ISO 13485 and MDSAP

A Beginner’s Guide

10 September 2025

Agenda: Part 1

1 Overview of ISO13485

Brief overview of ISO13485

2 Initial certification

Types of audits and minimum implementation

3 What to expect at an audit

Hybrid audits

4 Corrective Action Plans

What happens after the audit

Overview of ISO 13485

ISO 13485 QMS standard

The purpose of ISO 13485

Provide QMS requirements that are applicable to the medical device industry

Serve as the basis for:
- Regulatory compliance
- Contractual relationships
- Third party certification
- To facilitate global alignment

BS EN ISO 13485:2016

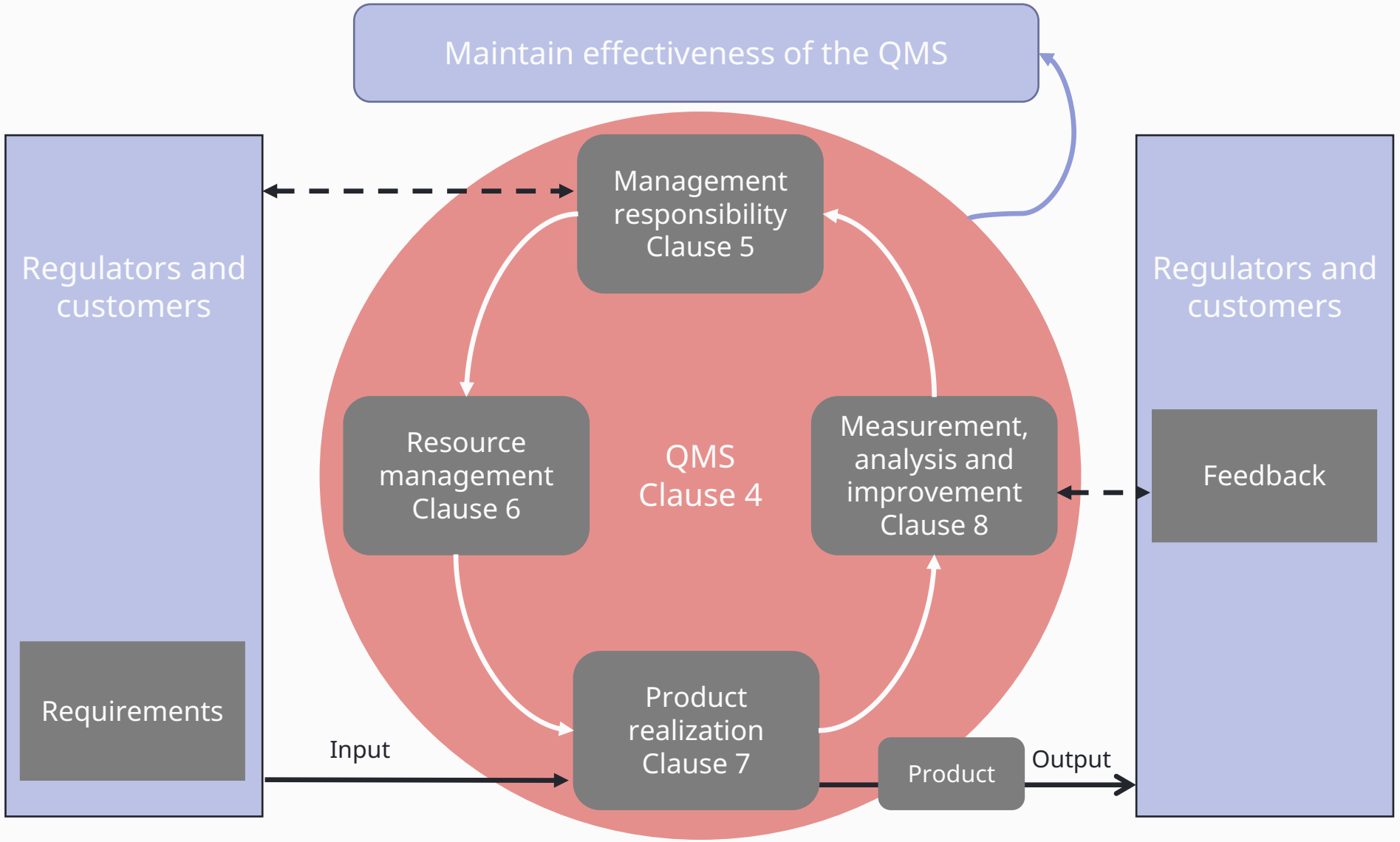
BSI Standards Publication

Medical devices — Quality management systems — Requirements for regulatory purposes

...making excellence a habit.

Industry applicability of ISO 13485

ISO 13485 Process model



Permissible exclusions

Permissible exclusions must be:

- Limited to design and development (Clause 7.3)
- If applicable regulatory controls allow
- Justified with details in the quality manual (regulations may be a justification)

- Parts of Clauses 6, 7 and 8 can be non-applicable, e.g. requirements for sterile devices

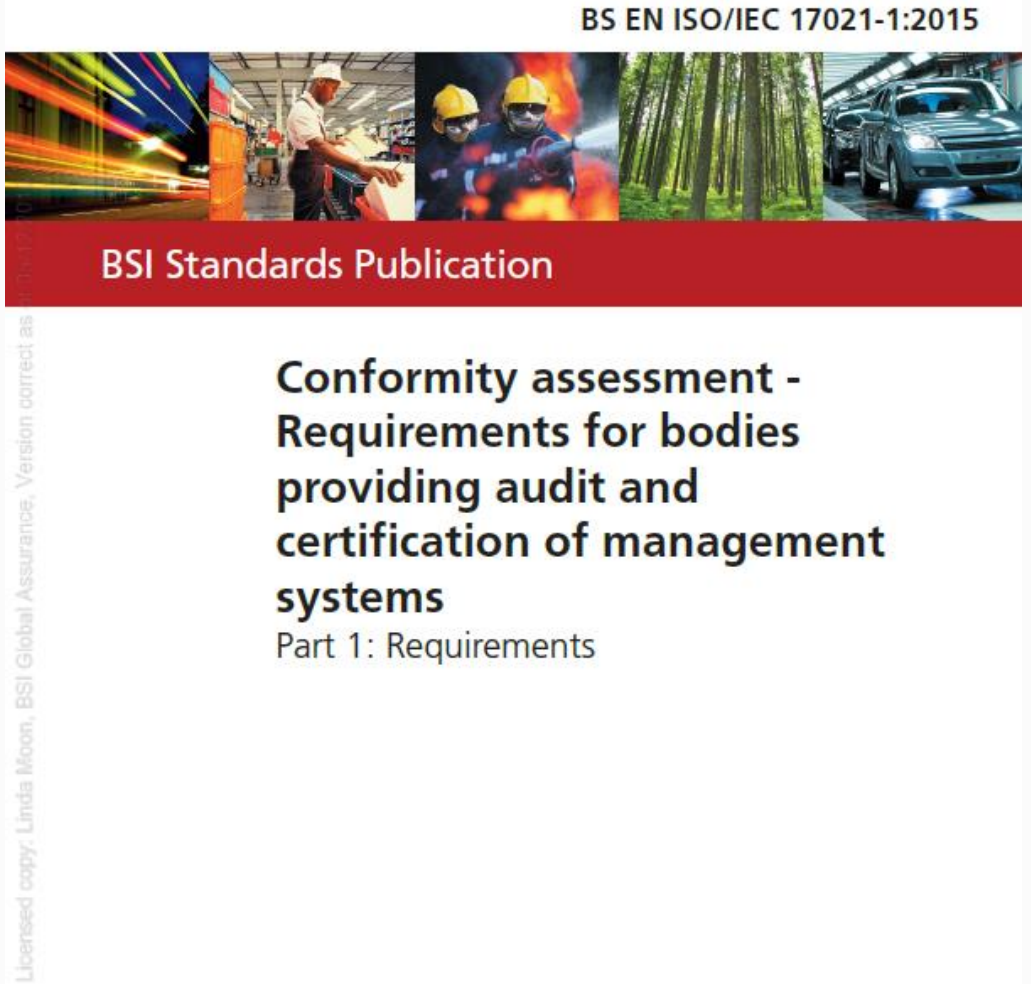
POLL QUESTION

Initial Certification

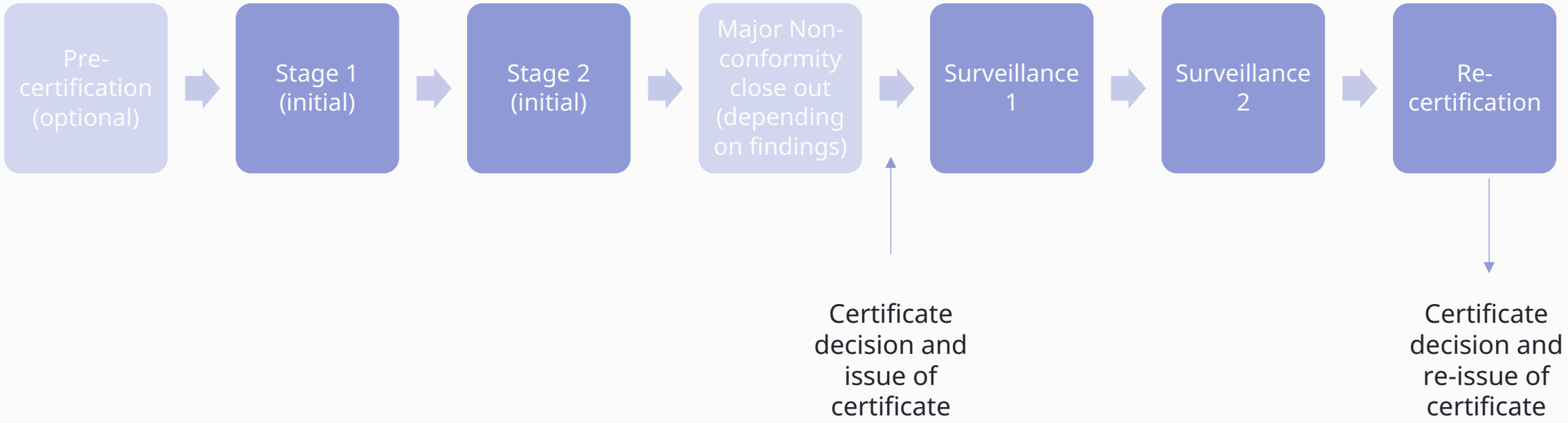
Types of audits and minimum implementation

ISO/IEC 17021-1:2015

- Contains requirements for certification bodies
- Includes specific requirements to conduct certification audits
- BSI is audited by accreditation bodies against this standard



Types of audits



Stage 1 - ISO17021

BSI QMS Team shall:

1. Review the client's documented QMS against the requirements included in the scope of the audit
2. Evaluate the client's site-specific conditions and undertake discussions with the client's personnel to determine the preparedness for stage 2 assessment
3. Review the client's status and understanding regarding requirements of the standard; in particular with respect to the identification of key processes, objectives and the operation of the management system
4. Obtain necessary information regarding the scope of the management system, including:
   a. The client's site(s)
   b. Processes and equipment used
   c. Levels of control established particularly in the case of multi-site clients, and applicable statutory and regulatory requirements
   d. Confirm the provisional scope of certification
5. Review the allocation of resources for stage 2 and agree details of stage 2 with the client. Confirm audit duration

Stage 1 - ISO17021

BSI QMS Team shall:

6. Plan the stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative documents

7. Evaluate if the internal audits and management reviews and being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2

8. Make sure that the client is aware that at the stage 2 there shall be present **3 months evidence** of effective operation of the QMS

9. Document a summary of these discussions in the report

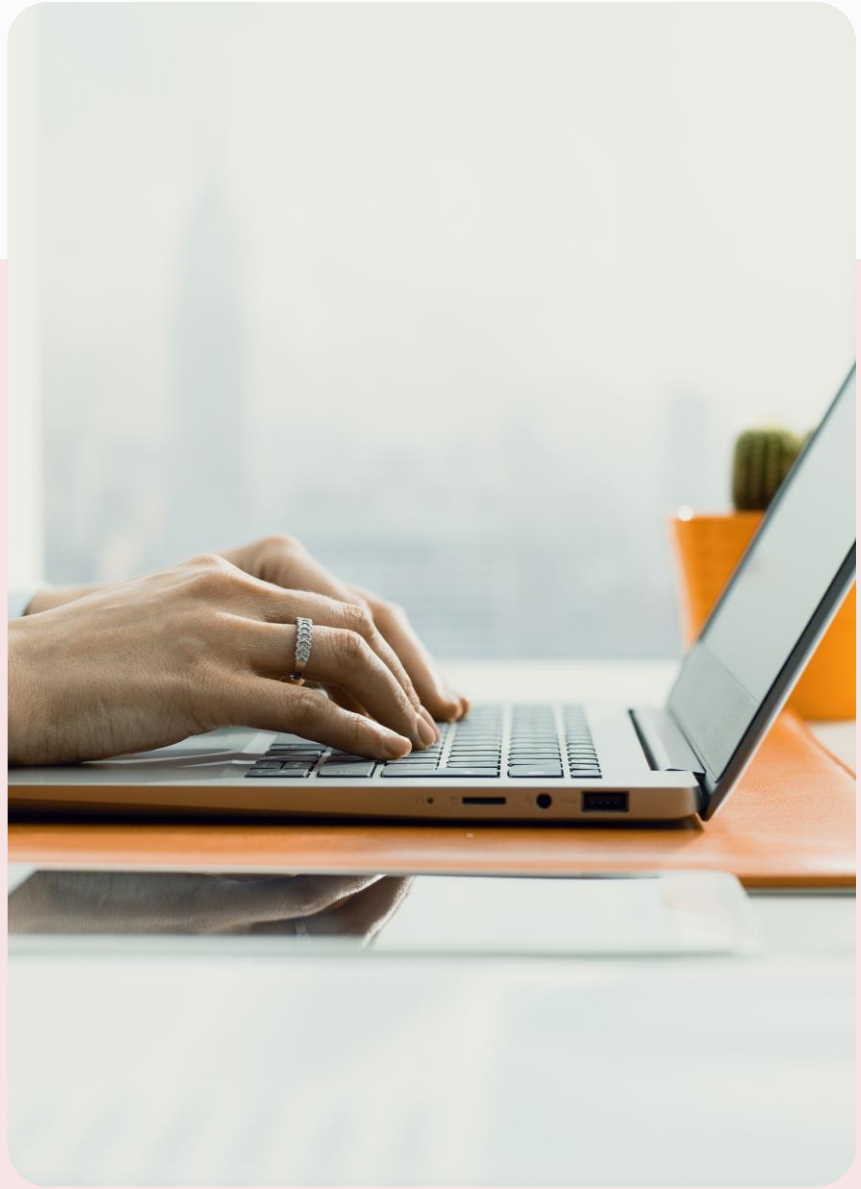
10. Provide a clear recommendation of what is going to happen next

Stage 2

The purpose of the stage 2 is to evaluate the implementation and effectiveness of the client's management system. The stage 2 shall take place at the site(s) of the client. As a minimum it shall show:

a) Information and evidence demonstrating conformity to all requirements of the applicable management system standard/ regulatory requirements

b) Performance in monitoring, measuring, reviewing and reporting against objectives



Stage 2

c) The client’s management system ability and its performance in the meeting of applicable statutory, regulatory and contractual requirements

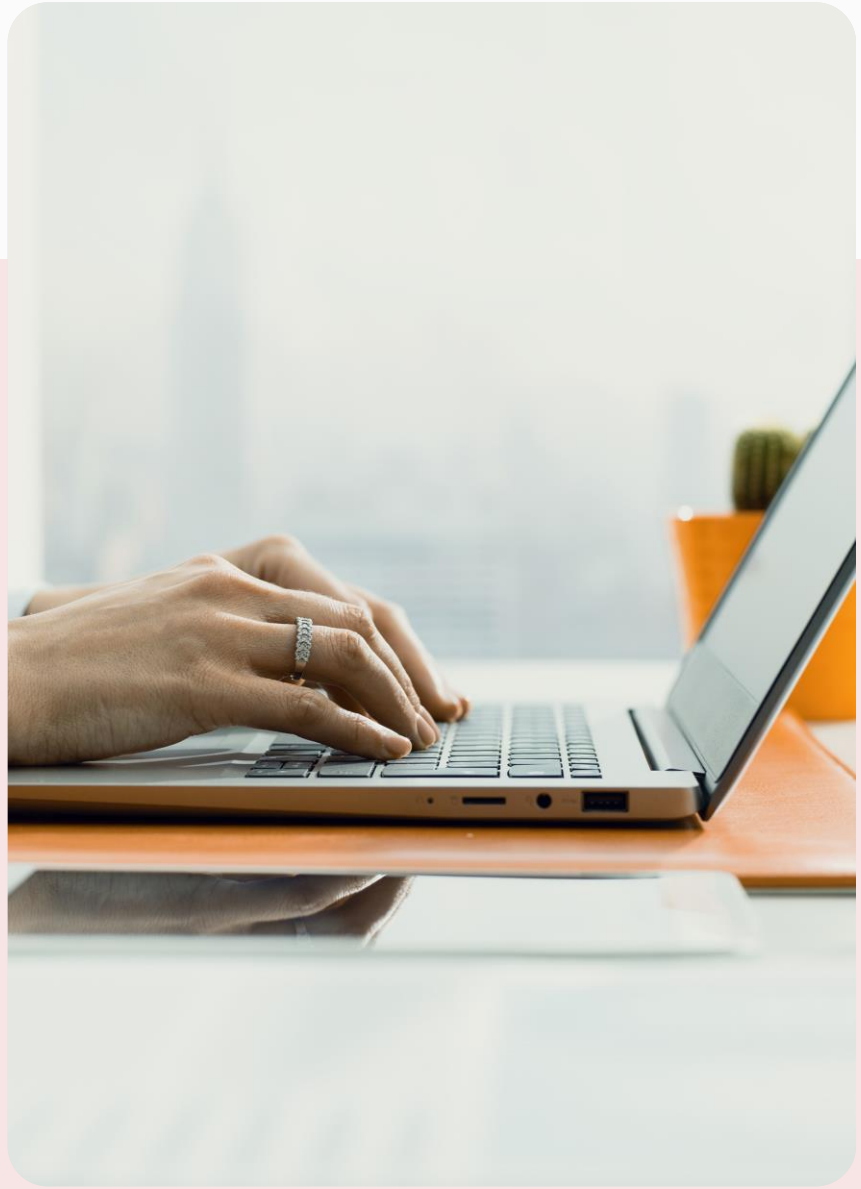
d) Operational control of the client’s processes relevant to the proposed certificate scope

e) Internal auditing and management review

f) Management responsibilities

g) Identification of and evidence of justification for any non-applications

For a positive recommendation to be made, objective evidence must be seen during the stage 2 audit that the management system has been operating for at least 3 months



Minimum Implementation - Design (Stage 2)

01

The balance of completed design activities must support the certification

02

Enough design activities must be completed per procedures

03

All 7.3 clauses require documented processes and evidence of implementation of those processes

04

Validation processes need to be documented and planned in detail

Minimum Implementation - Manufacture – Stage 2

01

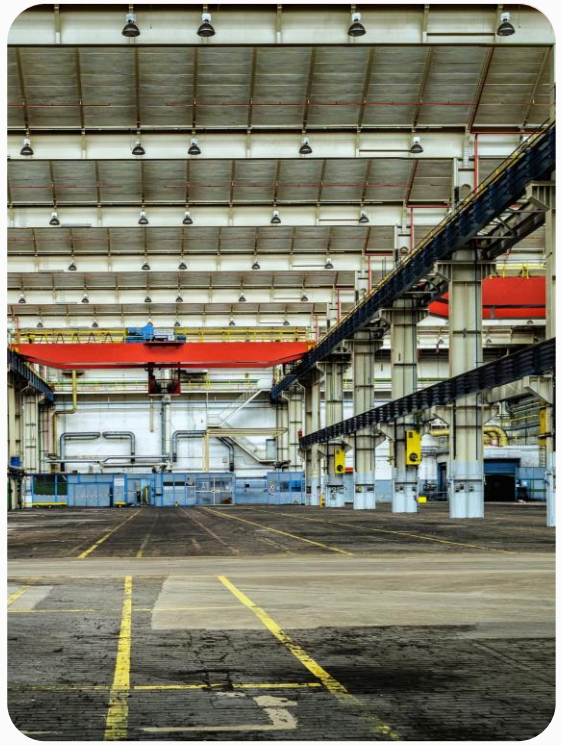
The balance of manufacturing activities must support the recommendation for certification

02

Must have minimum evidence during the Stage 2 of a sample batch /pilot run that demonstrates manufacturing controls are in place. Not necessary to have placed product on market

03

Evidence of all processes, procedures, design validation & transfer, manufacturing, validation of manufacturing processes and audit trails through to and including sterilization if applicable. This area will normally be conducted on-site during a hybrid audit



Hybrid Audits

Why Hybrid?

01

Hybrid audits provide much greater flexibility for manufacturers and BSI

02

Helps all parties reduce their carbon footprint and achieve sustainability targets

03

Regulators require an on-site component

04

Particularly useful for manufacturers at unannounced audits as experts can join the remote audit stream

What to expect at hybrid audits

Closing the Audit – Corrective Action Plans

At the end of the audit

Closing meeting

Non-conformity = non-fulfilment of a requirement

Major non-conformity = non-conformity that affects the capability of the management system to achieve the intended results

— if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;

— a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity = nonconformity that does not affect the capability of the management system to achieve the intended results.

Plan for Post Audit Activities

Post audit activities and 15-day CAP submission timeline

Corrective action plans

Important: take time to carefully investigate NCs and write corrective action plans

- Take time to investigate root cause – you generally have 15 days to investigate and communicate your corrective action plan
- If correction/containment is not needed this must be clearly justified – it cannot be N/A
- On-time CAPA still needed during an appeal
- At closure, auditor will sample objective evidence to check root cause has been addressed and corrective actions have been taken to prevent recurrence + verification of effectiveness has been evaluated

- A Corrective action plan must contain:
- Description of NC and BSI unique reference number
- Root cause
- Correction/containment
- Corrective action
- Responsible person
- Date for action completion
- Is it a systemic problem/applies to other sites?

Why choose BSI?

Trusted excellence

Multiple accreditations: UKAS, RvA, SAC, NABCB + other local schemes

Optimal resource utilisation

Hybrid audits are more efficient for manufacturer – SMEs can dial in to the audit

Global network

Can initiate audits within 30-60 day from submission of application

Thought leaders

Representation on standards committees such as ISO13485: TC210/WG1

Timely certification process

From submission of application and typically issuance of certificate within 6-9 months assuming compliant audits

Agenda Part 2:

Introduction to MDSAP

Brief overview of MDSAP

Stakeholders

Key players in MDSAP

Key Elements

Core processes in MDSAP

Use of MDSAP

Utilisation of MDSAP by various stakeholders

POLL QUESTION

Introduction to MDSAP

MDSAP
Medical Device Single Audit Program

https://www.mdsap.global/

"

To jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers' quality management systems.

- MDSAP Functional Statement, MDSAP P0001.002

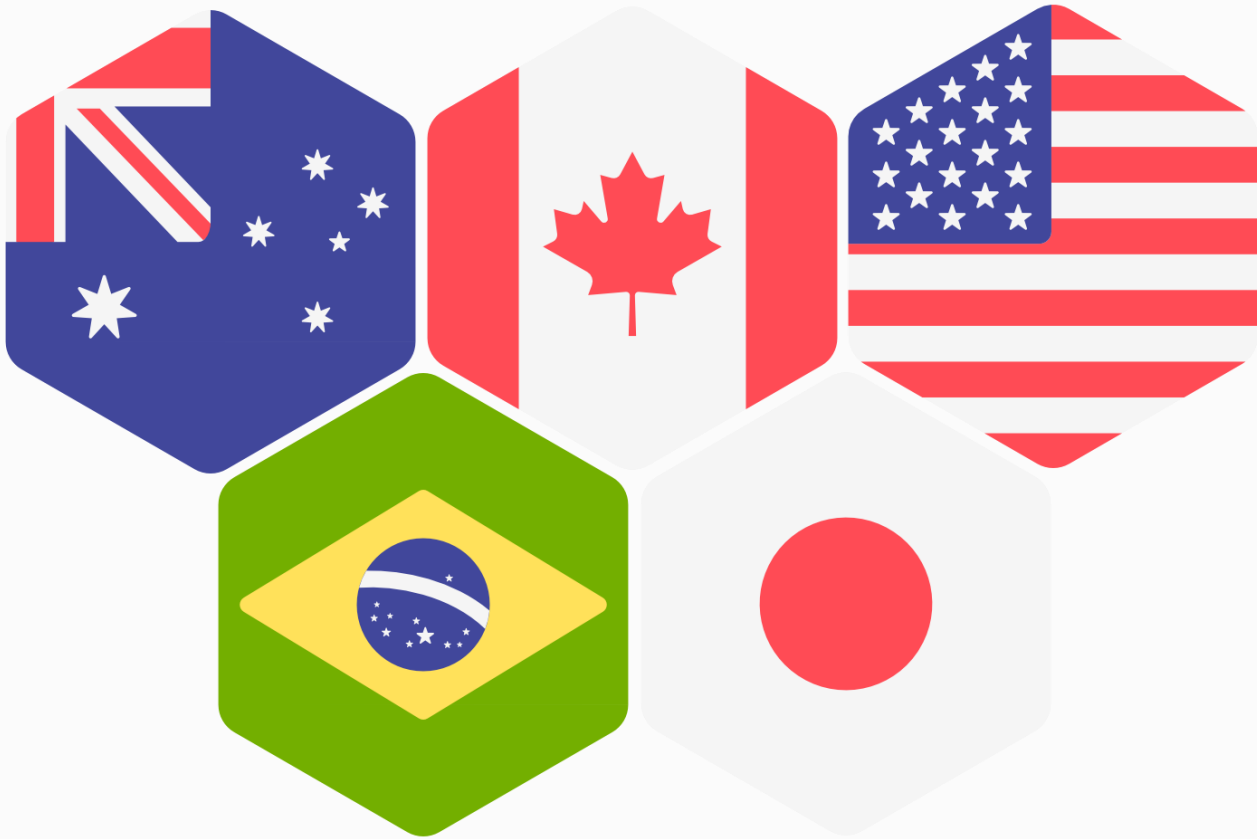
What is MDSAP?

Single regulatory audit of manufacturer’s QMS

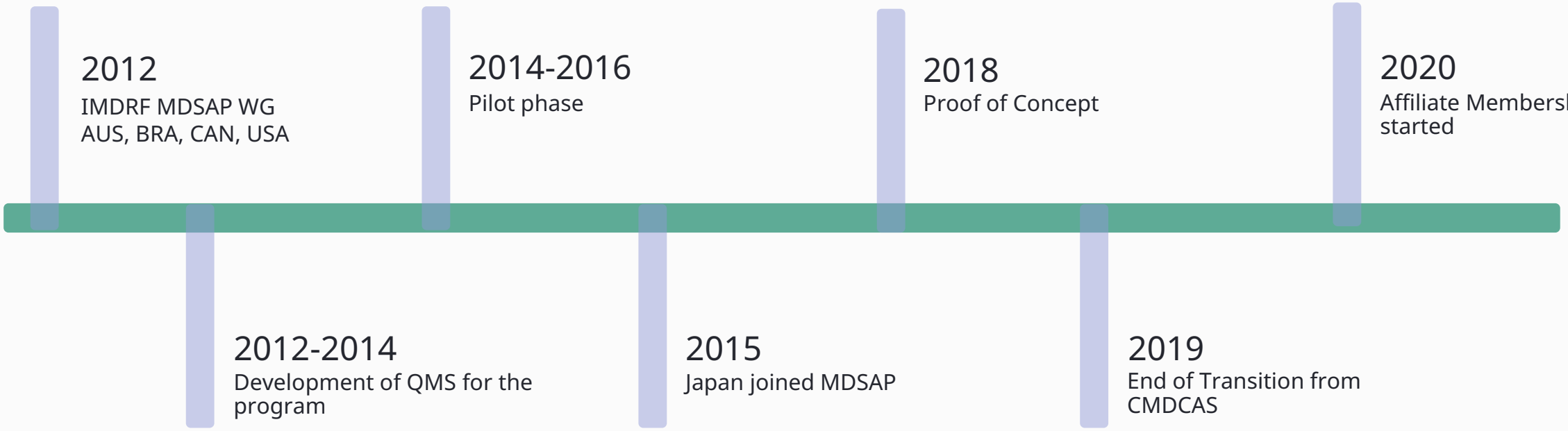
Conducted by an MDSAP recognised Auditing Organisation (AO)

Satisfies requirements of ISO 13485 and the participating regulatory jurisdictions

Australia, Brazil, Canada, Japan & United States



History



Market Access

MDSAP Outputs

Certificate

Audit Report

Issued by AO

Market Authorisation by Regulatory Authorities

Market Access

Individual jurisdictions independently determine how MDSAP outputs are utilised in their regulatory framework

Key Stakeholders

Key Players in MDSAP

Participants

Regulatory Authorities (RA)

- Manage the program
- Assess and recognise AOs
- Utilise outputs within their marketing authorisation (MA is not part of MDSAP)

Auditing Organisations (AO)

- Conduct QMS audit of MF
- Share audit reports with RAs
- 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 to RAs

Regulatory Authorities

Full Members *

- TGA, Australia
- ANVISA, Brazil
- Health Canada
- MHLW & PMDA, Japan
- FDA, USA

* members in the MDSAP Regulatory Authority Council (RAC)

Official Observers

- EU
- MHRA, UK
- WHO (prequalification of IVD)
- HSA, Singapore

Affiliate Members

- ANMAT, Argentina
- MoH, Israel
- PPB, Kenya
- MFDS, South Korea
- COFEPRIS, Mexico
- SAHPRA, South Africa
- TFDA, Taiwan

Membership criteria and roles per tier are documented

Manufacturing Facility

Legal Manufacturer

- Certificate holder
- Overall responsibility for placing device on the market
- Used by AUS and CAN in their definition of manufacturer

Manufacturing Locations

- Location where physical activity (design and/or manufacture) takes place
- *May or may not be a certificate holder
- Used by BRA, JAP and USA in their definition of manufacturer

Statistics

31,000+

Number of MDSAP audits conducted

15

Number of AOs recognised to conduct MDSAP audits

36%

Of total sites are in the USA

82

Number of countries where MDSAP audits occurred

7357

Number of active facilities registered for receiving MDSAP audits

25%

Of total sites are in the EU

Statistics as of Jun 2025

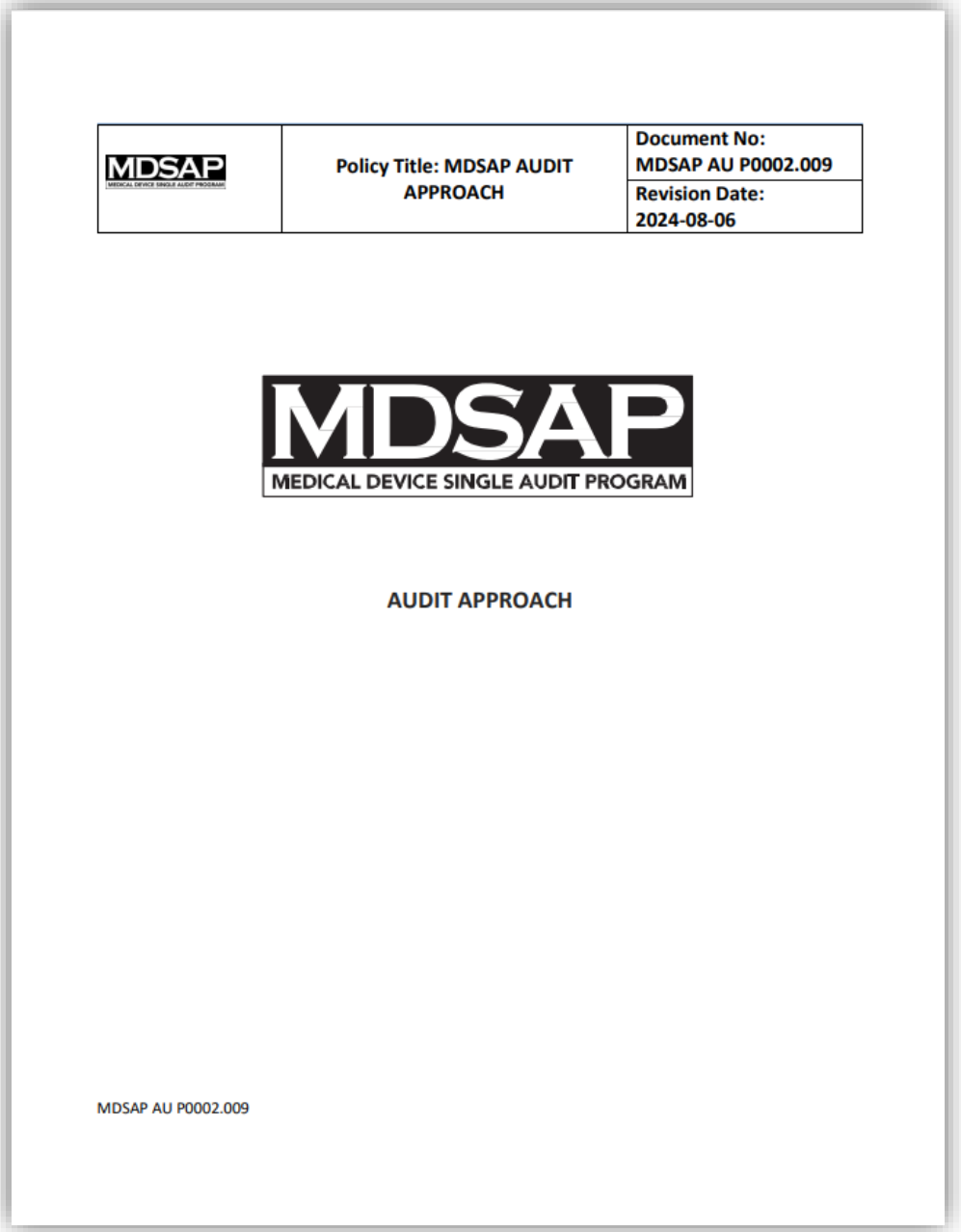
Key Elements

Core process in MDSAP

How MDSAP Works

Audit Approach

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



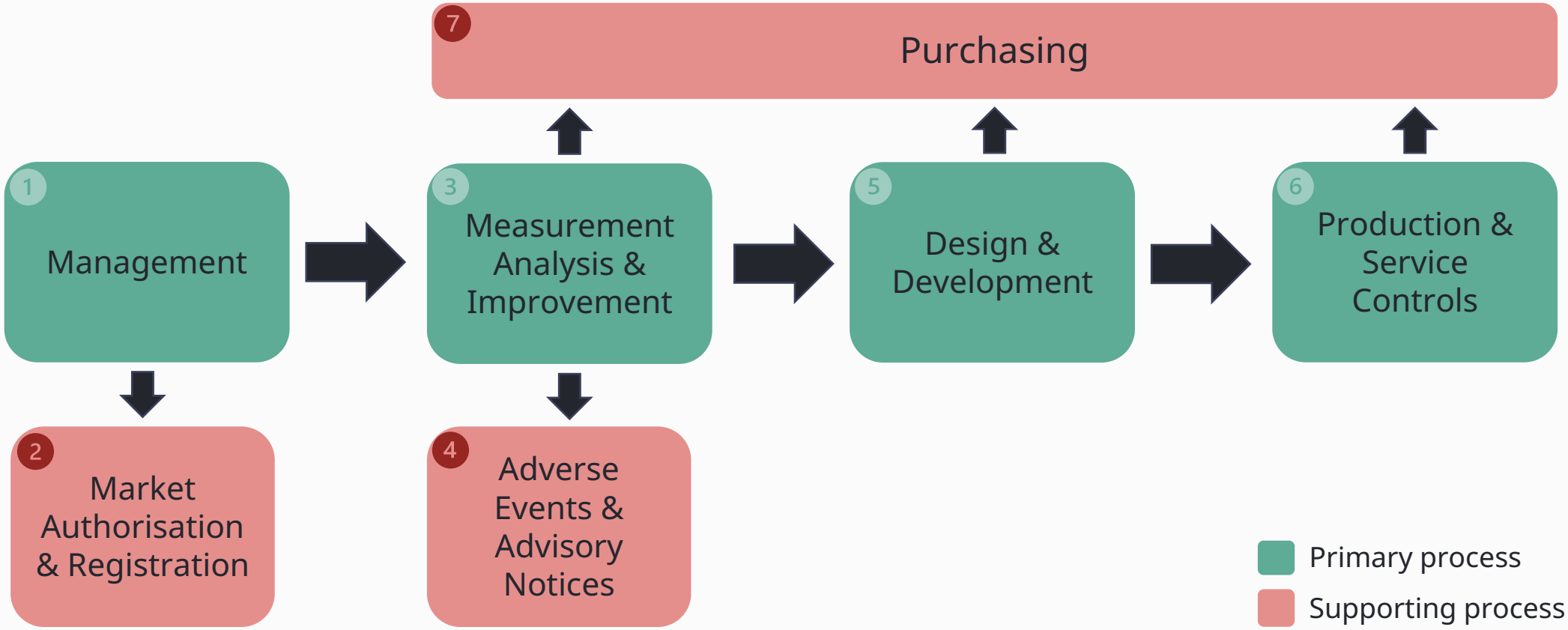
MDSAP	Policy Title: MDSAP AUDIT APPROACH	Document No: MDSAP AU P0002.009
		Revision Date: 2024-08-06

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

AUDIT APPROACH

MDSAP AU P0002.009

MDSAP Audit Sequence



Example

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].

Nonconformity Grading

QMS Impact	Occurrence	Escalation Criteria	
Indirect Vs Direct	First Vs Repeat	Failure to document and implement	Release of nonconforming product
	+1	+1	+1

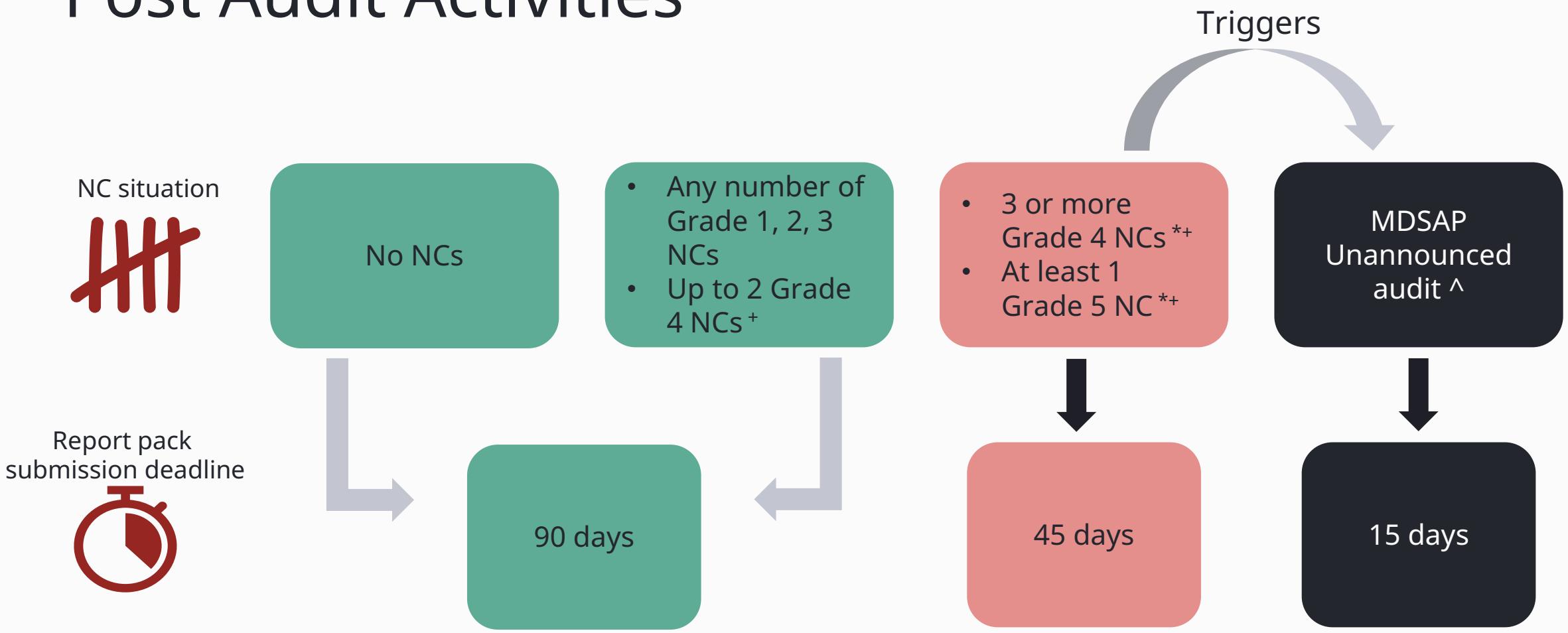
Repeat = Same subclause X.X.X

	ISO 13485:2016 clauses
Indirect	4.1 to 6.3 (except 4.2.3)
Direct	6.4 to 8.5 (except 8.2.4)

	First	Repeat
Indirect	1	2
Direct	3	4

Highest grade is a 5

Post Audit Activities



^ Conducted by AO within 6-9 months

* For all NCs, MF must submit corrective action plan within 15 days

+ MF must submit evidence of remediation implemented within 30 days

* AO must notify RAs within 5 working days

Use of MDSAP

Utilisation of MDSAP by various stakeholders

RAC Members

Certificate:
- Device registration

Audit Report Pack:
- Conformity assessment
- Post-market surveillance

Certificate:
- NA

Audit Report Pack:
- Initial certification
- Re-certification

Certificate:
- Medical device licence

Audit Report Pack:
- Post-market surveillance

Certificate:
- NA

Audit Report Pack:
- Desktop inspection
- Reduced submission burden

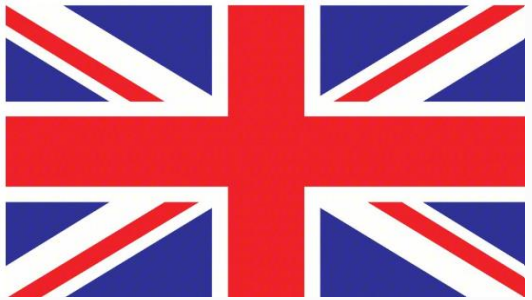
Certificate:
- NA

Audit Report Pack:
- Substitutes routine inspections
- Post-market surveillance

Official Observers

Utilised for the prequalification program. Review of reports in lieu of onsite inspection.

May use MDSAP Report as supporting evidence of QMS compliance. NB/AOs deliver joint QMS audits.



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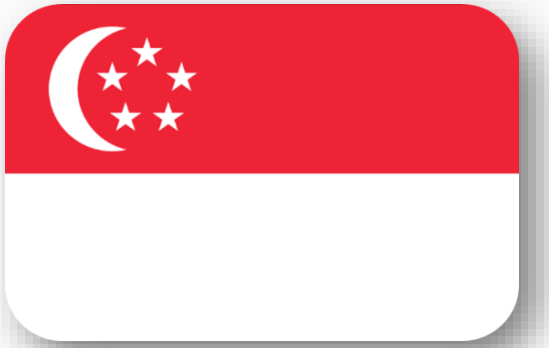


Certificate accepted as evidence of compliant QMS

Affiliate Members

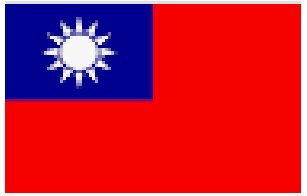
Use MDSAP Report as evidence of QMS compliance

Use MDSAP Report as part of reliance-based regulatory pathway

May use MDSAP Report as evidence of QMS compliance

Use MDSAP Certificates and Reports to grant exemptions from on-site GMP audits by MFDS

Use MDSAP Certificate as equivalency pathway for QMS compliance



Use MDSAP Report under the cooperation program to supplement QMS document review

Use MDSAP Report to support market access

MDSAP Benefits

Faster access 

Reduced time-to-market for devices incorporating advanced technologies

Optimal resource utilisation 

Reduced duplication of regulatory effort and costs to companies and regulatory authorities

Global regulatory convergence 

Enhanced sharing of regulatory knowledge and relationships between public health authorities

Continuous improvement 

Annual MDSAP Forum attended by RAs, AOs and industry representatives

Consistency, transparency, predictability 

RAs, AOs and manufacturers have the same reference for QMS audits: the Audit Approach document

Enhanced visibility 

RAC members have full access to the MDSAP IT Portal (REPS) – used for metrics, reporting, market surveillance

Why choose BSI?

Trusted excellence
BSI Group Americas Inc. is a recognized Auditing Organization for MDSAP active since the pilot phase of the program.

Optimal resource utilisation

Combined hybrid audits for ISO13485, MDSAP, EU MDR/IVDR and UKCA schemes available globally

Global network

A global network of approx 300 MDSAP and ISO 13485 QMS assessors worldwide in 20 countries speaking local languages

Thought leaders

Lead in MDSAP Forum presentations and discussions

Predictability

Timely report review + on-time submission of reports to REPS and manufacturers

Timely certificate decisions

On-time delivery of certificate issue

Q&A

Thank You!

BSI Group

389 Chiswick High Road

London, W4 4AL

+44 345 080 9000

bsigroup.com