / labeling)	☐ Monitoring and Measurement (verification of purchased product / processes, product)
☐ Production (device-biologic combination)	☐ Preservation (storage / delivery)	☐ Monitoring and Measurement (Final product release)
	☐ Production (refurbishment)	

Other, specify:

Activities taking place at that address that are not included in the Scope of Certification (NA if none)

Number of staff | Number of shifts | Number of staff working in shifts

☒ Attach the list of medical devices relevant to each address, including for each jurisdiction the class and the marketing authorization number

Section 7. Critical Suppliers (to include outsourced processes)

☐ Not Applicable

☐ Check if Critical Supplier List is attached

Note: Suppliers that have been visited in connection with the audit of this facility must be listed below.

Organization

Address | City | State/Province | Zip Code | Country

\+ -

Products or services used in audited processes

Was the supplier visited jointly with the Audited Facility? ◯ **Yes** ◯ **No**

Section 8. Audit History (All Audit / Certification Scheme Considered)

☐ Non Applicable (No prior audit)

List of prior audit reports taken into account in the preparation of the audit and/or for the grading of nonconformities (including "mock audits", "gap audits" or "pre-assessment audit")

	Audit Date	**Audit Report Reference**	**Audit Type**
\+ -			

Summary of findings from prior audit listed above

Section 9. Exclusions and Non-Applications of Requirements in the QMS

Section 10. Outcome of Pre-Audit Activities (including Stage 1 as applicable)

☐ Check if documentation of Pre-Audit Activities is attached

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

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

Section 12. Nonconformities

Import Nonconformity Information

NC Ref #	Statement of Nonconformity / Supporting Evidence	ISO 13485	Grade

Section 13. Significant Deviations from the Audit Plan

Duration of the Audit (in auditor-days) Planned Actual

Obstacles

Section 14. Follow-up of Past Nonconformities (record details of the review in the nonconformity reports)

☐ Not Applicable

	Reference of the nonconformity	Status of the nonconformity	Reference of new superseding nonconformity, if applicable
+ -			

☐ Check if any record of the follow-up of past nonconformities is attached (using NGE form or any other form)

Additional Comments

Section 15. Summary of Major Changes to Audited Facility

Section 16. CONCLUSIONS

Total # of Open Nonconformities (NC):		Including # of NCs from Past Audits Left Open:		# of NC Issued During this Audit:	

Conformity with Audit Criteria	
Effectiveness of the QMS in meeting Quality Objectives	
Achievement of Audit Objectives	
Factors encountered that may affect the Audit Reliability	
Recommendations on the Certification Status	
Recommendations on Follow-up Actions	

Section 17. Attachments

List of Audit Report Attachments

Audit Plan

List of medical devices

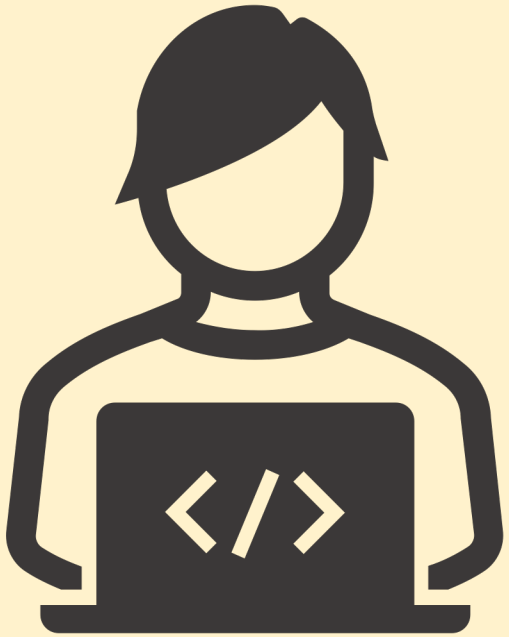
+

-

Section 18. Audit Report Approval

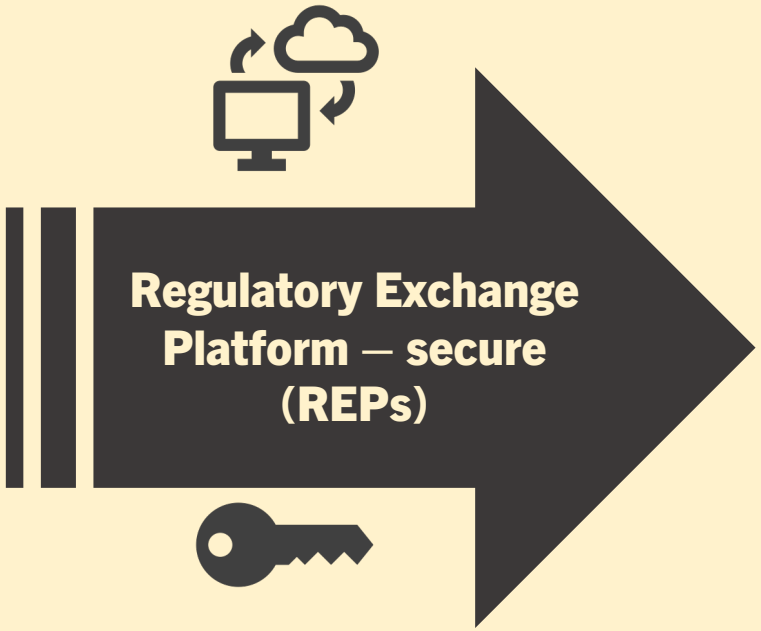
Approver	
Title	
Signature	

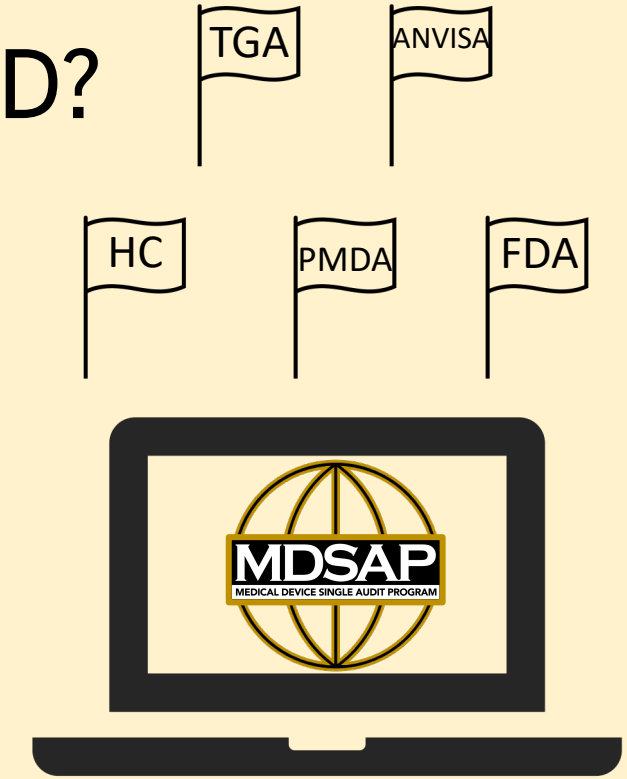
HOW ARE AUDIT REPORTS SUBMITTED?



AUDITING ORGANIZATION

AUDIT REPORT TIMELINES 45 OR 90 CALENDAR DAYS






Let’s Look
at an
example!

Medical Device Regulatory Audit Report

Reference # 8417853

Audited Facility Bioventus LLC

Audit Starting Date 2016-07-18

Audit Report Reference # (assigned by the AO): 8417853

Section 1. Auditing Organization (AO)

DUNS # 04-738-9387

AO Name: Auditing Org.

Section 2. Audited Facility

DUNS # 07-845-1540

Organization: **Bioventus LLC**

Address: 1900 Charles Bryan Road, Ste 275

City: Cordova **State/Province:** TN

Country: United States **Zip/Postal Code:** 38016

GEOCODE (visit www.freegeocoder.com to determine coordinates): **Latitude:** 35.176597 **Longitude** -89.826974

Section 2.1 Audited Facility Contact Person

Name:	**Keith Biggs**	**Title:**	**Senior Manager of Quality**
Telephone:	(b)(6)	**Email:**	(b)(6)

Section 2.2 Facility Identification Number(s) - if no number or field is not applicable, indicate NA

Jurisdiction	Identification Number	Jurisdiction	Identification Number
Australia - TGA	(b)(4)	Brazil - ANVISA	NA
Canada - Health Canada	(b)(4)	United States - FDA	3010203571
Japan - MHLW and PMDA	NA		

2.3 Manufacturer (as specified on product labeling, if different from audited facility)

☐ Same as Audited Facility

Organization:	Bioventus, LLC	**DUNS #**	00-000-0000
Address:	4721 Emperor Blvd, Suite 100		
City:	Durham	**State/Province:**	North Carolina
Country:	United States	**Zip/Postal Code:**	27703
GEOCODE (visit www.freegeocoder.com to determine coordinates):	**Latitude:** 35.877308	**Longitude**	-78.839954

2.4 Identification Number(s) of Manufacturer - if no number or field is not applicable, indicate NA

Jurisdiction	Identification Number	Jurisdiction	Identification Number
Australia - TGA	(b)(4)	Brazil - ANVISA	NA
Canada - Health Canada		United States - FDA	30095995577
Japan - MHLW and PMDA	NA		

Section 3. Audit Type & Criteria

MDSAP AUDIT? YES

☐ **Initial** ☒ **Surveillance #** ☐ **Re-certification** ☐ **Special** ☐ **Unannounced**

☐ **Other, specify:**

Clarifications, if necessary:

3.1 - Jurisdiction and Audit Criteria (exclusions to be listed in section 9)

Standards ☒ ISO 13485 ☒ Other, specify: ISO 9001:2008

3.1 - Jurisdiction and Audit Criteria (exclusions to be listed in section 9)

Standards ☒ ISO 13485 ☒ Other, specify: ISO 9001:2008

Jurisdictions and corresponding Medical Device Regulations

☒ **Australia**

(b)(4)Foreign Regulations

☐ **Brazil**

☒ **Canada**

☐ **Japan**

☒ **United States**

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

☒ 21 CFR Part 820 - Quality System Regulation

☐ 21 CFR Part 821 - Device Tracking

☒ **Europe**

(b)(4)Foreign Regulations

Other Jurisdiction	Regulation

+ -

Documents used as reference for the audit

MDSAP AU P002.003 - MDSAP Audit Model

Section 4. Scope of Audit Program / Certification

If this is an **ISO 13485:2003 under MDSAP** audit ensure a full description of each type of activity and medical device covered.

	Audit / Certification Scheme	Scope of Audit Program / Certification	New or Amended?	Active Certificate?
+ -	MDSAP	Design, Development, Manufacture and Distribution of Non-Animal Hyaluronic Acid Based Implants. Design, Development, Manufacture, Distribution and Servicing of Active Ultrasonic Fracture Healing Systems	No	Yes
+ -	ISO 13485:2003 (CMDCAS)	Design, Development, Manufacture and Distribution of Non-animal Hyaluronic Acid Based Implants. Design, Development, Manufacture, Distribution and Servicing of Ultrasonic Fracture Healing Systems	No	Yes
+ -	ISO 9001:2008	Design, development and manufacture of Exogen and Durolane Devices	No	Yes
+ -	MDD 93/42/EEC, Annex II	Design, development and manufacture of active ultrasonic fracture healing systems and non-animal hyaluronic acid based implants	No	Yes

4.1 - Scope of Audit Program / Certification at the Audited Facility (if different than above)

☐ Not Applicable

	Audit / Certification Scheme	Scope of Audit Program / Certification	New or Amended?	Active Certificate?
+ -	MDSAP	Manufacturing, customer service, design and development, purchasing, receiving and incoming inspection.	No	Yes
+ -	ISO 13485:2003 (CMDCAS)	Manufacturing, customer service, design and development, purchasing, receiving and incoming inspection.	No	Yes

4.2 - Related Sites (included in the Scope of Audit Program / Certification) ☐ Not Applicable

	Related Site	Related Site DUNS	Relationship to Audited Facility	Related Site's Audit Report
+ -	Bioventus LLC, Durham NC	07-845-0878	Headquarters	8356764

Section 5. Audit Objectives

The objective of the assessment is to conduct a surveillance assessment to ensure continued effective implementation of the management system to applicable scope of registration in accordance with the company objectives, policies and procedures, applicable regulatory requirements, and the AO Terms of Service and to determine whether a recommendation for continued certification can be made.

5.1 - Audit Dates, Duration and Languages

Audit Starting Date:	2016-07-18	**Audit Ending Date:**	2016-07-20	**Audit Duration (in Auditor-Day):**	5

Languages used: English

Section 6. Audited Facility Description

Total staff in the scope of the Audit Program: (b)(4)

☐ Shift Work

6.1 Activities under the Audited Facility's responsibility

	Performed in-house		Outsourced	
☒ Design and development	◉ Yes	○ No	○ Yes	◉ No
☒ Manufacturing (finished device)	◉ Yes	○ No	◉ Yes	○ No
☒ Manufacturing (components)	◉ Yes	○ No	◉ Yes	○ No
☒ Manufacturing process (other than sterilization)	◉ Yes	○ No	○ Yes	◉ No
☒ Assembly	◉ Yes	○ No	○ Yes	◉ No
☒ Packaging / Labeling	◉ Yes	○ No	○ Yes	◉ No
☒ Sterilization	○ Yes	◉ No	◉ Yes	○ No
☐ Installation				
☒ Servicing	◉ Yes	○ No	○ Yes	◉ No
☒ Import/Distribution of other manufacturers' devices	◉ Yes	○ No	○ Yes	◉ No
☒ Repackaging/relabeling	◉ Yes	○ No	○ Yes	◉ No
☒ Refurbishing	◉ Yes	○ No	○ Yes	◉ No

Clarifications, as necessary

Supartz and Durolane are manufactured and sterilized by a subcontractor. Exogen may have some component manufacture at a supplier however the finished device is manufactured/packaged by Bioventus LLC in Cordova TN.

6.2 Senior Management of Audited Facility

	Name	Title
+ -	Anthony James	VP of Operations and Quality

6.3. Corporate Information

Bioventus LLC has corporate office in Durham NC and a manufacturing site in Cordova TN. Sites share the Quality Manual and many high level procedures with the Quality Management System.

Bioventus LLC is a global provider of medical devices designed to help repair bones, alleviate pain, and promote healing.

Section 7. Critical Suppliers (to include outsourced processes)
if more than 5, attach the Critical Supplier list to the report

☐ Not Applicable

☒ Check if Critical Supplier List is attached

Company Name:

Address:

+ - **City:** **State/Province:**

Country: **Zip/Postal Code:**

Product or services used in audited processes:

Section 8. Audit History (All Audit / Certification Scheme Considered)

☐ Non Applicable (No prior audit)

List of prior audit reports taken into account in the preparation of the audit and/or for the grading of nonconformities (including "mock audits", "gap audits" or "pre-assessment audit")

	Audit Date	Audit Report Reference	Audit Type
+ -	2015-08-12	8332490	Upgrade Assessment

Summary of findings from prior audit listed above

There were three nonconformances raised during the last assessment. Two of the three nonconformances were completely closed out. One remains open, awaiting effectiveness verification. The actions taken for each of the nonconformances are documented below.

NCR: 1227051N1 - Closed

(b)(4)Foreign Regulations

NCR: 1227051N2 - No, awaiting effectiveness verification for the CAPA.
Nonconformance: The process for controlling product with a limited shelf-life was not found to be entirely effective. Procedure 0059997, Distribution Center, Rev 0, dated 2/20/14, states that the Distribution Centers shall not distribute product with less than 6 months shelf-life remaining. The Exogen Sonic kit contains gel with a 5 year shelf-life, but the shelf-life of the gel is not traceable to the kit. Therefore it is not possible to ensure there is at least 6 months of shelf-life remaining for the gel shipped with the Sonic kit.
Actions: CAPA-2015-018 was initiated in response to this nonconformance.
Containment: Not required, product turn around currently would not have any products meeting within 6 months of the 5 year shelf-life
Root Cause: A procedure has not been established which requires devices with a shelf-life to be appropriately controlled so as to prevent expired product from being placed on the market. Shelf life is not monitored/maintained for the system level SKUs and components.
Corrective Action Plan:
1. Determine components where shelf life is a concern
2. Establish expiry for part master data in SAP
3. Ensure expiry for system level SKUs is below or equal to expiry established for components.
4. The design transfer form will be revised to require the evaluation of product shelf life prior to product release for production
5. The process risk analysis procedure will be revised to require the evaluation of risks associated with distribution of expired product
6. The PFMEA for the Exogen Ultrasound Bone Healing System will be updated to cover the evaluation of risks associated with distribution of expired product.
7. Update 0059997 Distribution Center Specification to require reporting on item shelf life and quarantine items with remaining shelf life below minimum threshold.
Corrective Actions Taken:
1, 2 - Memo generate 7/19/16 - SAP Shelf Life Establishment for Exogen Systems and Gel Pump. Establish the required shelf life in SAP to ensure that items can be removed from stock locations prior to expiration and therefore won't be shipped.
3 - Memo generated 11/3/15 - Project E11 - SONIC-003, SONIC DHF on SONIC battery device shelf life. Estimated that the

Section 9. Exclusions and Non-Applications of Requirements in the QMS

No exclusions are claimed. Non-application to ISO 13485 have been identified as the following areas:
7.5.1.2.2 - Installation activities
7.5.3.2.2 and 8.2.4.2 - Only aspects of relating to Active Implantable Medical Devices are not applicable

Section 10. Outcome of Pre-Audit Activities (including Stage 1 as applicable)

☐ Check if documentation of Pre-Audit Activities is attached

Previous audit report

Section 11. Audit Findings

MDSAP Audited Process 1. Management

Related Audit Tasks (check all that apply)

- [x] 1. Documented QMS
- [x] 2. Management Representative
- [x] 3. Quality Policy and Quality Objectives
- [ ] 4. Organizational Structure, Responsibility, Authority, Resources
- [ ] 5. Extent of Outsourcing
- [x] 6. Personnel Competency & Training
- [ ] 7. Risk Management Planning and Review
- [x] 8. Document Controls
- [x] 9. Management Reviews
- [ ] 10. Device Marketing Authorization and Facility Registration
- [x] 11. Top Management Commitment to Quality

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

Major changes observed? ○ Yes ◉ No

The Quality Manual has been established to describe the structure and responsibilities of the multi-site corporation. The Quality Manual Section No. 5.2 In this sections of the manual the organization establishes its commitment to developing, implementing and maintaining the Quality Management System

3) Establishing a Quality Policy and Objectives
a) The Quality Policy (defined in the Quality Manual) is appropriate to the organization
b) Sections 5.2.4.1 of the QM is linked to the objectives and Management review. The objective are supportive of the Quality Policy are measurable. The policy is communicated via training and as revised using the internal "Biolearn" system.
4) Ensuring the availability of resources - By reviews need during the Management review meetings as input to the meetings. Input include;
a) Customer feedback
b) Process Performance and and Product conformity
c) Recommendations for Improvement
d) Management With executive responsibility is responsible for ensuring the required resources are made available.

A Quality Policy has been established and is documented in the Quality Manual and reviewed for applicability and suitability during Management Review meetings. Management Representatives have been assigned for each site. Management Review meetings are held at scheduled frequencies (2X per year) with all sites participating. Required inputs are included for discussion during Management Review in addition to Quality Objectives and KPIs. The Quality Objectives are listed below. Key performance metrics have been established as goals for each metric to define success. The current KPI metrics utilize a red, yellow, green status. Review of the Quality Dashboard showed that generally being met, with no significant negative trends. Areas of concern may feed into Management Review action items or CAPAs. The Management Review meeting from June 2016 was reviewed during this assessment and found to

Products or components relevant to the process or activity audited

Exogen, Durolane, Supartz

Key documents reviewed related to this specific process or task

Q100001-BC Rev. 1 - Quality Manual
0057382-BC Rev. 0 - Bioventus Quality Management Review (QMR) Procedure
Management Review Meeting Minutes/Presentation June 28, 2016
2016 Top Level X-Matrix
Bioventus No. Q1000001-BC Quality Manual
Quality System Training Specification No. Q1 18002-BC
Document and Records Control Specification No. Q10505003-BC
Appendix A Quality System Record - (Document Control and records Retentions)
Change Order procedure No. 00000-BC
Internal Audit Quality Audit Program No. Q117004-BC REV B
Operating the document Management System No. 0000255-BC Rev D

Number of records reviewed: 15

Names and Titles of persons interviewed:

	Name (last, first)	Title
+ -	Keith Biggs	Sr Manager, Quality
+ -	Amber Trickett	Quality Engineer II
+ -	Mason Robbins	Regulatory Affairs Project Manager

Concluding statement regarding whether the activity or process under audit is in conformity with the audit criteria

Based on the documents and records reviewed, the Management processes reviewed were found to be effectively implemented and in compliance with audit criteria.

Nonconformity? ○ **YES** ◉ **NO**

If YES, the nonconformity must also be documented in the MDSAP Nonconformity Grading and Exchange Form and on the AO's nonconformity report form


Questions

MDSAP Audits

Competency Requirements for Auditors

Affiliation

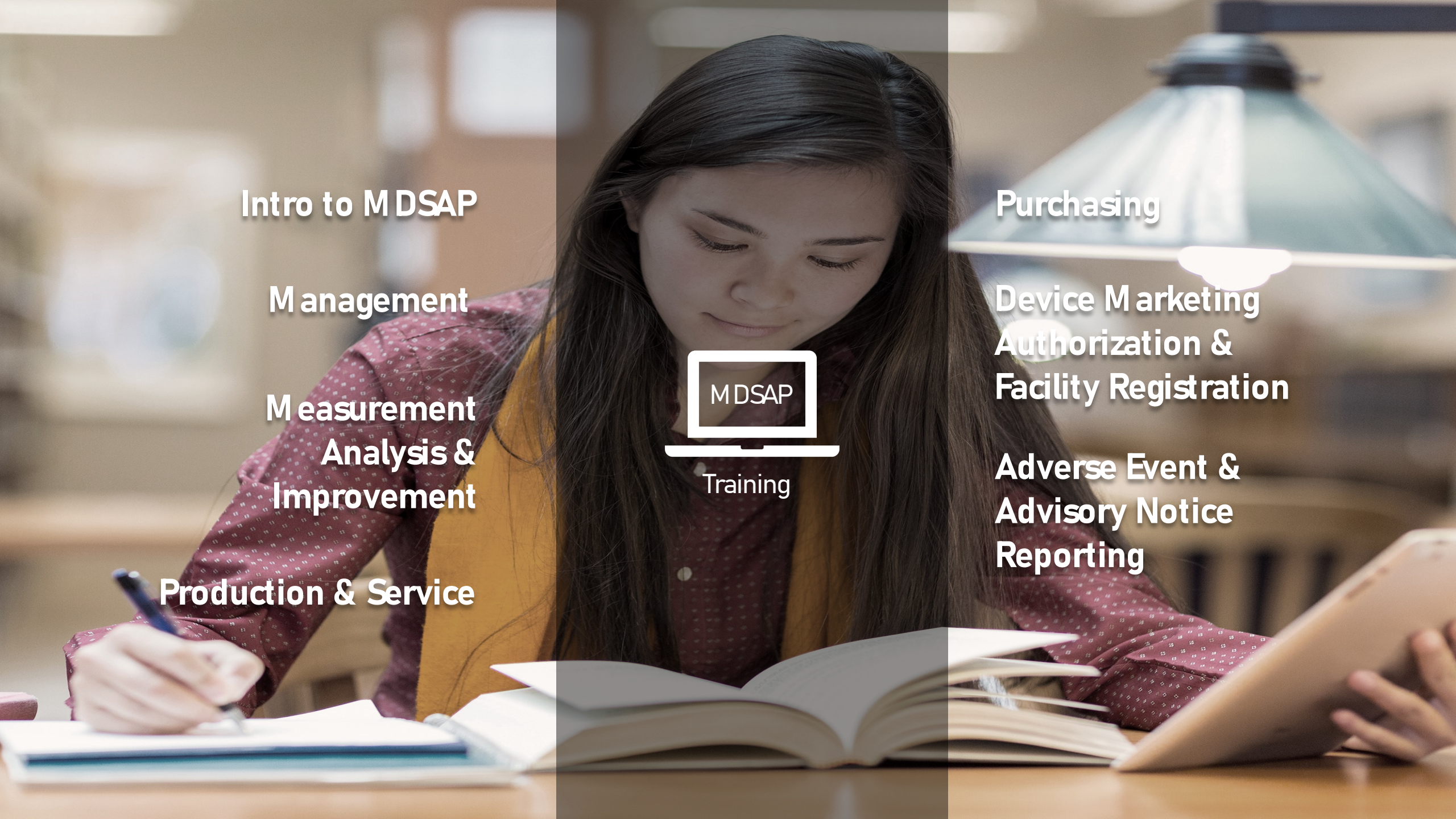
MDSAP AO

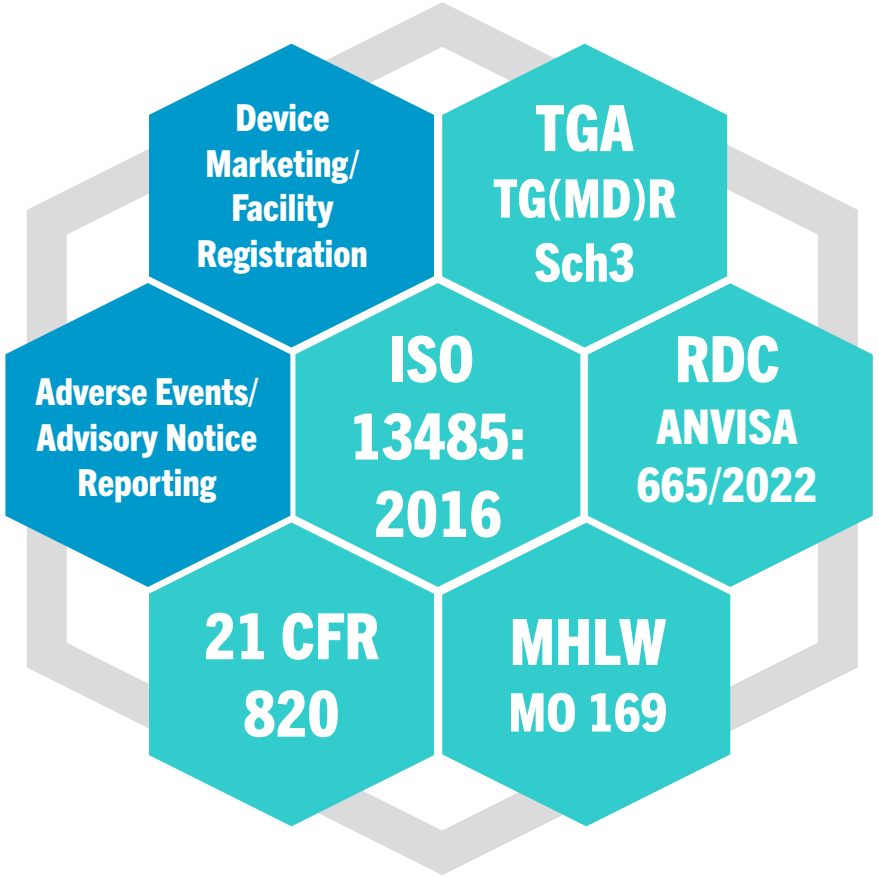
Knowledge

ISO 13485

Country-specific Requirements

MDSAP Training Program

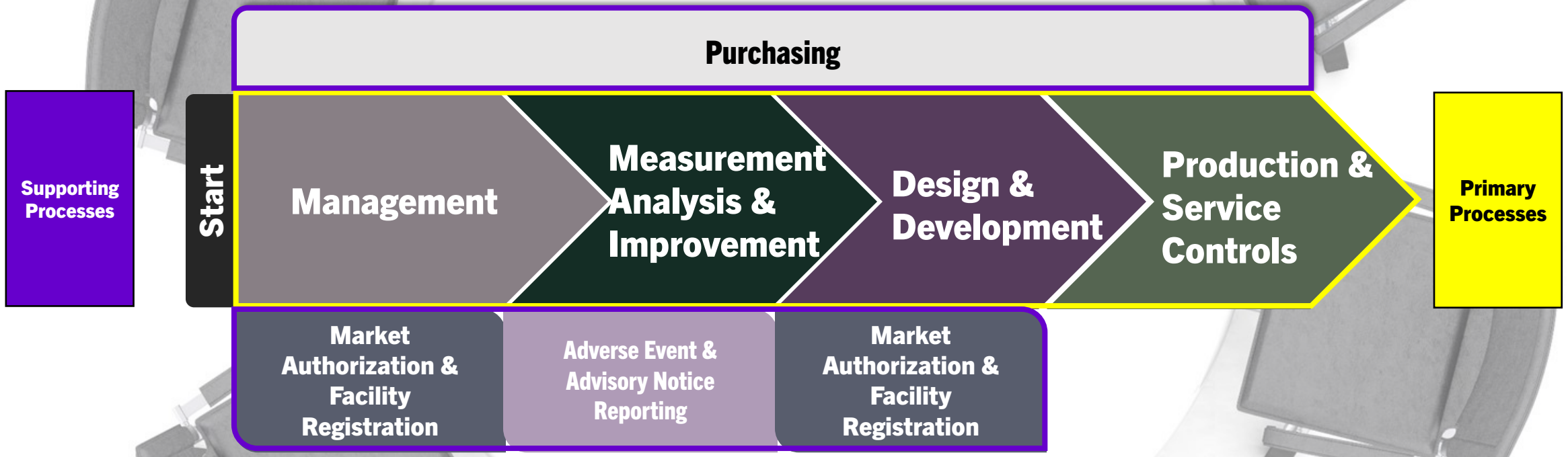

Intro to MDSAP
Management
Measurement Analysis & Improvement
Production & Service
MDSAP
Training
Purchasing
Device Marketing Authorization & Facility Registration
Adverse Event & Advisory Notice Reporting



MDSAP Audits

- QMS Requirements
- Country-Specific Requirements
- Foundation built on Risk

MDSAP Audit Approach Sequence



Primary Processes

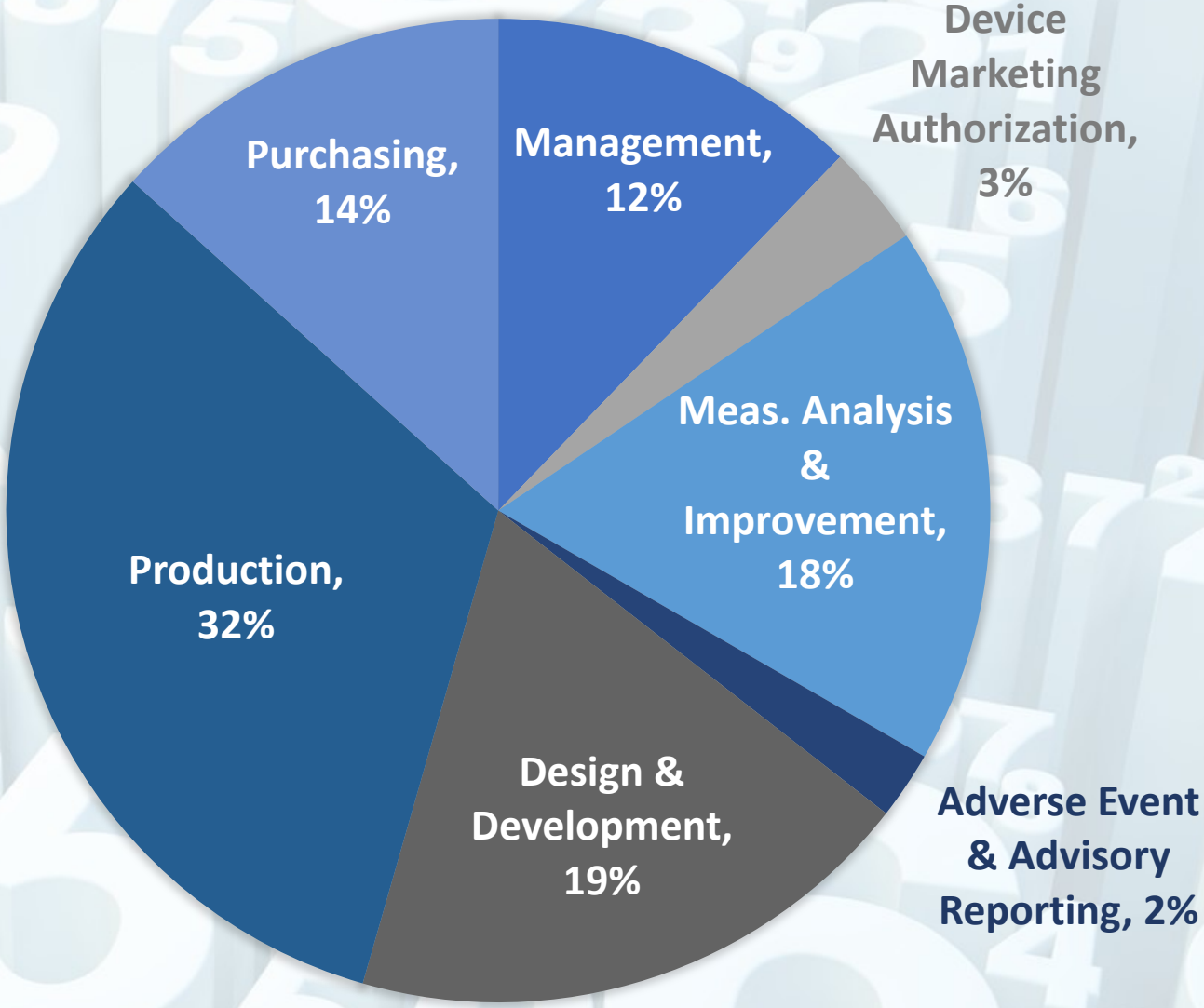
- Management (**11 tasks**)
- Measurement, Analysis & Improvement (**16 tasks**)
- Design & Development (**17 tasks**)
- Production & Service Controls (**29 tasks**)

Sub Processes

- Purchasing (**12 tasks**)
- Device Market Authorization & Facility Registration (**3 tasks**)
- Adverse Event & Advisory Notice Reporting (**2 tasks**)

90 Total Tasks

AUDIT APPROACH TASKS



WHY IS THERE A SEQUENCE?

CONSISTENCY

Same order & flow
Logical order

INFORMATION FLOW

Info drives audit decisions & controls communication

INTERRELATIONSHIP

Identifies systemic problems

MDSAP Audit Types

3 Year Audit Cycle

- Initial
- Surveillance (2x)
- Recertification

Other Audits

- Special
- Unannounced
- RA Audits

INITIAL

STAGE 1
Documentation
Review

STAGE 2
On Site Audit

Certification
Decision

Full Audit

STAGE 1
Documentation
Review (as
needed)

Review of
Changes, Mgmt
process, MA&I,
Registration,
Authorization,
etc.

Partial Audits

SURVEILLANCE

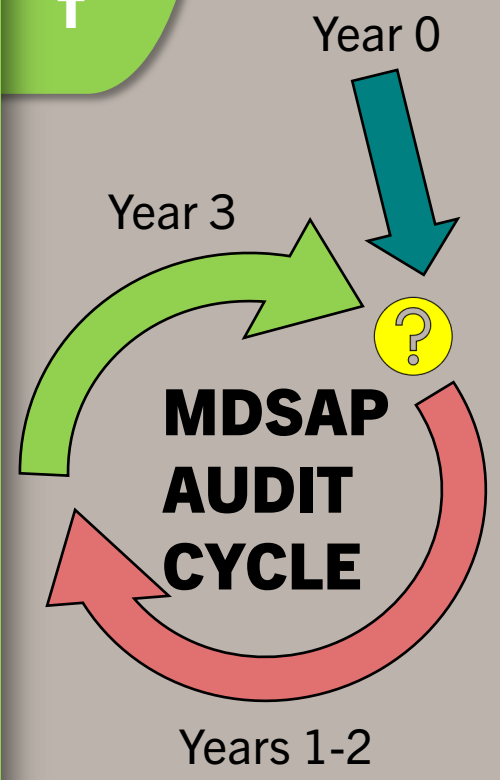
2x

STAGE 1
Documentation
Review (as
needed)

Review of audit
reports,
corrective
actions, etc.

Full Audit

RECERT



Surveillance Audits

PARTIAL AUDITS

Fixed Tasks with some variability

TASKS COVERED

Changes – site, QMS or products

Tasks listed in Audit Time Deter. Procedure

PRIMARY PROCESSES

Alternate Coverage of Design & Production Tasks

Process: Management Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1			X
2			X
3			X
4			X
5	X		
6		X	
7			X
8			X
9	X		
10	X		
11	X		

Task 1 – QMS Planning, Implementation, Changes and Quality Manual

Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives.

Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced.

Verify that a quality manual has been documented.

Not required every Surveillance Audit

Required every Surveillance Audit

Task 5 - Extent of Outsourcing

Determine the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verify the proper documentation of controls in the quality management system.

Verify the list of critical suppliers is current and accurate.

Task 6 – Personnel Competency and Training

Confirm the medical device organization 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.

Required 1 of 2 Surveillance Audits

Question

Which is NOT a primary process of the MDSAP Audit Approach?

a. Management
b. Design & Development
c. Production
d. Adverse Event & Advisory Notice Reporting

Question

How many years is a full MDSAP Audit Certification Cycle?

a. One (1)
b. Two (2)
c. Three (3)
d. Four (4)

Grading of Nonconformities

QMS Impact
Direct = 3
Indirect =1

+

Repeat?
Yes = 1
No = 0

+

Procedure?
Yes = 1
No = 0

+

Release of Nonconforming Product
Yes = 1
No = 0

NC Grade = Sum of 4 Parameters with Max Grade of 5

Individual Nonconformity Information

Nonconformity number or reference 11

Statement of nonconformity

The procedure for transfer of design and development outputs to manufacturing is not documented.

Supporting evidence

The design and development processes are documented in the IVD material design and development procedure (ID# K14N0340 Rev. E). In the procedure, it is mentioned that design transfer from design to manufacturing shall be implemented. However, it is not the procedure.

Unsatisfied requirements

Hide/Show Audit Task and Linkages

Audit task: process: Design and Development — Task number: 04

QMS Impact	Repeat NC ?	Required Procedure Lacking ?	Nonconforming Products Released ?	MDSAP Grade	ISO 17021 Grade
○ Indirect ◉ Direct	◉ No ○ Yes	○ No ◉ Yes	◉ No ○ Yes	**4**	Major

☐ The organization detected and properly addressed the nonconformity prior to the audit

Auditee's response to the nonconformity

I. Remediation plan

Due date for providing the remediation plan: 2018-04-28

Outcome of the investigation of the nonconformity, including its cause analysis

Cause Analysis:
The IVD material design and development procedure (ID# K14N0340) only mentioned that design transfer from design to manufacture shall be implemented. The procedure did not specify detailed steps for the design transfer because the Pharmaceutical regulations in Japan require assessment of manufacturability of IVD reagents, which should ensure that the design transfer to manufacture is surely performed without

Post Audit Timeline

5 Day Notice Sent to RAs

More than 3 Grade 4 NCs or any Grade 5 NCs

5 Working Days
Inform RAs of Audit Outcome

90 Calendar Days
Due date for complete audit report package

15 Calendar Days
Recommended date for remediation plan from MDM

30 Calendar Days
Recommended date MDM to provide AO with evidence of implementation

45 Calendar Days
Due date for complete audit report package

5 Day Notice

- **Refusal to Certify**
- **Suspension or Withdrawal of Certification**
- **Reduction of Scope of Certification**
- **Public Health Threat**
- **Fraud**
- **Counterfeit**

Due dates listed are days after audit has ended

Question

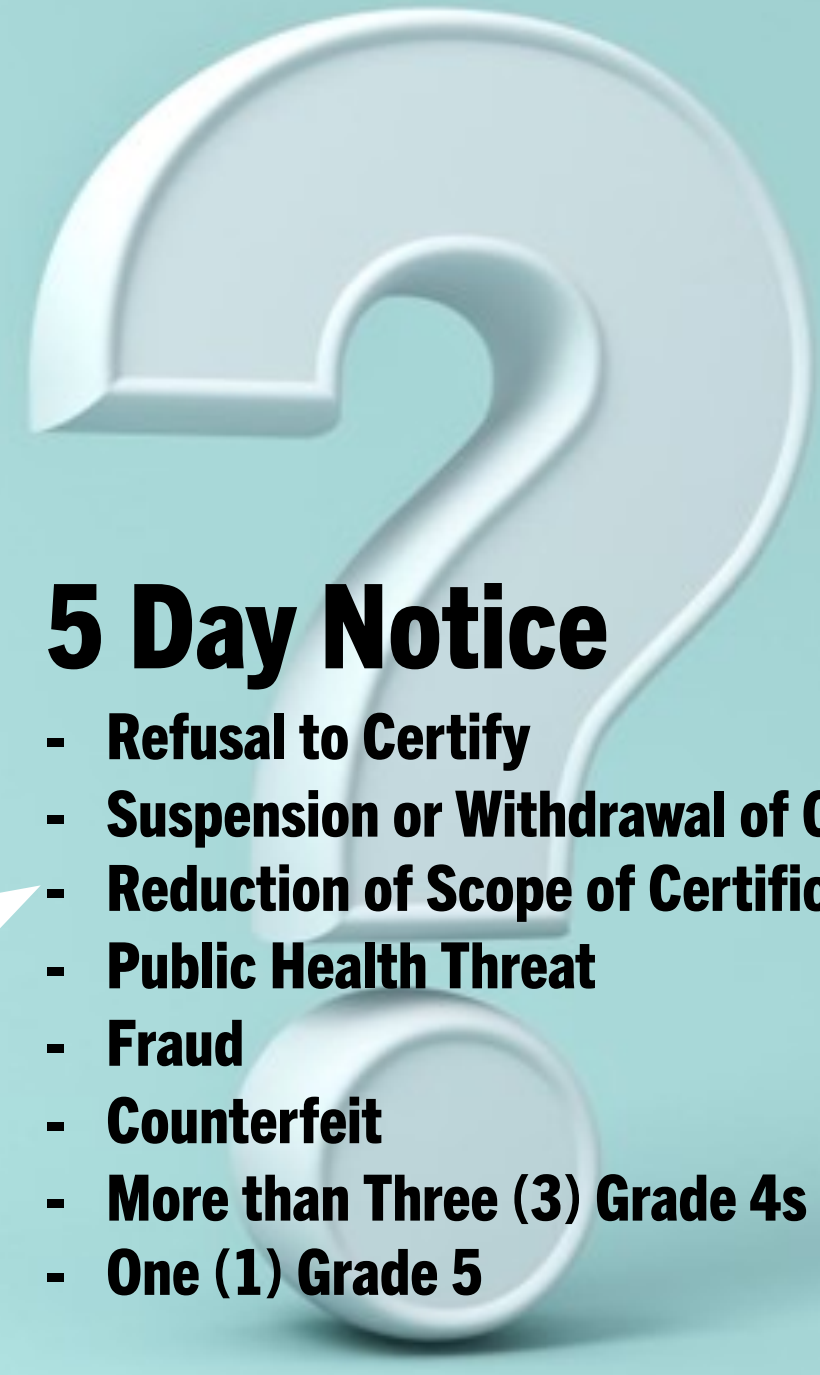
What is the highest grade (poorest result) a nonconformity can have?

a. Three (3)
b. Four (4)
c. Five (5)
d. Six (6)

Question

Which meets the criteria for a 5 Day Notice?

a. Twelve (12) Grade 3 NCs
b. Six (6) Grade 4 NCs
c. One (1) Grade 5 NC
d. B & C
e. All of the Above



5 Day Notice

- **Refusal to Certify**
- **Suspension or Withdrawal of Certification**
- **Reduction of Scope of Certification**
- **Public Health Threat**
- **Fraud**
- **Counterfeit**
- **More than Three (3) Grade 4s**
- **One (1) Grade 5**


Questions

MDSAP Assessment Program

Pre-requisite Requirements for Assessors

Education

University Degree – Medicine, Science or Engineering

Experience

4 years experience in Medical Devices or related sector

Competence

Foundational – communication, critical thinking

Functional – project/time mgmt

Technical – regulatory, risk assessment skills

Training Requirements for Assessors

Initial

40 hours – Quality Management Systems Training (ISO 9001) with 8+ hours dedicated to ISO 13485

32 hours – ISO 17021-1:2015 – Conformity Assessment, country specific requirements, IMDRF documents

8 hours – Risk Management (ISO 14971)

Continual Development

6 hours – Professional Development

8 hours – annual training on changes to regulatory requirements or training on updates to regulatory requirements

Auditing Organization Journey to Recognition

Assessment Activity	Status
Application reviewed favorably	Application Received
Stage 1 + Stage 2 (+ Critical Locations) + Response to any nonconformity deemed acceptable	Authorized to conduct MDSAP audits (the first 3 to be witnessed)
3 Witnessed Audits + Response to any nonconformity deemed acceptable Recognition Decision	Recognized

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

Focus of Regulatory Authority Assessment of Auditing Organizations

- Management (including Impartiality)
- Measurement, Analysis and Improvement
- Competency Management
- Certification Process
- Information Management

Outsourcing

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM


Questions

State of the Program

MDSAP

22,252

Number of MDSAP Audits Conducted
(January 2018-October 2023)

5.3 days

Average number of days MDSAP Audits are open

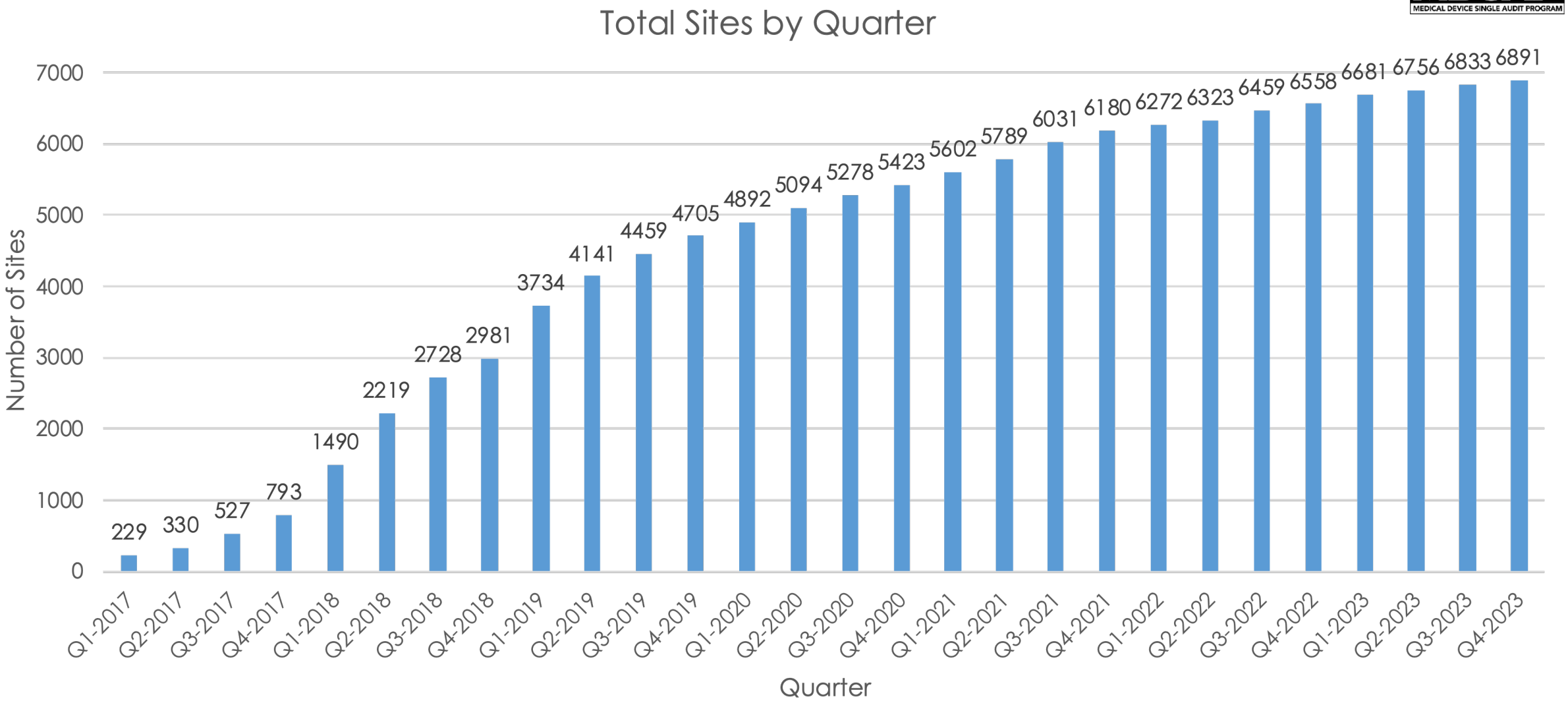
74

Number of Countries where MDSAP Audits occurred

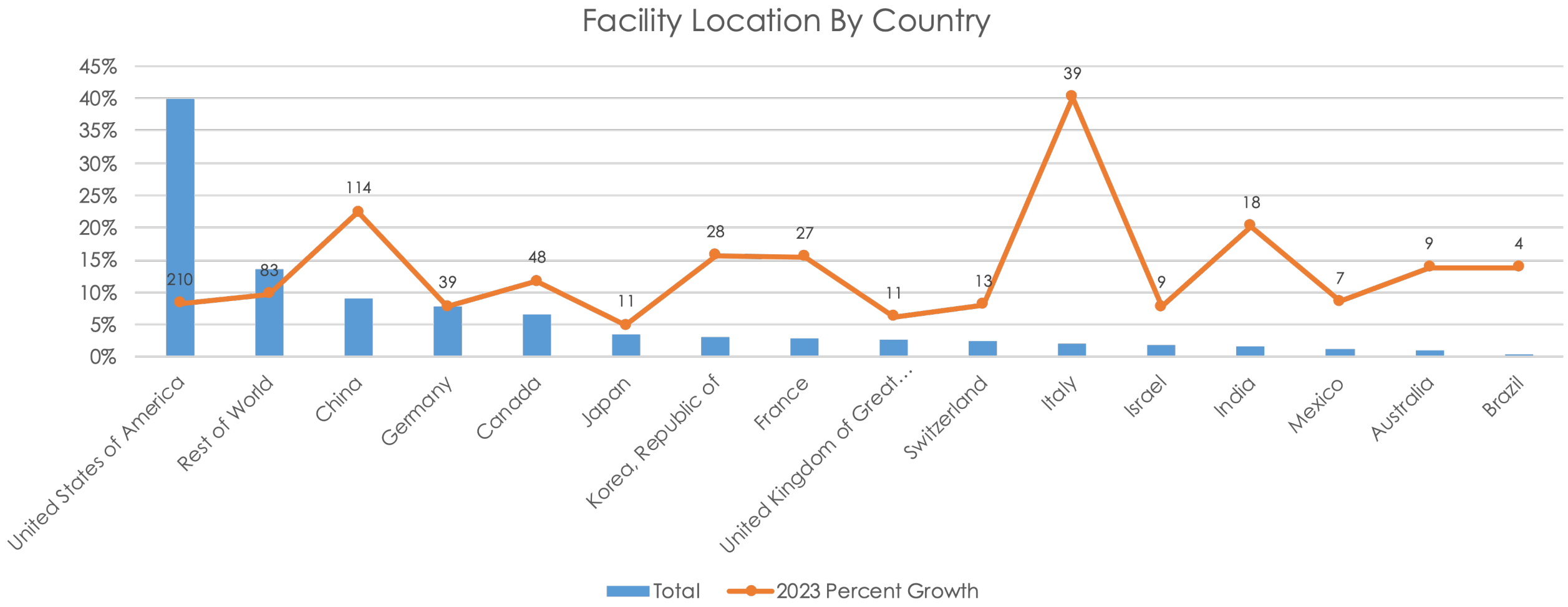
6,891

Number of Active Facilities Participating with MDSAP

MDSAP Participating Facilities

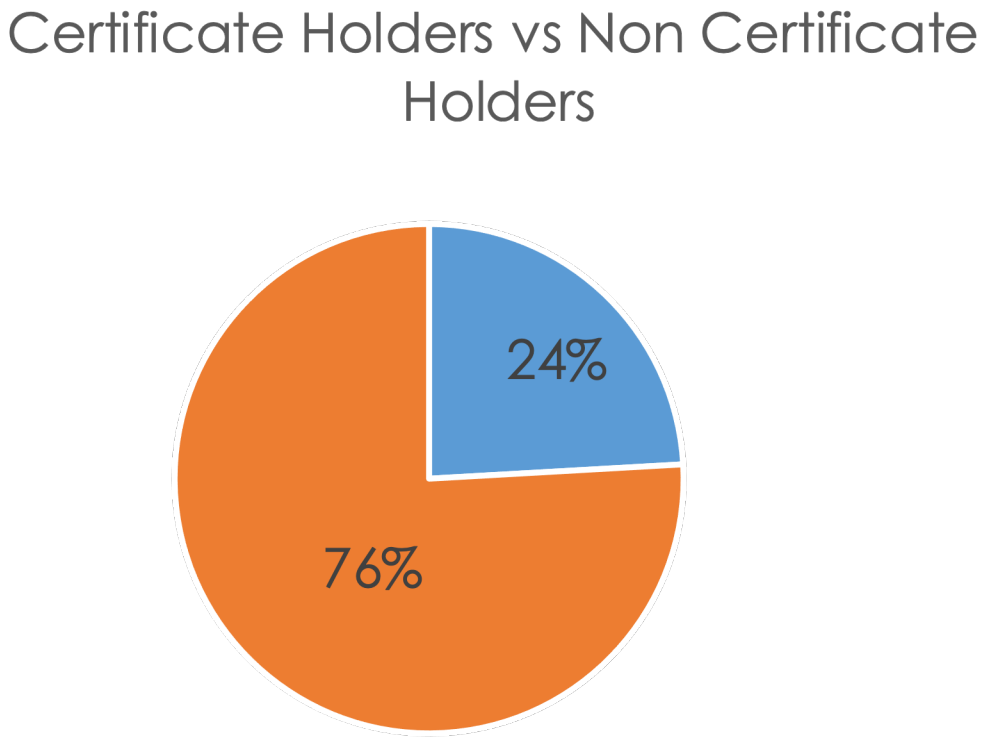


MDSAP Sites by Country



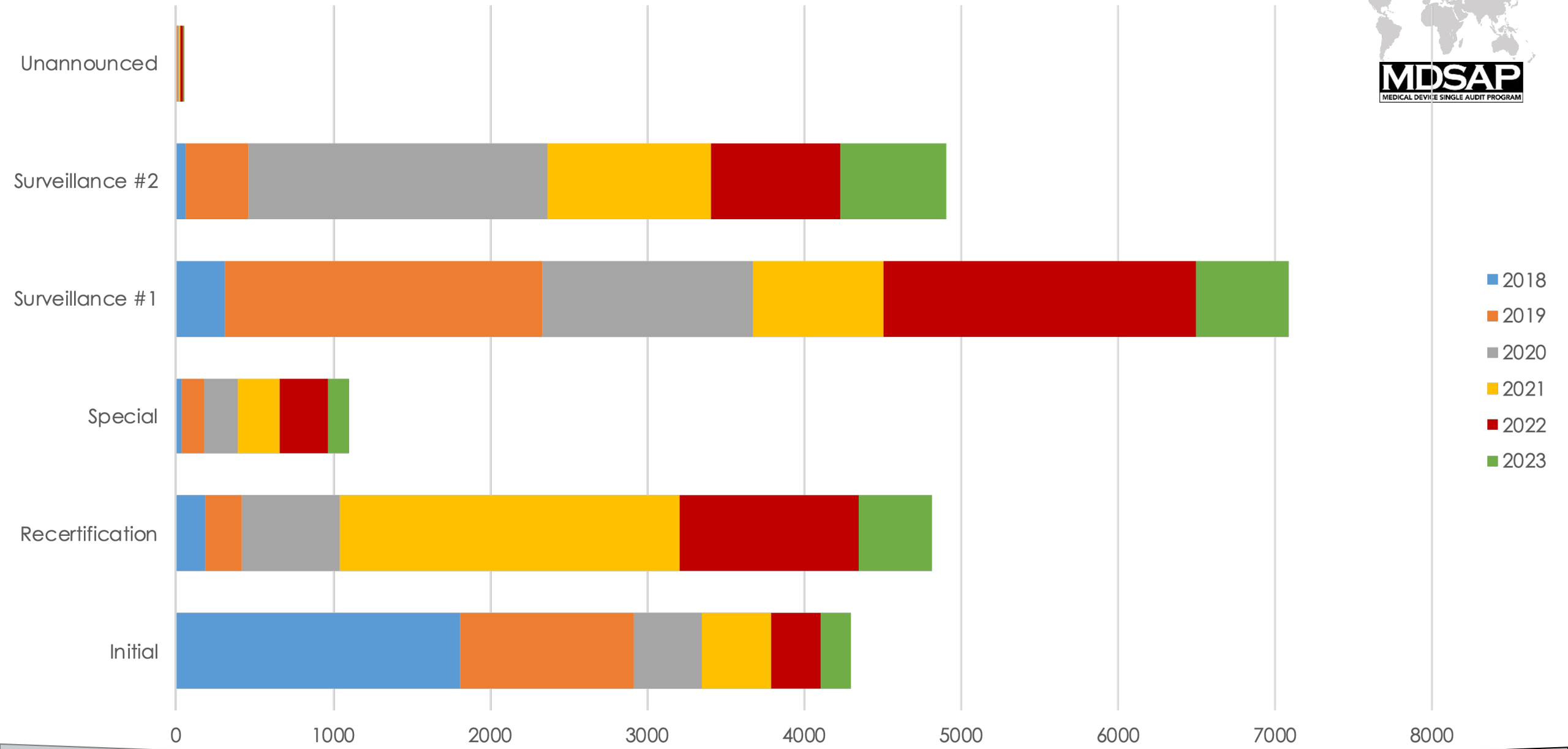
Facilities by Certificate Status

- Facilities: 6,891
  - 6,116 Certificate Holders
  - 2,101 Non-Certificate Holders




COLOMBIA
Bogotá
RR
Belém
São Luís
Fortaleza
Manaus
PARÁ
Teresina
MARANHÃO
CEARÁ
RIO GRANDE DO NORTE
ECUADOR
AMAZONAS
BRAZIL
PIAUÍ
PARAÍBA
PERNAMBUCO
Recife
ALAGOAS
TOCANTINS
ACRE
SE
Aracaju
BAHIA
RONDÔNIA
MATO GROSSO
PERU
Salvador
Lima
Brasília
Cuiabá
GOIÁS
BOLIVIA
MINAS GERAIS
Santa Cruz de la Sierra
MATO GROSSO DO SUL
ESPÍRITO SANTO
Sucre
Campo Grande
SÃO PAULO
Campinas
RIO DE JANEIRO
PARAGUAY
São Paulo
PARANÁ
Salta
Asuncion
Curitiba
CHILE
SANTA CATARINA
San Miguel de Tucumán
Florianópolis
RIO GRANDE DO SUL
Porto Alegre
Cordoba

MDSAP Audits Performed by Type



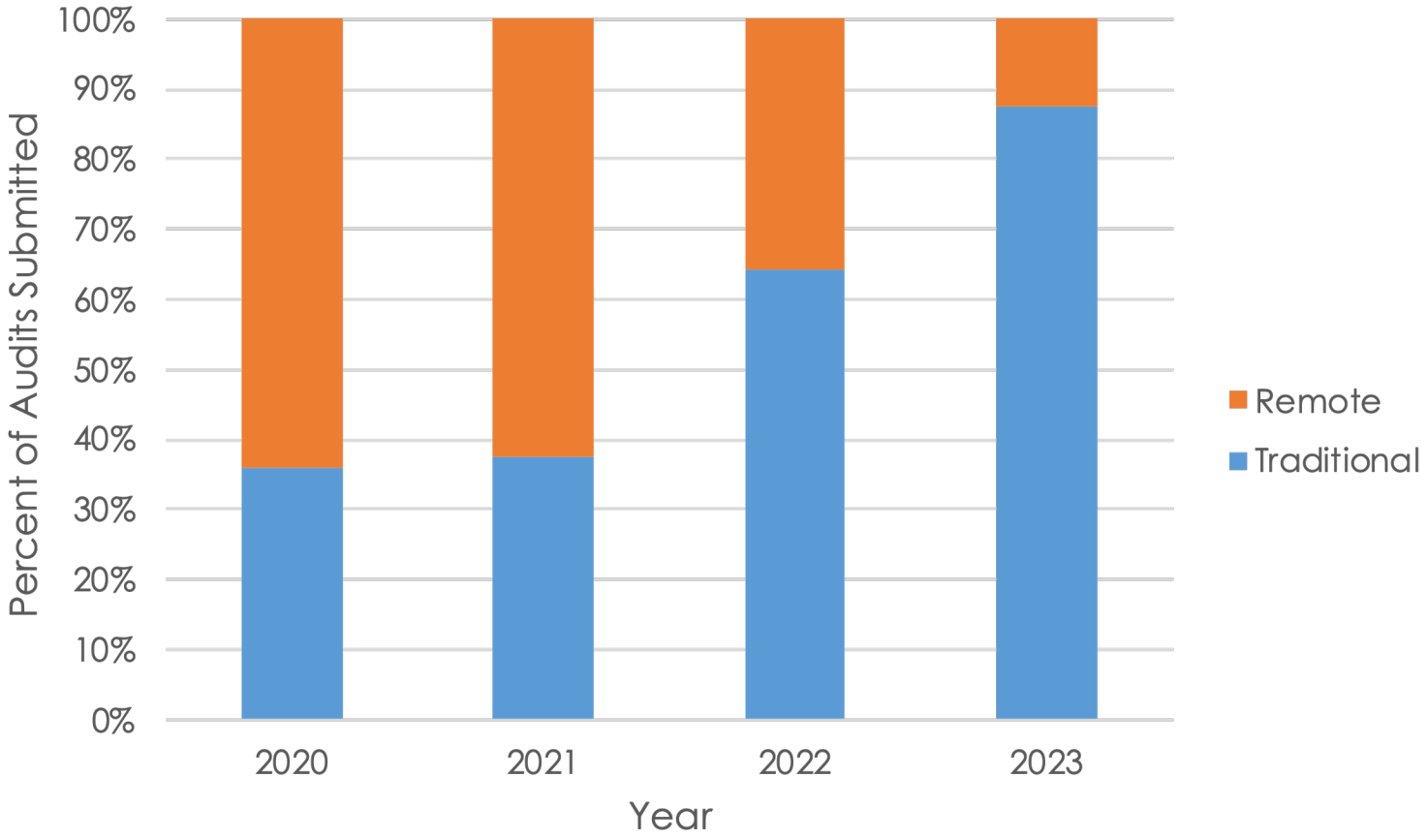
Remote Audits

~45% of Audits

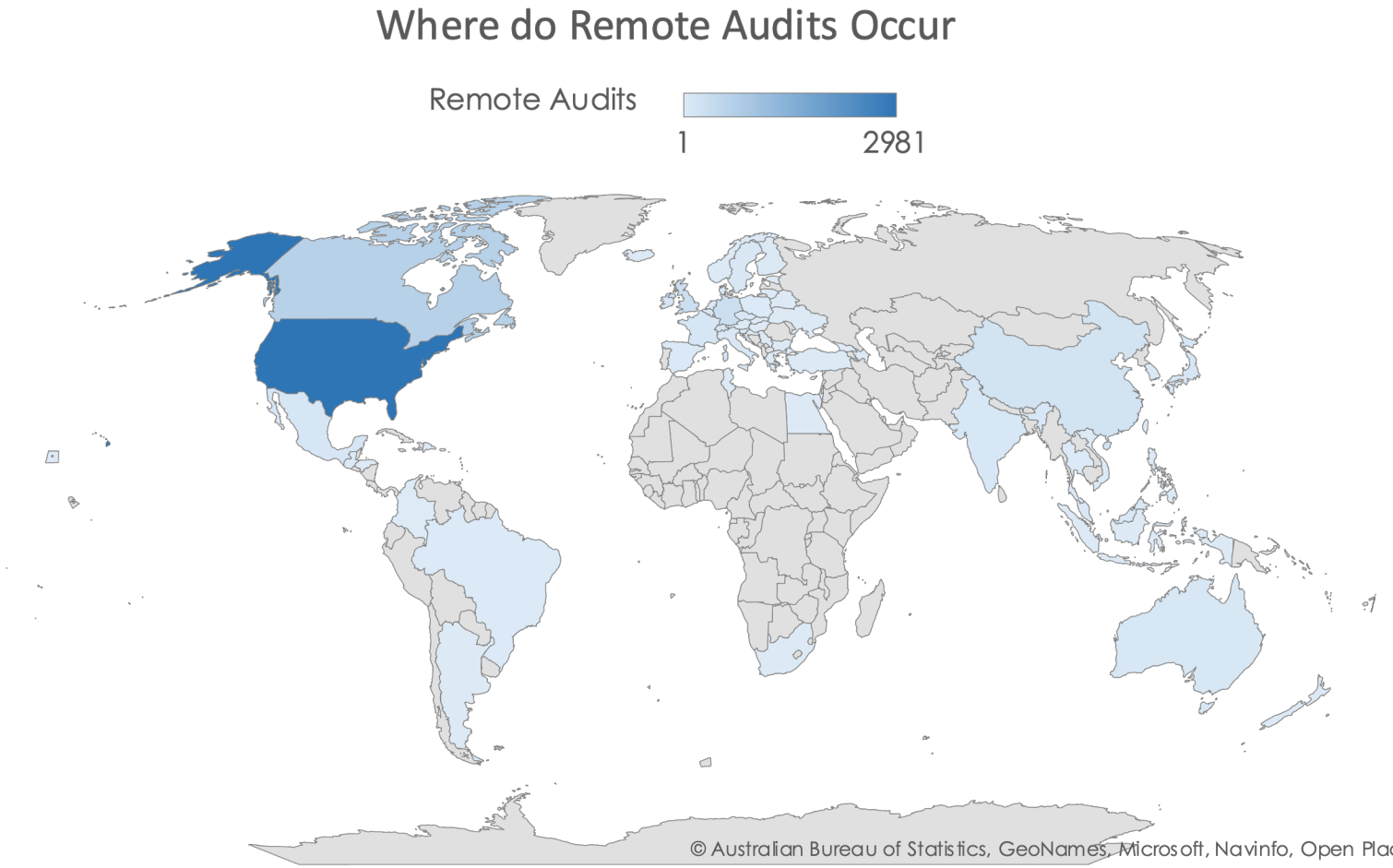
During 2020 through 2022 were performed at least partially remote

~9% of Audits

Submitted in 2023 were performed at least partially remote

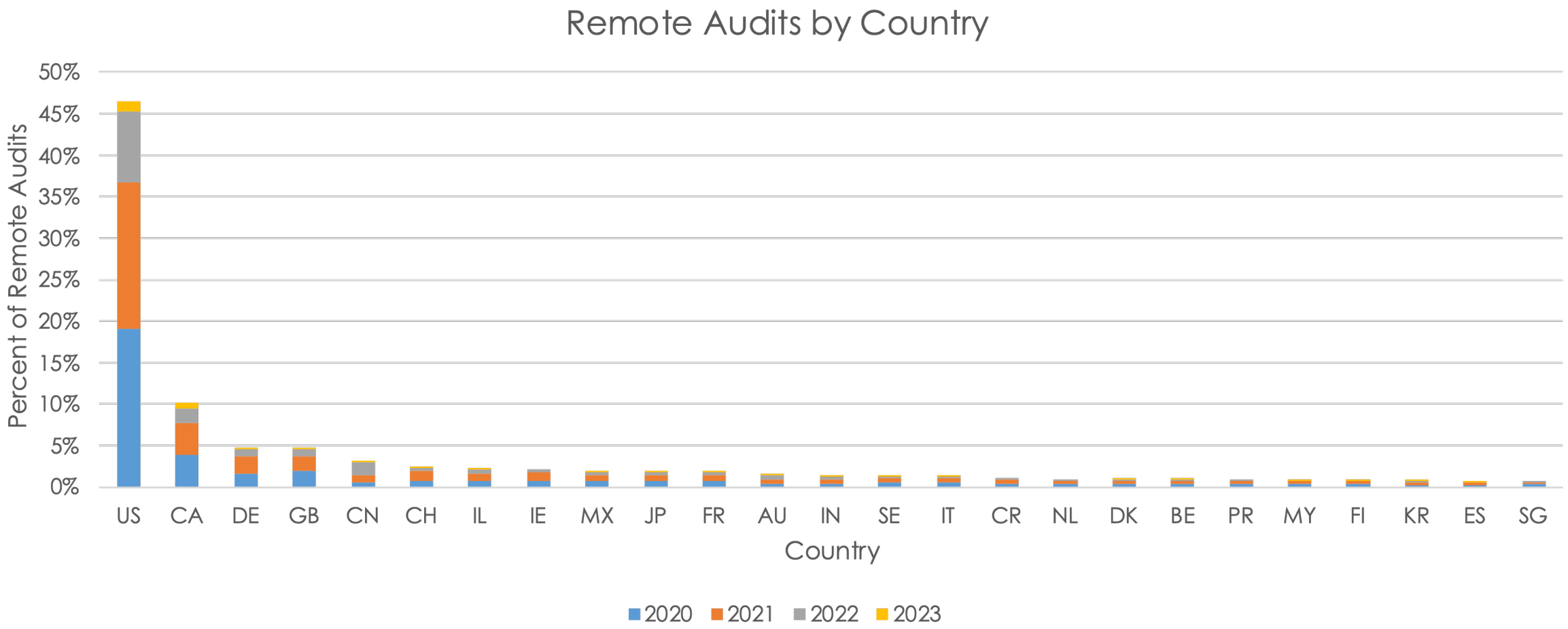


Where do Remote Audits Occur



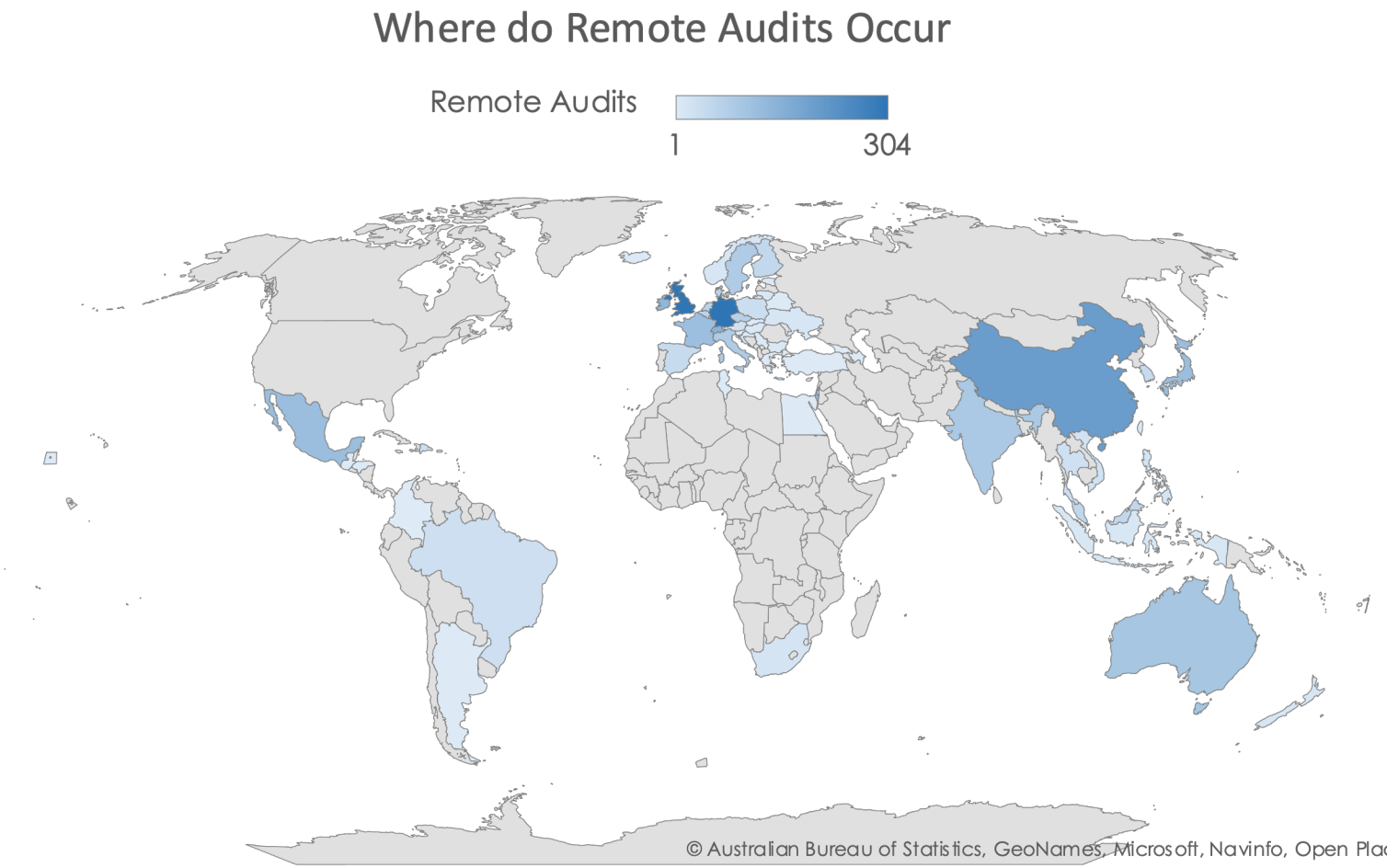
Where do Remote Audits Occur

Top 25



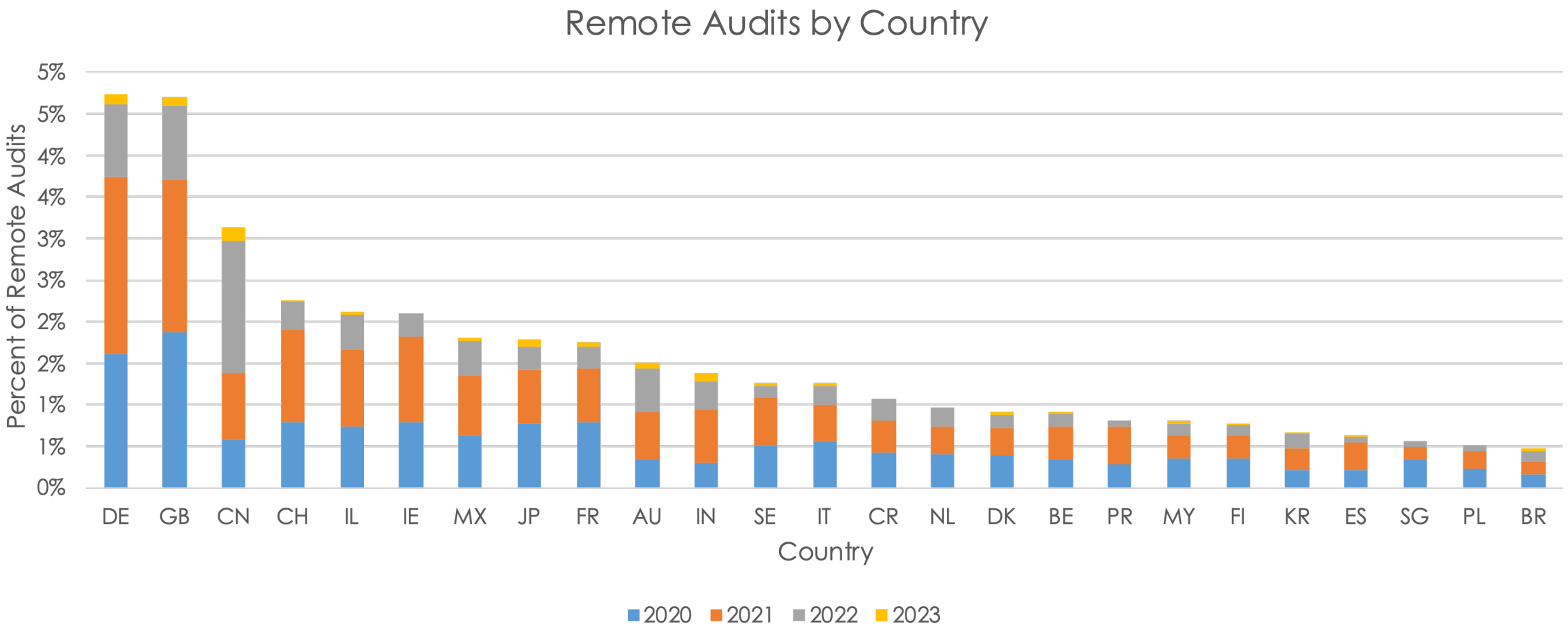
Where do Remote Audits Occur

(excluding US and Canada)

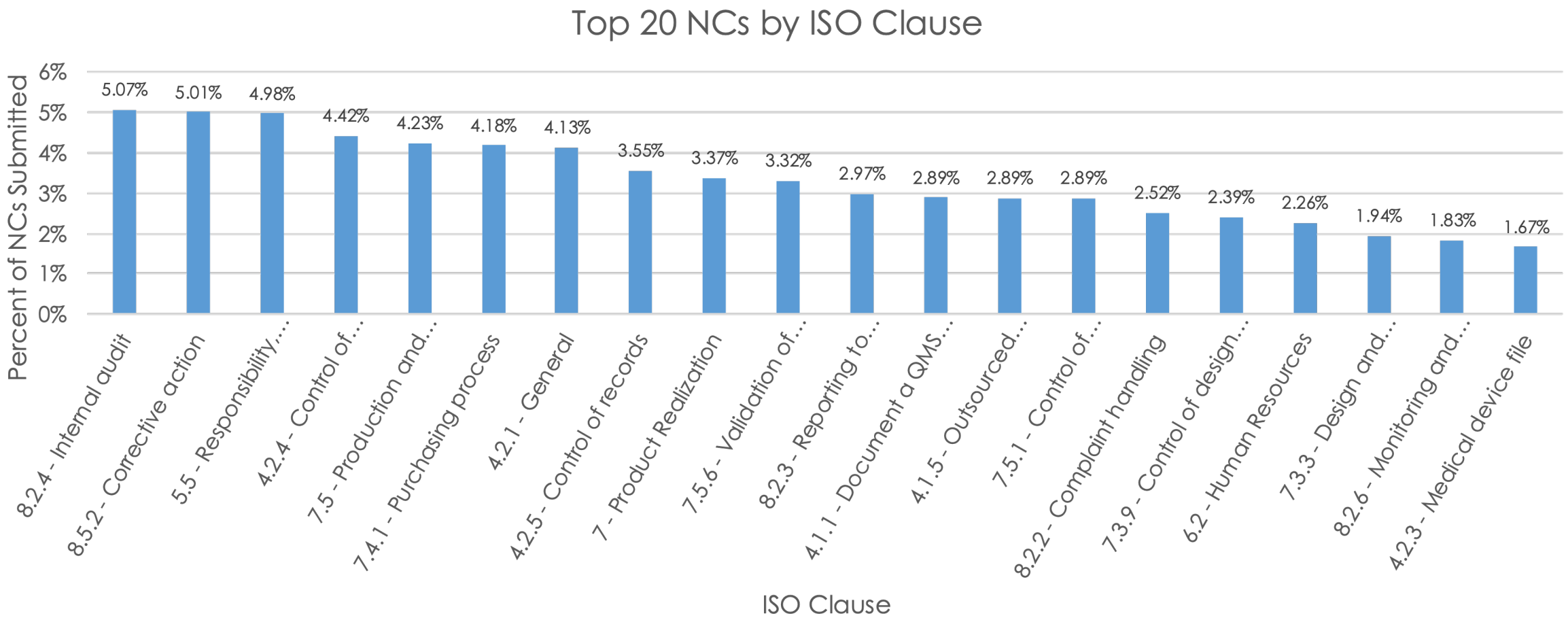


Where do Remote Audits Occur

Top 25 (excluding US and Canada)



Number of NCs by Clause




Questions

MDSAP Future State

MDSAP RAC initiatives for 2023

- Audit, Assessment process updates
- Strengthening the organization

To Enhance Credibility and Stability of the Program

Audit, Assessment process updates

Audits:

- Launch Pilot to permit hybrid/remote audit practices in a post-pandemic world (Mar 2023)

AO Assessments:

- Introduce systematic management process of AO assessment, utilizing IT technologies and additional human resources (on-going)
- Explore new considerations for AO candidates (under development)

Considerations for AO Candidates

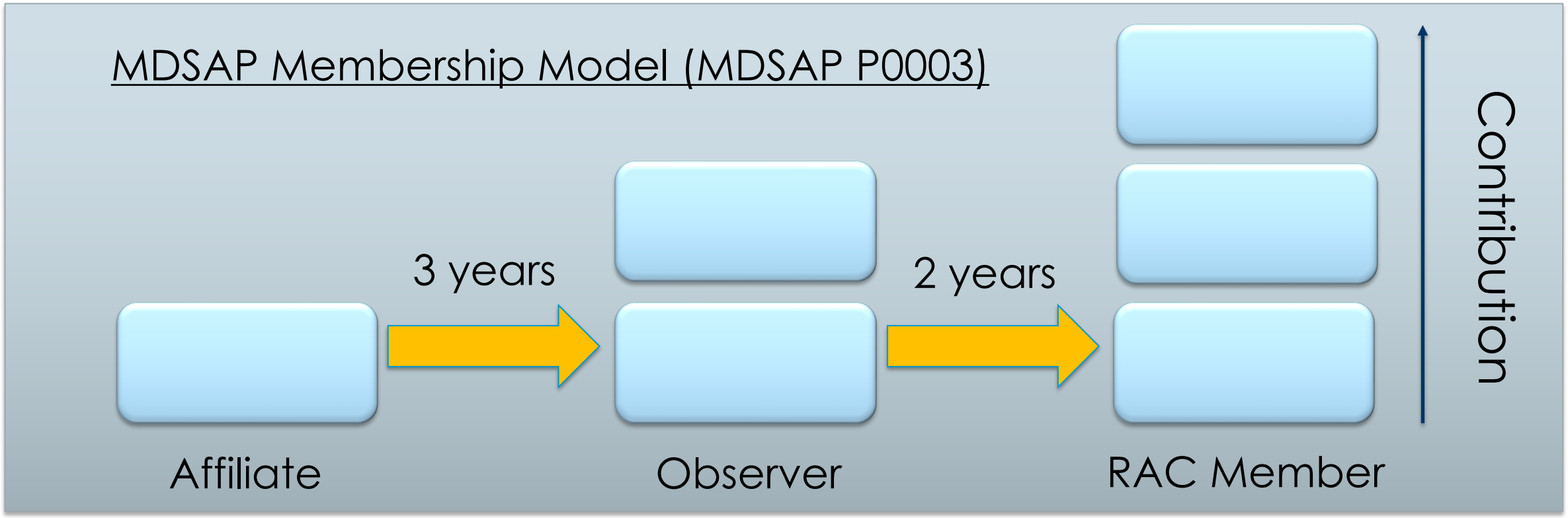
- Consortium is exploring additional considerations for new AO candidates to ensure efficient use of resources, when processing of new candidates resumes

- Considerations will build on foundational documents such as N3 in order to help determine the candidate assessment queue

- Intent is to focus future recognition efforts on candidates with the best chances of being recognized

Strengthening the organization

- Establish MDSAP membership recognition criteria(Jan 2023)
- Addition of Taiwan FDA as an Affiliate Member (Sept 2023)



Recent Efforts of the MDSAP RAC

- Performance Enhancement of MDSAP

For Further Strengthen the Program

Performance Enhancement of MDSAP

Aim:

- Create more transparency about MDSAP performance
- Demonstrate benefits and value of MDSAP participation
- Communicate the effectiveness, continuous improvement and efficiency of the MDSAP
- Highlight the maturity and trust of the MDSAP in its operations
- Partnership approach between the RAC, SMEs and AOs to deliver and report on the performance of the MDSAP

Performance Enhancement of MDSAP

Proposed Elements:

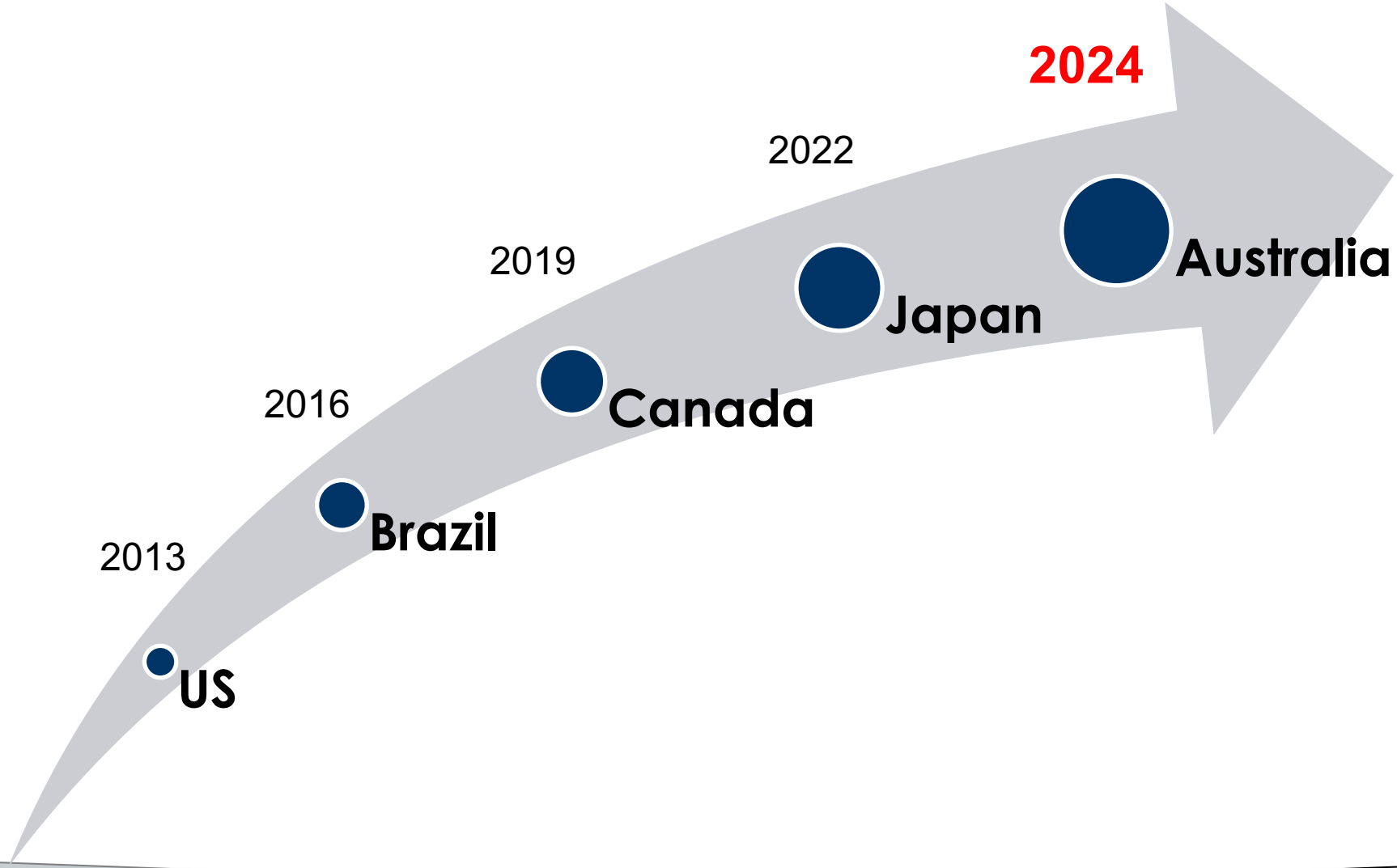
1. Increase capacity
2. Monitor performance
3. Improve timeliness
4. Enhance quality
5. Rapid identification, escalation and resolution
6. Reporting of performance
7. Increased engagement

Performance Enhancement of MDSAP

Next steps:

- RAC to continue discussions and considerations
- RA SMEs to have input to the proposals
- Feedback from AOs to the proposals
- Finalize the list of proposed actions, identify potential timeframes and ways to implement = a plan

Chair Country Transition



Thank you!

Contact information
Mail: mdsap-rac-secretariat@pmda.go.jp


Questions

State of the Medical Device Audit Industry

Auditing Organizations Perspective

Brasilia, 2023-10-24

AI and Digitalization

AI and Digitalization

Incorporating AI into medical devices and AO work

Expanded and new Guidance/regulations

platforms/systems for exchanging of information

Remote/Hybrid Auditing

Challenges

Challenges

Global Harmonization

- Navigating multiple schemes is burdensome
- Harmonization when crossover of regulations with medical devices

Resources

- Tapping out on capacity to hire across industry
- Difficulty meeting requirements of N4

Highlights/Benefits

Highlights/Benefits

- Global Harmonization/Acceptance of MDSAP
- Increase interest in MDSAP
- Maturing and Stability of Program


Questions

FDA

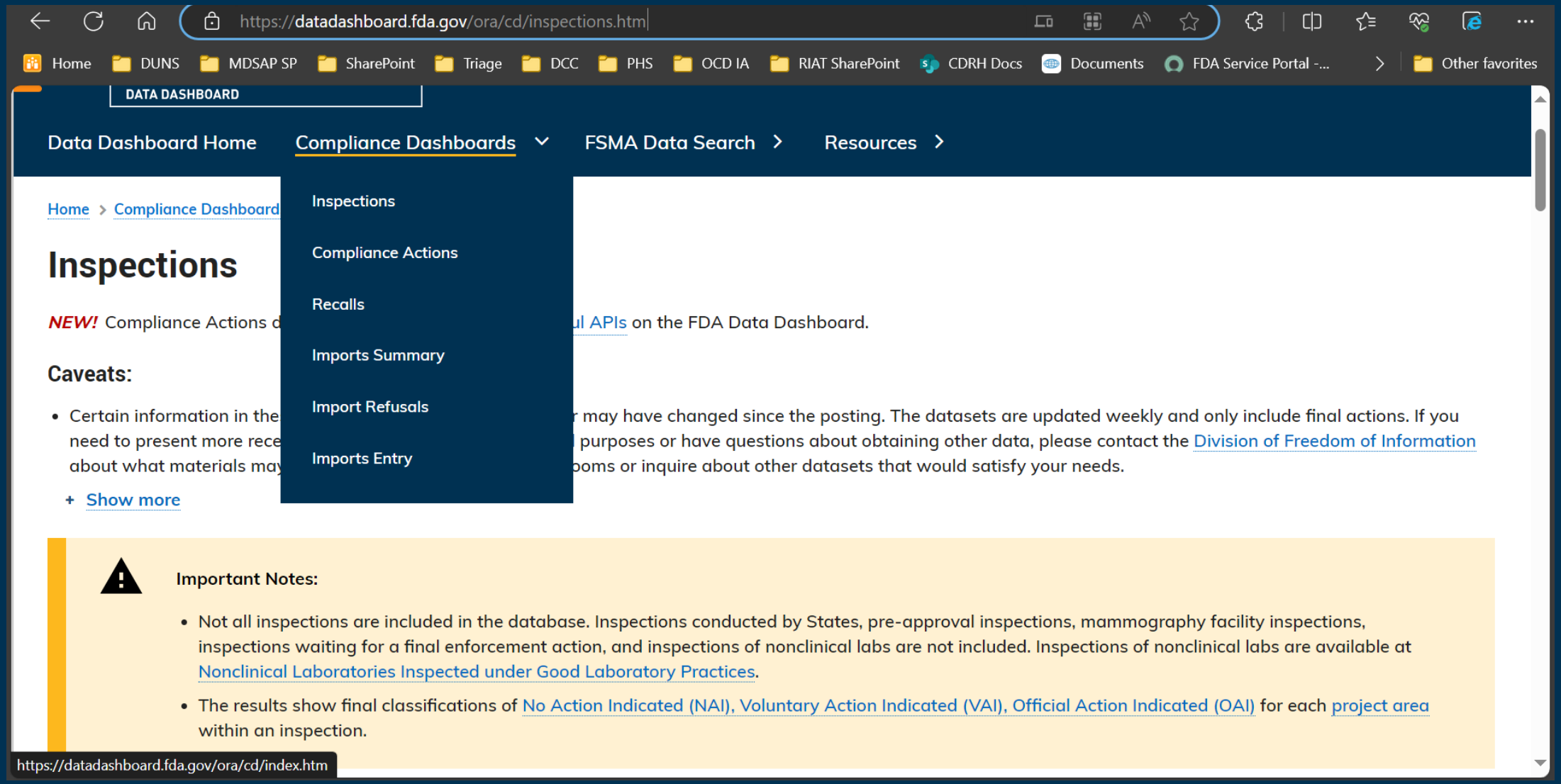
U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

Databases

FDA Data Dashboard

https://datadashboard.fda.gov/ora/cd/inspections.htm



Warning Letters

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Filter by

Issuing Office

Letter Issue Date

- Any -

Letters with Response or Closeout

- Any -

Posted Date

- Any -

Year

- Any -

Clear Filters

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

Medical Device Databases

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

Devices@FDA	Devices@FDA is a catalog of cleared and approved medical device information from FDA. It includes links to the device summary information, manufacturer, approval date, user instructions, and other consumer information. Devices@FDA searches the following databases: Premarket Notifications (510(k)s) and Premarket Approvals (PMA).	Weekly
Premarket Approvals (PMA)	Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of all devices classified as Class III devices. An approved Premarket Approval Application (PMA) is, in effect, a private license granted to the applicant for marketing a particular medical device. This database may be searched by a variety of fields and is updated once a week.	Weekly
Product Classification	This database contains medical device names and associated information developed by the Center. It includes a three letter device product code and a Device Class that refers to the level of CDRH regulation of a given device.	Weekly
Premarket Notifications (510(k)s)	Medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. This database of releasable 510(k)s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information is available via the web interface for more recent records. The database is updated once a week.	Weekly
Recalls of Medical Devices	This database contains Medical Device Recalls classified since November 1, 2002. Beginning January 3, 2017, the database may also include correction or removal actions initiated by a firm prior to review by the FDA. The status of the action is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall and provides contact information for customers with questions. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. CBER recall information is available here.	Frequently as items become available

Questions?

CDRHInternational@fda.hhs.gov


Welcome to the
MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM
2022 Forum
Thank you!