ISO 13485:2016

Beginners Guide to ISO 13485:2016

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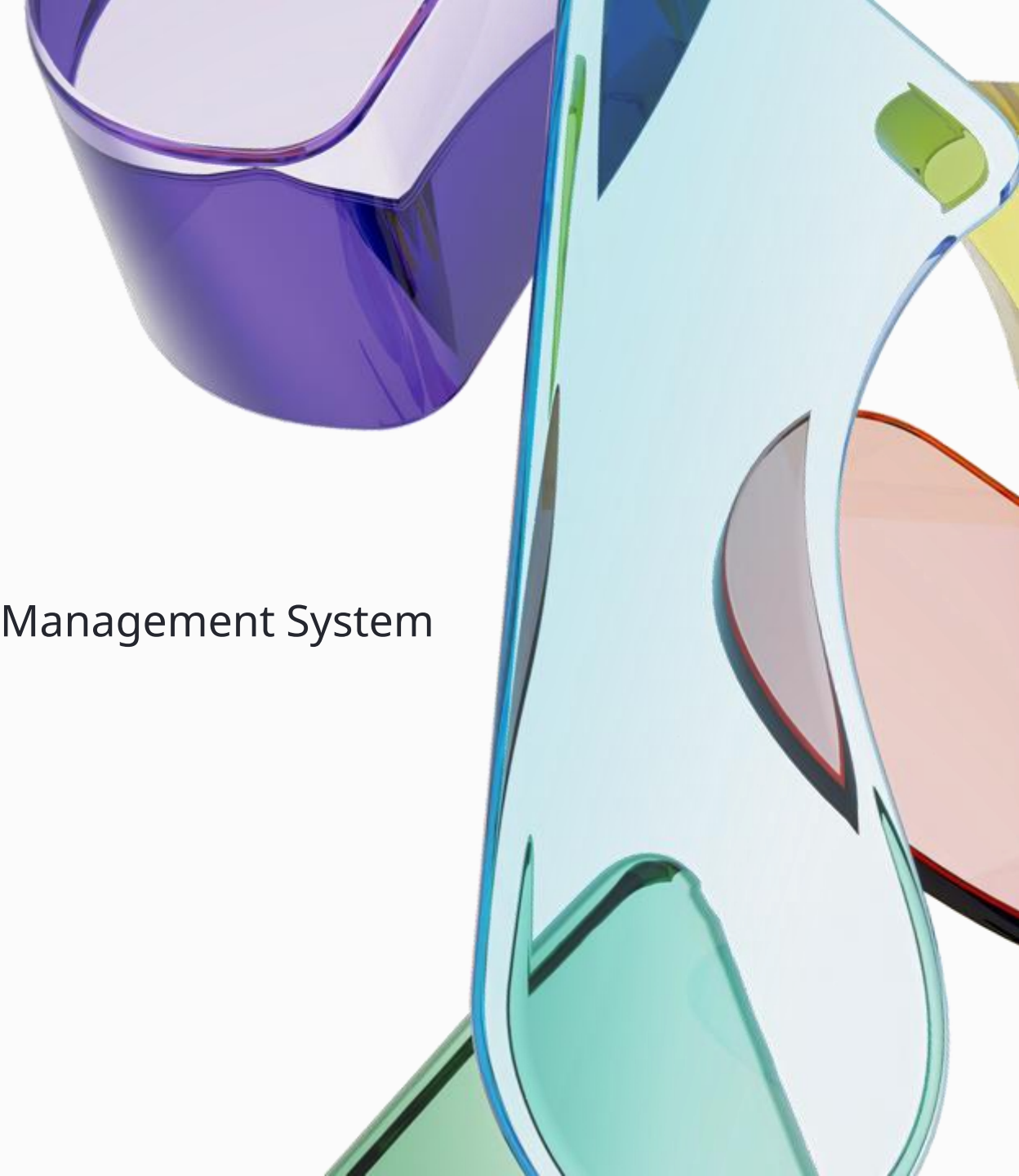
Agenda

- ISO 13485:2016 A Beginners Guide
- Value and Benefits of an ISO 13485 Quality Management System
- Why BSI? Our Expertise
- Question and Answers



ISO 13485:2016

ISO 13485:2016

- International standard officially adopted 01MAR2016
- Specifically for the Medical Device Industry
- Helps ensure manufactures meet customer requirements and regulatory requirements

Why an ISO 13485 certified Quality Management System?

What is ISO 13485?

ISO 13485 is the medical device industry's quality management system. ISO 13485:2016 is considered state of the art thus compliance yields a state-of-the-art Quality Management System. It is written to specify requirements for an organization to design and implement a quality management system to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Medical device manufacturing is one of the most regulated sectors in which significant quality systems and product requirements must be satisfied. The regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose.

Patient safety is at the very heart of ISO 13485, with its main purpose being to ensure the consistent design, development, production, storage and distribution, installation or servicing and disposal of medical devices

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Who needs ISO 13485:2016

ISO 13485:2016

- Medical Device Manufactures
- Suppliers and service providers
- Distributors and Importers

Principles of ISO 13485:2016

Principles of ISO 13485:2016

Risk Management

Product Safety and Effectiveness

Process Based Approach

Regulatory Compliance

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Requirements of ISO 13485:2016

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Requirements of ISO 13485:2016

Documentation and Record Keeping

ISO 13485:2016 requires thorough documentation including:

Quality Manual

A quality manual outlines the companies QMS and how it meets the requirements of ISO 13485

Document Control

Managing the creation, approval, distribution and maintenance of internal and external documentation used in the QMS

Record Control

Evidence of compliance with QMS and regulatory requirements including design, development, production and post production activities

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Management Responsibility

Top Management is responsible for establishing and maintaining the QMS by:

- Demonstrating a commitment to its effectiveness, and regularly reviewing the system (management review)

- This Includes:
- Setting a quality policy
- Goals and Objectives
- Ensuring adequate resources are available

Resource Management

Provision of Resources

The standard emphasizes a requirement to provide adequate resources to implement the QMS in order to meet applicable regulatory and customer requirements:

This includes determining competency and providing training or actions to ensure that an appropriate competent staff, and appropriate infrastructure (equipment and environment) to support the production of safe and effective medical devices

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Product Realization

This covers the entire process of producing a medical device from conception to decommissioning, including

Design and Development

Documenting and verifying the product design

Production and Servicing

Ensuring processes are controlled validated and documented.

Purchasing

Ensuring that materials and components meet quality requirements

Accreditation

Managing customer feedback, complaints, and ensuring clear communication

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Measurement Analysis and Improvement

ISO 13485 requires organizations to monitor and measure the effectiveness of their QMS; which includes the following

Feedback

Includes Complaint Handling, reporting, internal audit and monitoring and measuring product and processes. Regularly checking that the system is functioning as intended.

Control of non conforming product

Addressing nonconforming product and preventing the unintended delivery, rework and analysis of data

Improvement

Including Corrective and preventive actions.

Addressing nonconformities and potential issues to prevent recurrence

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How to Get Certified

What are the next steps?

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How to Get Certified

Develop and Implement the QMS

Organizations ahould document processes, train employees, and ensure that the QMS aligns with the ISO 13485 standard. **EVERY** process that impacts product quality should be controlled and monitored

Gap Analysis

Before certification some organizations will typically conduct a gap analysis to compare their current practice with ISO 13485 requirements. This helps identify gaps

Internal Audit

Before the external Audit conduct a thorough internal audit to ensure the system works as expected and to fix any issues before the certification body audit. Report the result in a full management review

External Audit

Certification is granted by an independent, accredited certification body that will audit the QMS. They will assess compliance with 13485:2016 looking to verify the system is implemented and maintained

Ongoing Maintenance

Once certified, organizations must maintain their QMS continuously improving it and undergoing surveillance audits typically annually by the certification body.

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Ongoing value of ISO 13485 Quality Management System

Benefits of ISO 13485:2016

What are the benefits of ISO 13485:2016 certification

Global Market Access

ISO 13485 certification is recognized worldwide and will help with regulatory approvals and market entry

Improved Product Quality

The focus on Risk Management, process control and customer satisfaction leads to better safer products

Customer Confidence

Certification demonstrates a commitment to quality and safety increasing customer trust

Regulatory Compliance

Meeting ISO 13485 helps ensures compliance with various regulatory frameworks making it easier to navigate complex legal requirements

Having accreditation through a Notified body if you are a contract manufacturer could also make your company more attractive for companies that have CE certification.

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The value of ISO 13485 is not just in the implementation.

How does ISO 13485 help my organization on a day-to-day basis?

Effective

Provides a way of capturing and sharing best practice in the organization.

Efficient

Creates a structure for performing processes consistently to yield more consistent results contributing to reduced scrap and waste.

Provides a vehicle to make and communicate changes and support their implementation.

Details a systematic way to investigate and resolve issues and drives continuous improvement.

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What opportunities does an ISO 13485 certification give my organization?

BSI Certification

Obtaining an ISO 13485 Certification with BSI ensures worldwide recognition for your organization compliance with ISO 13485 requirements.

Customer Value

Our accreditation reduces the risk to you and your customers and gives you complete confidence that we have been independently evaluated for our competence and performance capability. This may reduce the need for customer audits and your customers notified bodies.

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Why BSI?
Our Expertise

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Why BSI? BSI’s Expertise

Rigorous Approach to Compliance

Global Accreditation
Impartiality

Commitment to the Future

Sustainability

BSI’s Approach to Excellence

World Class Experts

Education
Experience
Training
Industry-specific Auditors

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Rigorous Approach to Compliance

Our Purpose, Mission and Vision

Established in 1901, BSI is a world-leading national standards body that helps our clients operate in a way that is safer, more secure and more sustainable. Incorporated by Royal Charter, we're truly impartial, and home to the ultimate mark of trust, the Kitemark.

Our purpose

Inspiring trust for a more resilient world.

Our mission

To share knowledge, innovation and best practice to help people and organizations make excellence a habit.

Our vision

To be the business improvement company that enables organizations to turn standards of best practice into habits of excellence.

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Rigorous Approach to Compliance

We are among the most respected and reputable management systems certification bodies in the world and are accredited by around 20 local and international bodies including:

Accreditation

American National Standards Institute - American Society for Quality National Accreditation Board LLC (ANAB)

Accreditation

China National Accreditation Service for Conformity Assessment (CNAS)

Accreditation

Raad voor Accreditatie (RvA) in the Netherlands

Accreditation

United Kingdom Accreditation Service (UKAS)

Accreditation means that we have been assessed against internationally recognized standards and operate to the highest levels of quality and service - providing further assurance to you that the certificates we issue are both credible and impartial.

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Impartiality

BSI Impartiality

Impartiality is the governing principle of how BSI provides its services. Impartiality means acting fairly and equitably in its dealings with people and in all business operations. It means decisions are made free from any engagements of influences which could affect the objectivity of decision making.

Commitment to the Future

Sustainability

“Sustainability is part of our purpose”

BSI was established in 1901 with 'responsibility to society' as one of its main objectives and this has never been more relevant than it is today. We are a signatory of the UN Global Compact, the world's largest sustainability network, and are proud to support its principles, as well as the UN Sustainable Development Goals.

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BSI’s Approach to Excellence

Word Class Experts

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BSI’s Approach to Excellence

World Class Experts

Experience matters.

BSI has a very selective recruitment process for the professionals we hire to conduct ISO 13485 audits. We continue to seek degreed engineers who have suitable qualifications and sufficient background and knowledge of medical devices design, manufacturing and application of the device technology.

BSI is always looking ahead to ensure that our clients are well informed of future changes to compliance and the regulatory landscape.

Our auditors undergo a several month rigorous onboarding training process that includes our own industry leading training . Auditors or not qualified until they demonstrate the ability to conduct audits in a manner that meets our standard of excellence. Auditors receive ongoing training monthly to ensure State of the Art Knowledge and drive continuous improvement to the audit experience for our clients.

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BSI’s Approach to Excellence

World Class Experts

We don’t stop with education, experience, and training.

At BSI we utilize a coding process which algins your organizations products and process with an auditor who has specific knowledge of your industry and medical device(s).

We continually benchmark to ensue that we are competitive in obtaining and retaining the World Class Experts that BSI represents.

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Reasons to make BSI your Certification Body

Experience and product expertise

The benefits of having experienced, professional and well qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry.

Global market access

We are a global organization, trusted and recognized around the world..

Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely.

Confidence and robust reviews

Our comprehensive review process combined with our world leading experience as a Certification and Notified Body and UK Approved Body.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology.

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Reasons to make BSI your Certification Body

MDSAP for contract Manufacturers

With recent decisions by the Medical Device Single Audit Program regulators contract manufactures may now be MDSAP certified. This means that in most cases the FDA will not come audit if you are MDSAP certified

Resources available for immediate delivery

BSI currently has adequate resources to bring on more companies and provide ISO 13485 certification still in 2024 if the company is ready

Resources available to provide MDSAP certification

BSI currently has adequate resources to bring on more companies and provide MDSAP certification still in 2024 if the company is ready

Resources available for MDR Certification

BSI currently has adequate resources to bring on more companies and provide MDR certification still in 2024 if the company is ready

Transfers

BSI has adequate resources to transfer your certification or MDR certification if you need a new partner.

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BSI
Your Partner In Progress

Trusted partner

Thought shapers

Opportunity accelerators

Digital trust

Sustainability

Quality

Health safety & wellbeing

Supply chain

Expertise

Insight

Network

Innovation

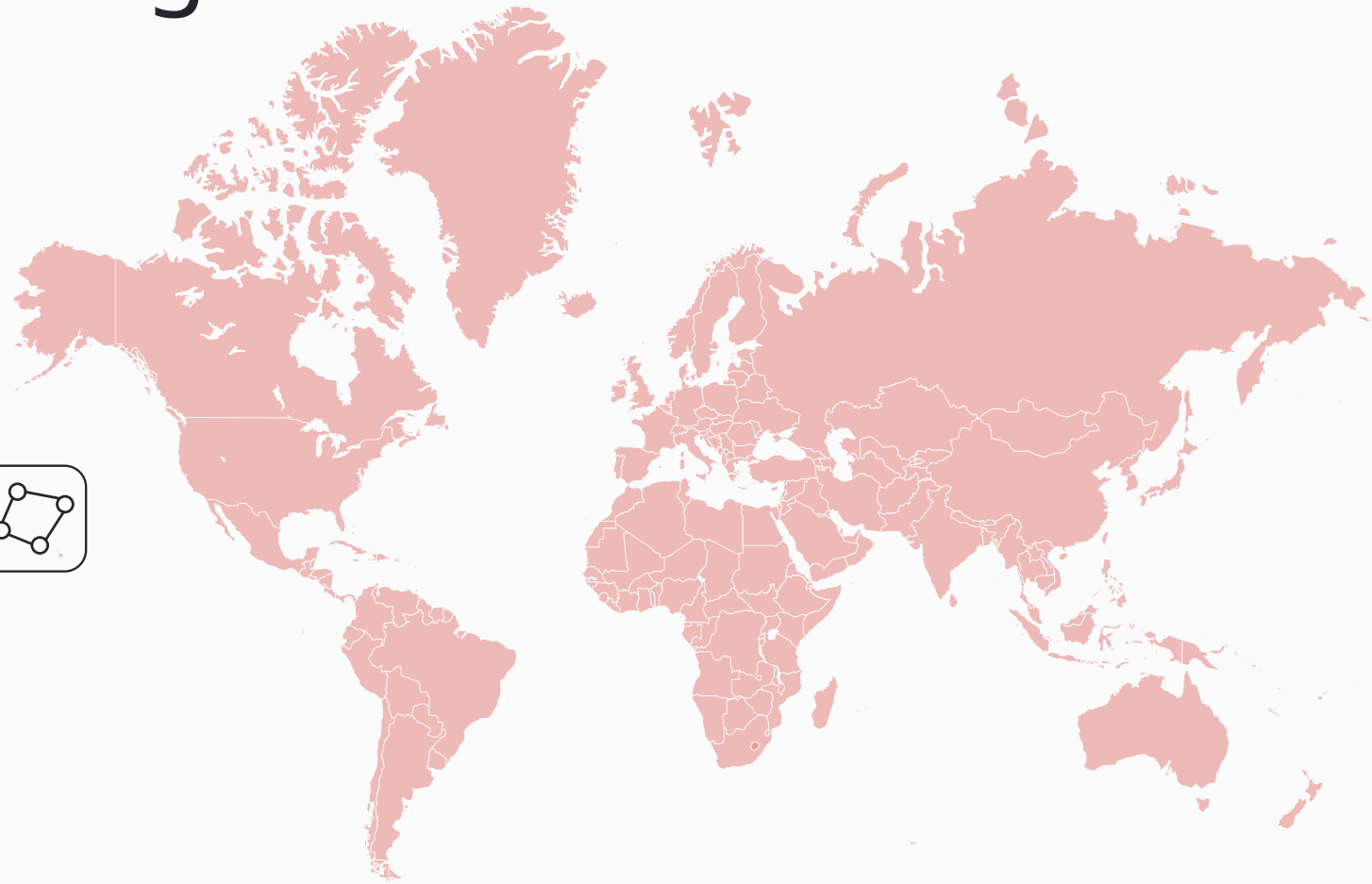
Collaboration

Consulting

Certification

Medical certification

Training



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Questions & Answers

Thank You

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