MDSAP

Medical Device Single Audit Program

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Why MDSAP Opens a World of Possibility

LIVE Webinar

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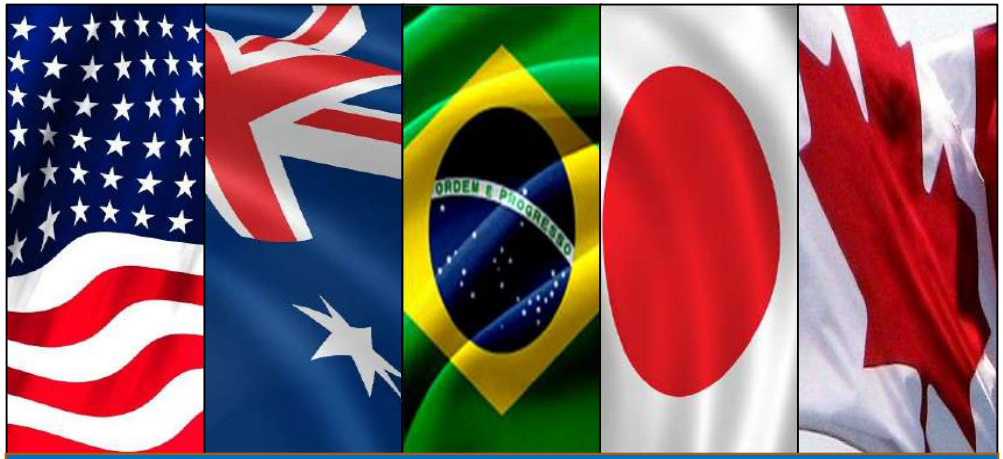
Agenda

- What is MDSAP?
- Participating Countries
- Eligible Auditing Organisations
- Auditing: ISO 13485:2016 and MDSAP compared
- Documentation Differences
- Audit Documentation Requirements
- Benefits of MDSAP
- Initial Reviews
- Questions
- Conclusion

What is MDSAP?



MDSAP

Medical Device Single Audit Program

The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a ***single regulatory audit*** of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

Countries Participating in MDSAP

Eligible Auditing Organisations

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14

Organisations authorised to conduct MDSAP Audits.

Current list at:
https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf

bsi.
DEKRA
DQS MED
Intertek
LNE Sharing a passion for progress
G MED
Lloyd's Register LRQA
NSAI
NSF Health Sciences Medical Devices
SAI GLOBAL
SGS
UL
TÜV SÜD America
TÜVRheinland
TÜV USA TÜV NORD GROUP

Auditing: ISO 13485:2016 and MDSAP Compared

Process and basic requirements for ISO 13485:2016 and MDSAP are aligned.

BUT significant differences include:

- Inclusion of geography-specific information
- MDSAP uses a point-based nonconformity grading system
- MDSAP Audits require two Stages in the initial assessment

Auditing: ISO 13485:2016 and MDSAP Compared
Nonconformity Grading

Aligned with the GHTF's *Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange.*

QMS Impact	**Direct**	**3**	**4**
	Indirect	**1**	**2**
		First	**Repeat**
		Occurrence	

Add 1 point for absence of a process or release of Non-conforming MDs.

Documentation Differences

- Pre-Market Regulatory
- Post-Market Regulatory
- Recalls and Product Notifications
- Design and Development
- Design Changes

Audit Documentation Requirements

Brandwood Biomedical has completed several MDSAP audits to date;
We have developed a basic list of documentation for the MDSAP Audit:

MDSAP Process and Audit Task	Required documentation
Management	Quality Manual
	Quality Policy
	Quality Objectives
	Organisational charts
	Policy / procedure on outsourcing
	List of suppliers
	Procedures for the control of documents and records
	Management review procedures and associated record templates
	Records of at least one completed management review

Audit Documentation Requirements (cont.)

MDSAP Process and Audit Task	Required documentation
Device Marketing Authorization and Facility Registration	Submission
	Marketing Clearance / Approval
	Change Notification QMS / Products
Measurement, Analysis and Improvement	Procedure for Control of NC Product
	Procedure for Investigations
	Procedure for CAPA
	Procedure for Data Analysis
	Procedure for Complaints
	Procedure for Recalls
	Procedure and Templates for Internal Audits
	Records for at least one completed internal audit

Audit Documentation Requirements (cont.)

MDSAP Process and Audit Task	Required documentation
Medical Device Adverse Events and Advisory Notices Reporting	Procedure for Adverse Events
	Procedure for Advisory Notices
Design and Development	Procedure for the control of the design and development
	Procedure for the control of design changes
	Procedure for design transfer
Production and Service Controls	Procedures for planning of product realisation
	Documented provisions for product cleanliness
	Policies/procedures for validation/revalidation of processes
	Procedures for statistical techniques
	Procedures for control and calibration for measuring and monitoring devices
	Procedures for validation of software systems
	Procedures for the establishment of DHF/DMF
	Procedures to ensure integrity and prevent accidental mixing

Audit Documentation Requirements (cont.)

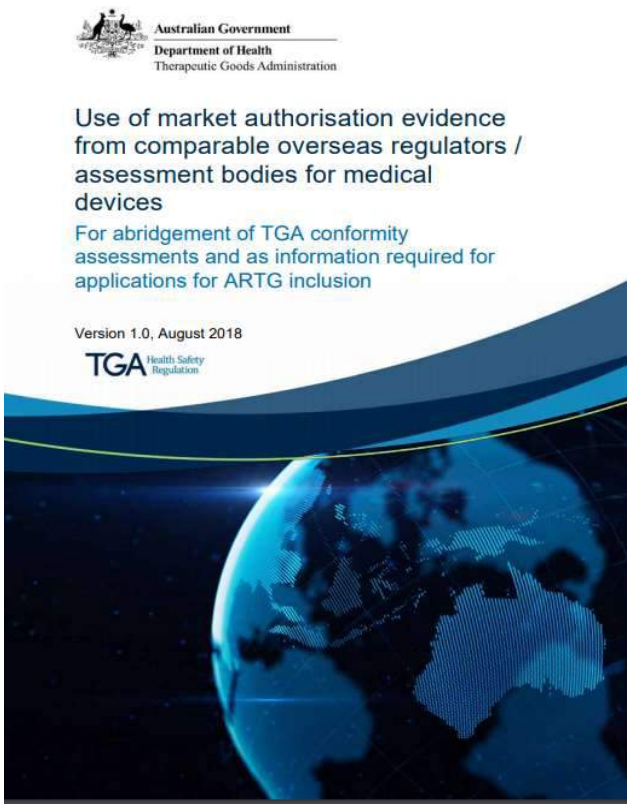
MDSAP Process and Audit Task	Required documentation
Production and Service Controls	Procedures for the establishment and completion of DMR
	Procedures for device tracking where applicable
	Procedures for handling customer property, as applicable
	Procedures for acceptance activities
	Procedures for establishing sampling plans
	Procedures for rework (where applicable)
	Procedures for preservation of products (components/parts)
	Procedures for distribution controls (keeping of records)
	Procedures for installation, if applicable
	Procedures for servicing, if applicable
Purchasing	Procedures for evaluation, selection and monitoring of suppliers
	Procedures for acceptance activities
	Template of supplier agreement

Benefits of MDSAP

Regulators included in the IMDRF will use the MDSAP audit (and its reports) to substitute for the evidence of manufacturer's QMS certifications.

These countries will not require additional country-specific audits and may create more pathways for product regulatory approvals in these target markets.

Benefits of MDSAP - Australia

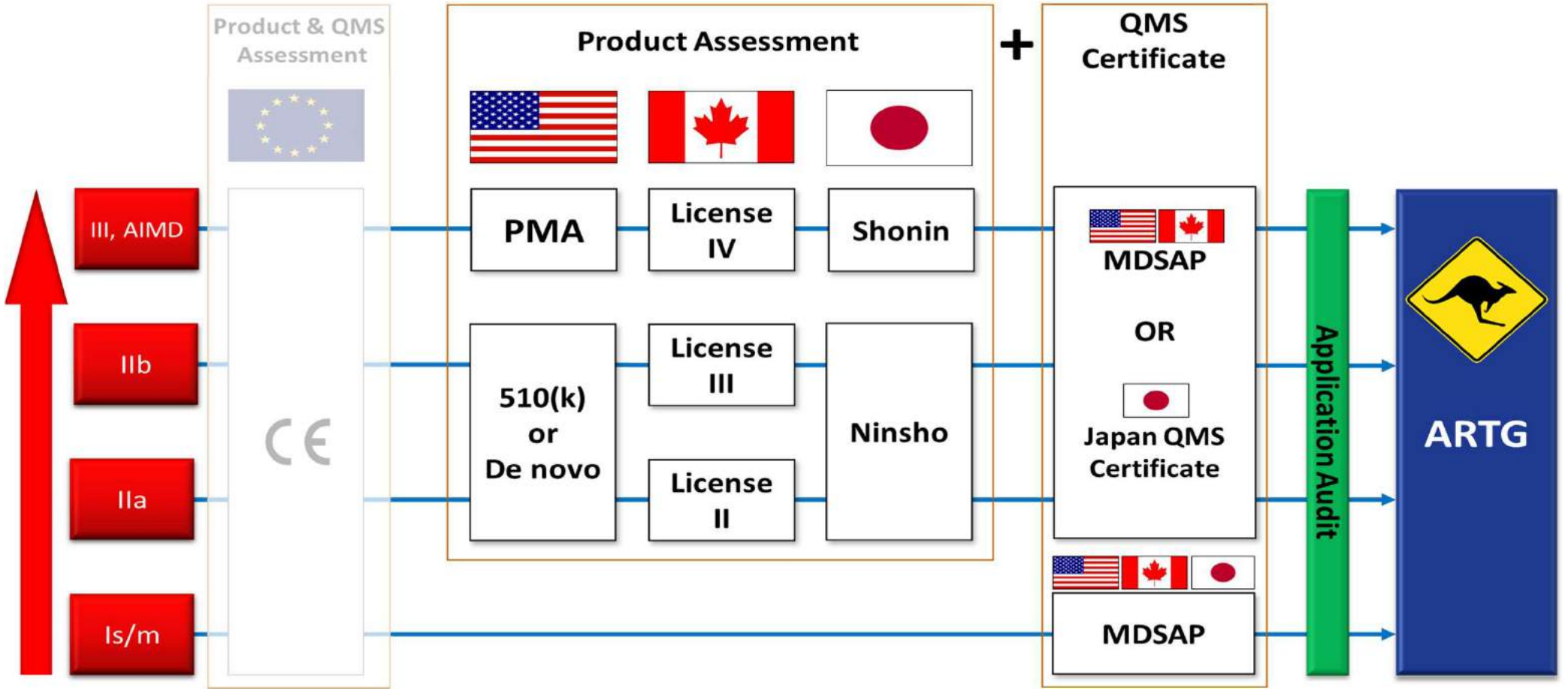


TGA guidance: *"Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices*

MDSAP audit, combined with a Canadian, Japanese or FDA approval, can be used to obtain TGA registration (ARTG Inclusion) of a Medical Device.

These are **new pathways,** in addition to current use of CE Mark for Australian registration.

Benefits of MDSAP - Australia



Benefits of MDSAP - Brazil

MDSAP Audit Certificates replace Brazilian GMP certificates.

ANVISA uses MDSAP certificates as evidence of conformity to *RDA no 16/2013* requirements.

Benefits of MDSAP - Canada

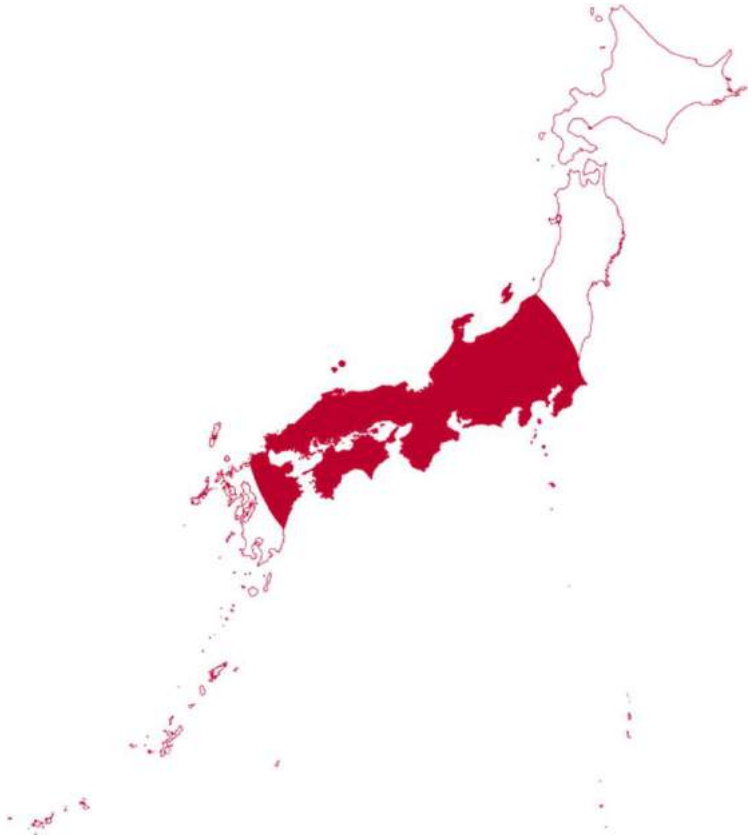
MDSAP Audit Certificates replace CMDCAS certificates.

Health Canada uses MDSAP certificates as evidence of conformity to *Medical Devices Regulations* sections 32(2)(f), 32(3)(j) and 32(4)(p).

Benefits of MDSAP - Japan

PMDA accepts MDSAP audit reports to reduce burden to medical device manufacturers.

PMDA may perform off-site inspection instead of on-site inspection or reduce documents for off-site inspection, when a MDSAP audit report is submitted.



Benefits of MDSAP - Japan

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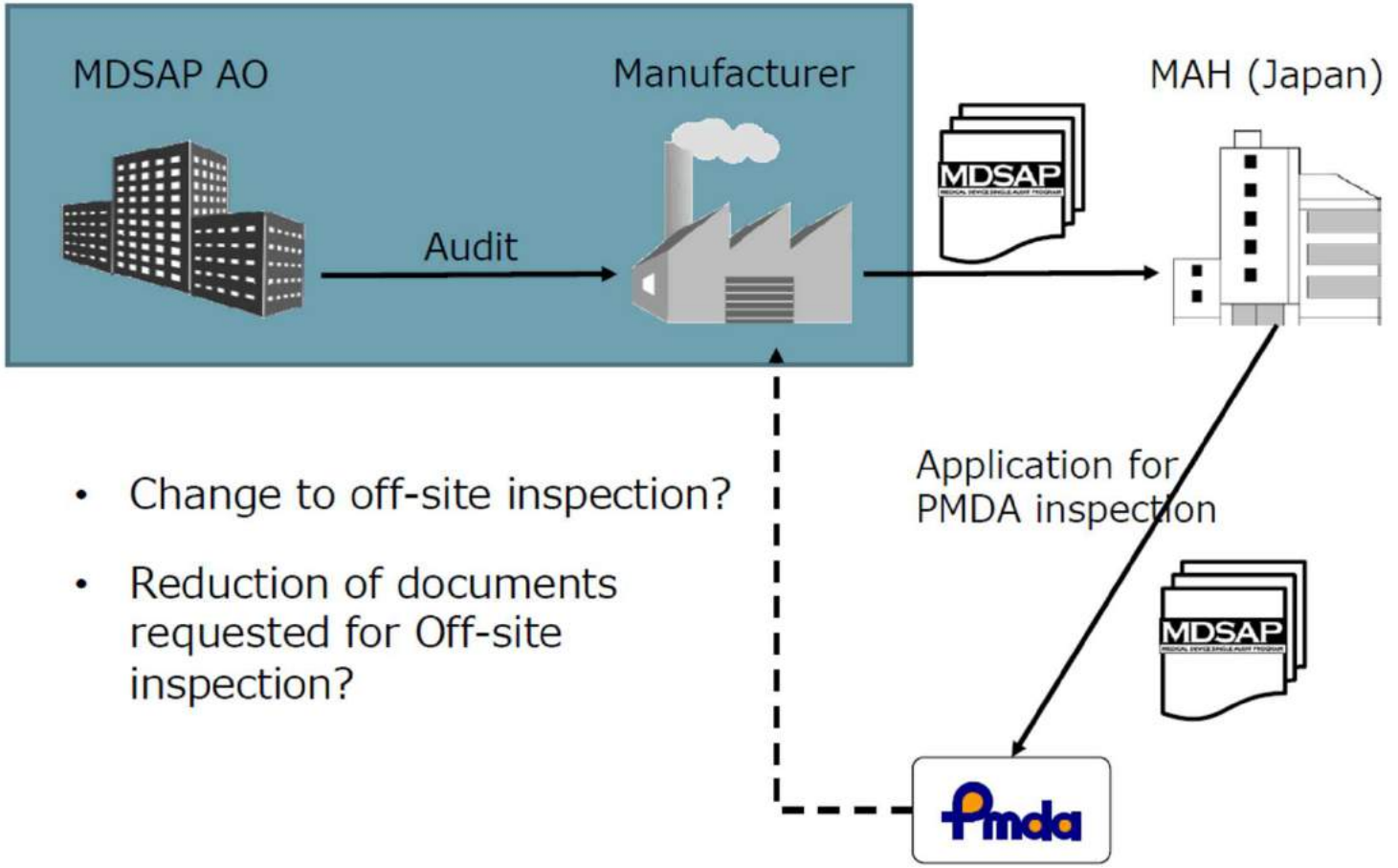
The Flow of PMDA QMS Inspection and MDSAP



Benefits of MDSAP - US

MDSAP audit reports are acceptable as a ***substitute for FDA routine inspections***.

However, MDSAP audits will not substitute certain types of inspections, including:

- For Cause
- Compliance Follow-up
- Pre-approval or post-approval
- Compliance with Electronic Product Radiation Control (EPRC) Regulations

Initial Reviews

Initial reviews of the MDSAP program and its implementation are overwhelmingly positive:

"MDSAP allows a reduction in the number of audits conducted resulting in less business disruption. The MDSAP audit was well planned and the well-organized audit expectations allowed us to plan resources ahead of time. Additionally, qualified and competent auditing organizations conduct audits in a consistent manner."

Conclusion

IMDRF regulators have completed successful MDSAP pilots

Wider adoption is imminent

Manufacturers who are ISO 13485:2016 certified are already a long way there

The increment from ISO 13485 is a manageable QMS update to be successful in MDSAP audits

MDSAP audits reduce/eliminate steps for country-specific requirements in IMDRF jurisdictions

MDSAP audits reduce the regulatory burden to medical device manufacturers

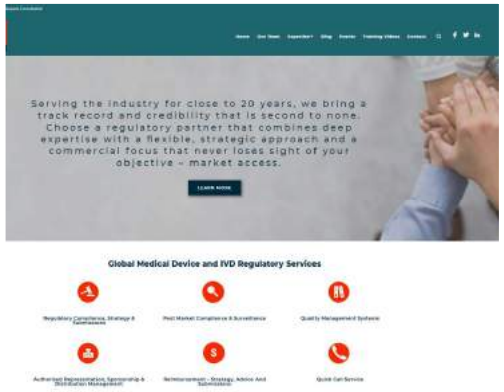
Conclusion

…MDSAP truly opens a world of possibility for medical device manufacturers.

Time for Q&A…

Think of something later? Ask us by email…

help@brandwoodbiomedical.com



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