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QMS PRINCIPLES

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TOPICS

1. QMS Overview
2. Introduction to ISO 13485
3. Introduction to ISO 14971 and Risk Management
4. QMS Certifications – ISO 13485 and MDSAP
5. How a QMS impacts Go-To- Market Strategy

QMS OVERVIEW:

WHAT IS A QUALITY MANAGEMENT SYSTEM (QMS)?

- **Quality Management System (QMS):** a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives.

  An effective QMS is based on the 8 Quality Management Principles.

QMS OVERVIEW:

WHAT IS THE PURPOSE OF A QMS

Purpose of a QMS

- The purpose of a QMS is to ensure that the activities of an organization are:
  - Planned
  - Proceduralized
  - Organized
  - Ensuring products, results, or services meet prescribed acceptance criteria
  - Recorded and those records maintained
  - Evaluated against risk criteria to minimize the likelihood of poor outcomes

Key aspects of a QMS

- Documented Processes and Procedures
- Proof that procedures are being followed
- Records
- Determination risk to patients if product is faulty
- Outline of responsibility and accountability
- Auditing

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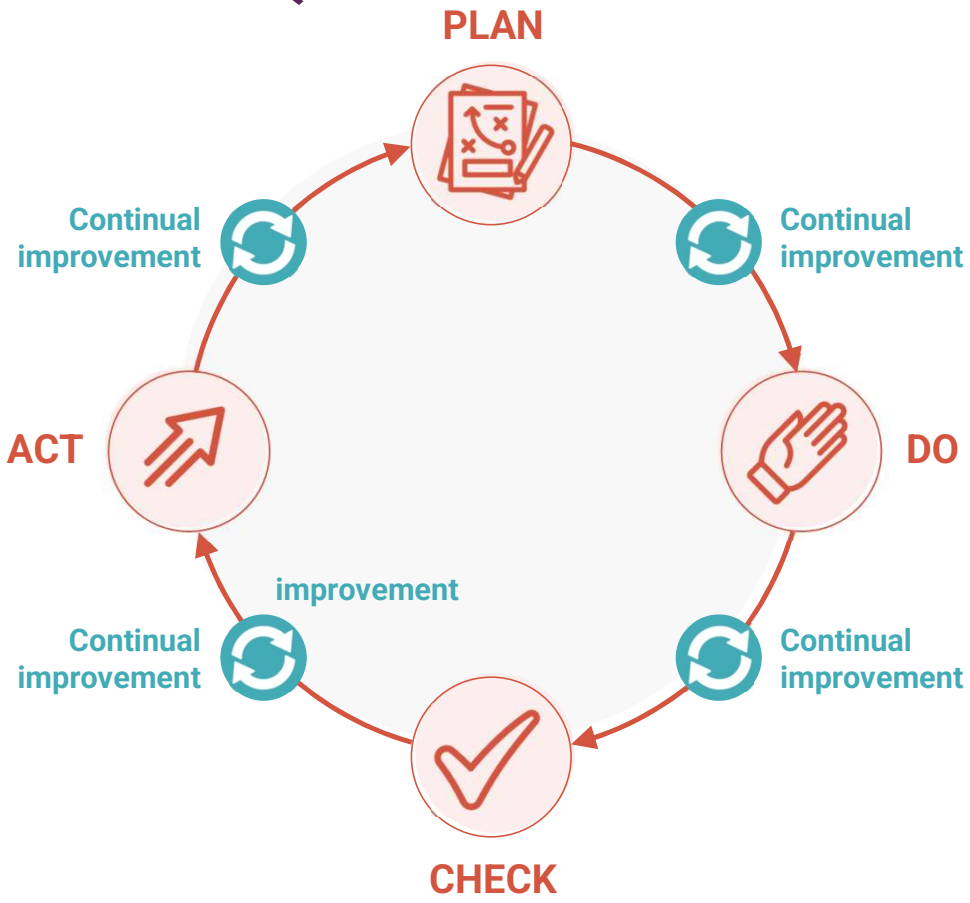
QMS OVERVIEW:

THE PLAN-DO-CHECK-ACT (PDCA) CYCLE IS THE HEART OF A QMS

- Analyse/review
- Decide/change
- Maintain or improve effectiveness



- Activities – includes understanding and meeting (regulatory/product) requirements
- Controls
- Documentation
- Resources
- Objectives

- Measure and monitor (conformity and effectiveness)

- Deploy
- Conform with the plan

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BENEFITS OF A QMS

- Meet Market Requirements/
- User Needs
- Increased Sales
- Market Adoption

- More Customers
- More Sales
- Repeat Business

- Lowering Costs
- Reducing Waste
- Expansion
- Growth
- Revenue/Profits

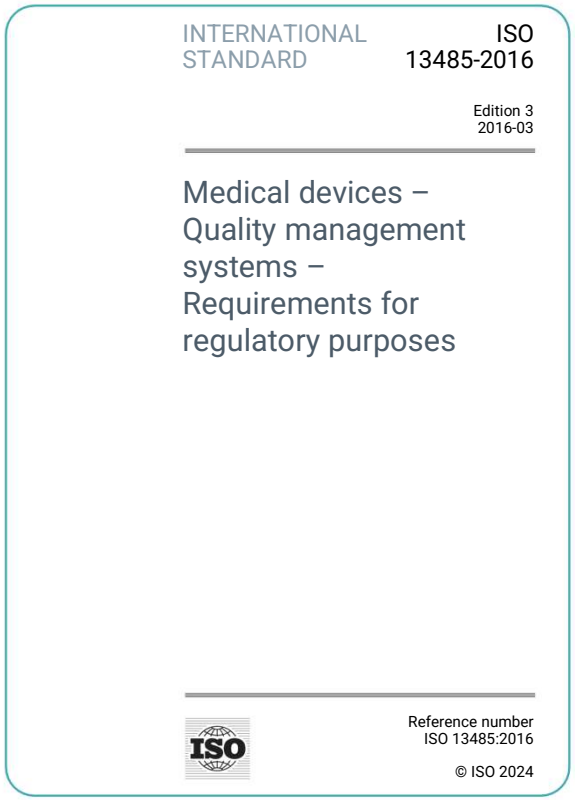
- Meet Regulatory Requirements
- Faster Approvals
- Efficient Go-To-Market Strategy
- Opens More Markets

WHY DO I NEED A QMS?

- Beyond the benefits of a well-run and well-organized company, nearly **every major market** requires the implementation and maintenance of a quality management system as a condition of product registration.
- Without a defined and documented QMS, a company will not be able to market and sell products in most countries/regions

INTRODUCTION TO ISO 13485

- **ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes**
- ISO 13485 was developed to outline the standard for a process-based approach to a QMS for the **design and manufacturing of medical devices (including IVDs)**
- The most common standard for quality management in medical device management across the globe
- Adoption of the standard indicates a c**ommitment to the highest quality and safety** across the development process



APPLICABILITY OF ISO 13485

ISO 13485 is an international quality management system standard and the **benchmark in quality management** for manufacturers of diagnostics **by regulatory authorities throughout the world**

- The basis of EU QMS requirements is the ISO 13485 standard
- US companies comply with the US FDAs Quality System Regulation (QSR, now QMSR which has been updated to align with ISO 13485)
- Canada has made ISO 13485 certification mandatory (MDSAP)
- Brazil and Japan have specific requirements, but overall are based on either ISO 13485 or FDA QSR
- TGA – ISO 13485 certification is required (MDSAP) or a TGA Conformity Assessment Certificate, both based on ISO 13485
- Singapore – only accepts ISO 13485 certificates from Singapore Accreditation Council accredited Certification Bodies
- WHO PQ does not require ISO 13485 certification, but QMS requirements are based on this standard

ISO 13485:2016

ISO 13485:2016 PRINCIPALS

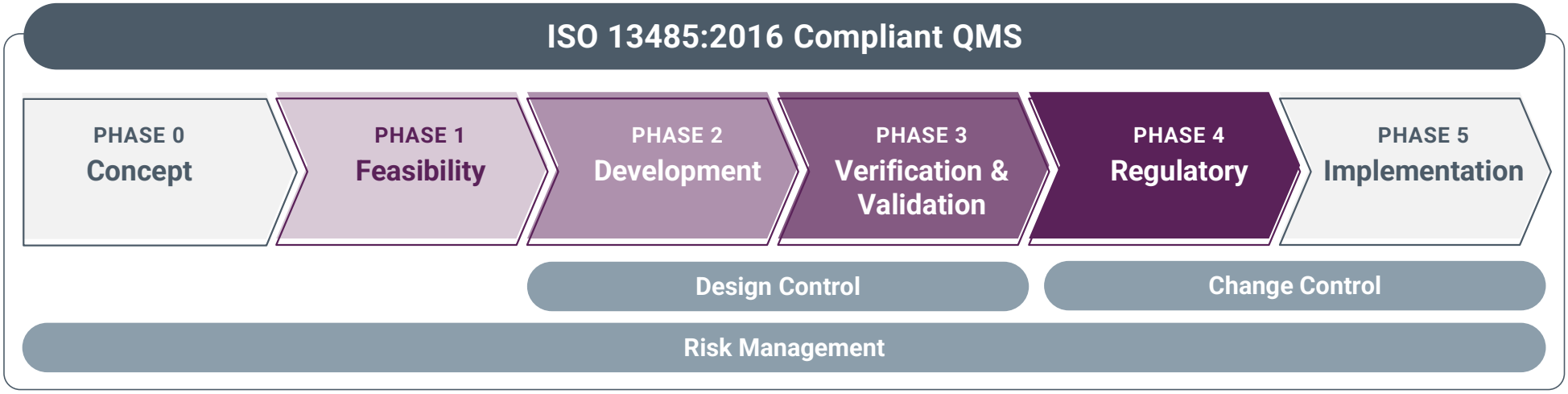
- Having an ISO 13485 certified QMS is not mandatory
  - Adoption of a standard is voluntary and only becomes mandatory if required by a country's specific regulation
  - Some countries have their own version of QMS requirements (e.g. US FDA QSR/QMSR, Australia TGA), but they are increasingly becoming aligned with ISO 13485
- By implementing an ISO 13485 compliant QMS and achieving certification, companies can have a **single, harmonized quality management system that meets global regulatory QMS requirements.**

ISO 13485 QMS FAMILY

- ISO 13485 and ISO 14971 are related:
  - ISO 13485 focuses on quality management principles and regulatory compliance,
  - ISO 14971 focuses on risk management *[discussed in later presentations].*
- They work together to ensure manufacturers have systems in place to meet regulatory requirements critical to the design of safe and effective devices.
- **Compliance with <u>both</u> standards is essential the ensure the safety and effectiveness of medical devices including IVDs.**
- Great information on how to meet ISO 13485 requirements are included in ISO 24971 (supportive document only)

ISO 13485	Medical Devices Quality Management Systems Requirements for Regulatory Purposes *(a standalone standard based on ISO 9001)*
ISO 14971	Medical Devices Application of Risk Management to Medical Devices *(guidance on risk management for ISO 13485)*
ISO 24971	Medical Devices Guidance on the Application of ISO 14971

ROLE OF ISO 13485 AND ISO 14971 IN IVD DESIGN AND DEVELOPMENT



- ISO 13485:2016 QMS relates to all processes in an organization and impacts ALL phases of the product lifecycle
- Requirement for a *risk-based approach* (risk management) is a top-level general requirement for a QMS (ISO 14971)
- QMS requirements vary based on device risk class [discussed further in Regulatory Requirements presentation]; all can be incorporated into the same QMS

CERTIFICATION

In order to achieve certification to the ISO 13485 standard, an organizations QMS must pass a third-party certification audit

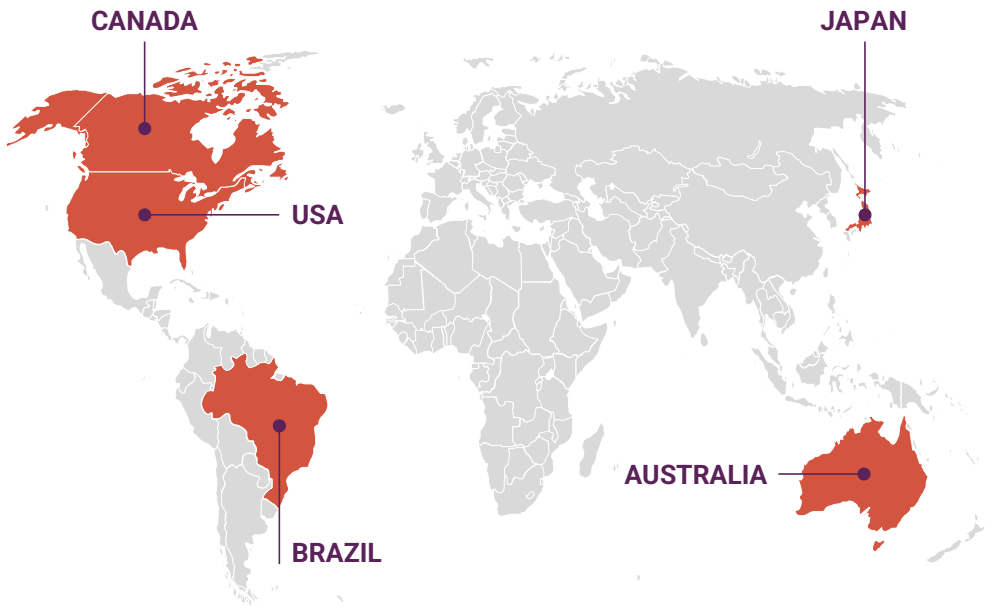
- To ensure global recognition of an ISO 13485 certificate, it is recommended to be audited and certified by an accreditation body that is a member of the International Accreditation Forum's Multilateral Recognition Agreement
- Re-certification audits occur on a 3-year cycle

BEYOND ISO 13485:

MEDICAL DEVICES SINGLE AUDIT PROGRAM (MDSAP)

- ***ISO 13485 certification is still required***
  (pre-requisite for MDSAP)
- Different SRA may require on-site QMS audits to ensure their specific regulatory requirements for a QMS are met, even for companies with ISO 13485 certification; not coordinated across jurisdictions
  - E.g. FDA, Health Canada, Brazil = LOTS of QMS Audits, large QA teams, increased costs
- MDSAP allows a single regulatory audit of a QMS that satisfies the requirements of multiple SRAs
  - 5 SRA members: Australian TGA, Brazil ANVISA, Health Canada, Japan MHLW/PMDA, US FDA
  - Only audited based on countries you sell product to
  - Once achieve MSDAP certification, are audited on a 3 year cycle
  - Challenging audit, but once achieved reduces resource requirements for both the SRA and the company

COUNTRIES PARTICIPATING IN THE MDSAP



HAVING AN ISO 13485 CERTIFIED QMS IMPACTS GO-TO-MARKET

- Most countries in the world use or accept ISO 13485 (only mandatory in Canada)
- EN ISO 13485:2016 now released with new annex A11:2021 that is harmonized with essential requirements of the European Union In Vitro Diagnostic Regulation (EU IVDR) requirements
- US FDA QMSR (effective 02 Feb 2026) is aligned with ISO 13485:2016
- Achieving ISO 13485 certification is the most widely recognized way to demonstrate implementation of an effective QMS that satisfies most SRAs
- This leads to a Wider Go-To-Market Strategy = Increased Revenue

KEY TAKEAWAYS

1

Medical device manufacturers must have some form of a QMS

2

Implementing an ISO 13485 compliant QMS assures a harmonized quality management system that meets global regulatory QMS requirements

3

ISO 14971 goes alongside ISO 13485 and promotes a risk-based approach throughout the QMS, including strong focus on risk of product design and development

4

Having a robust QMS based on ISO 13485/ISO 14971 meets global regulatory requirements, can improve product development efficiencies, and can open up new markets for a company

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QUESTIONS & FEEDBACK