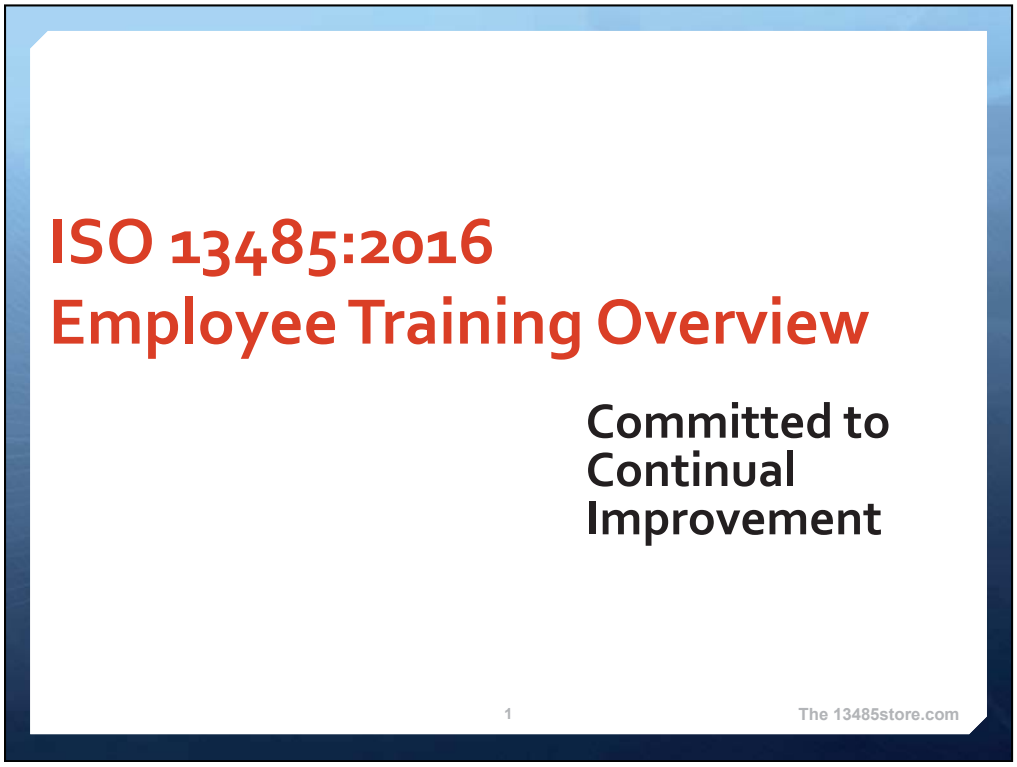
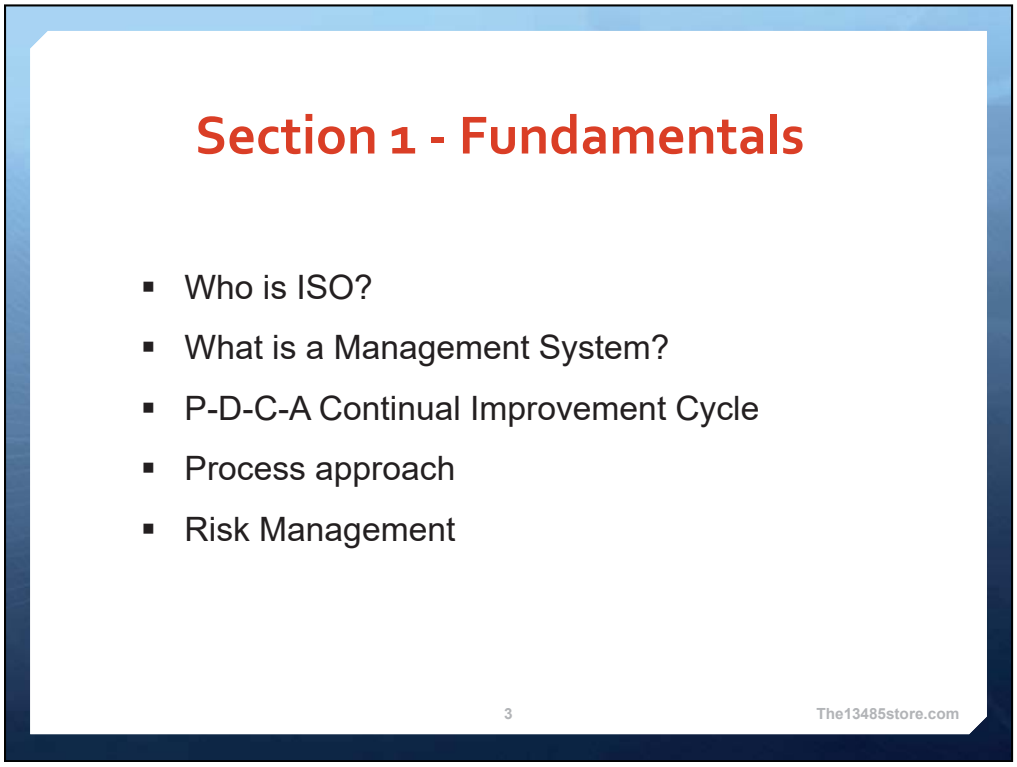
Trainer's Guide with Speakers Notes

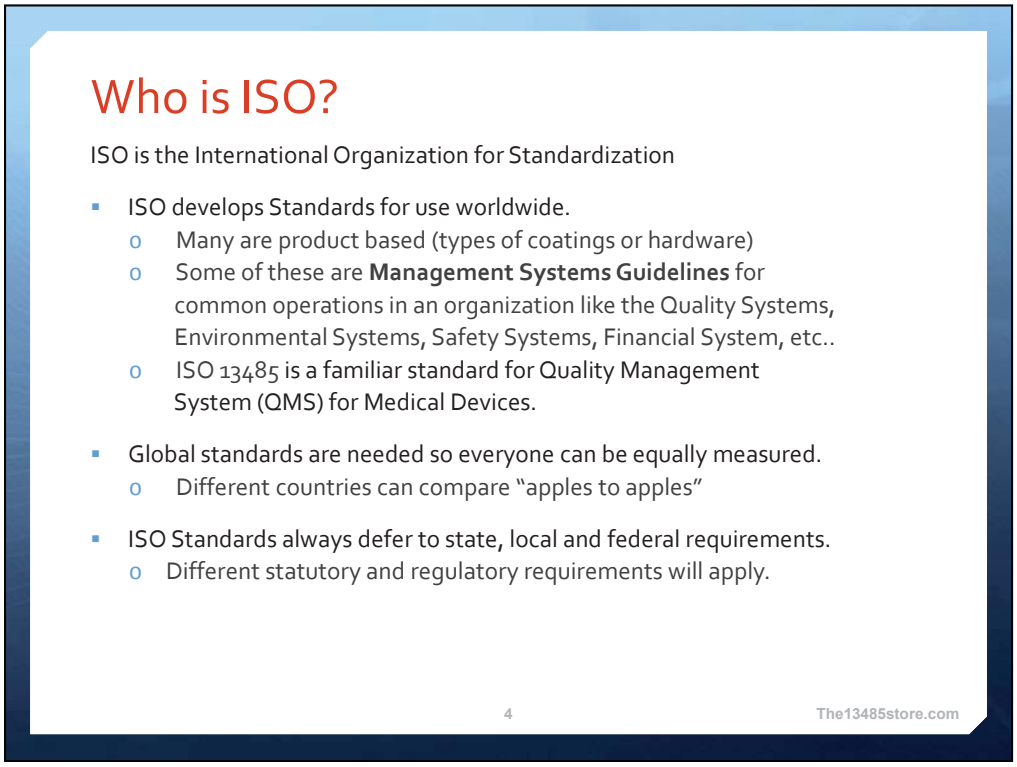


Every employee in your ‘Medical Device’ company has an important role to play in your Quality Management System (QMS)s.

You are participating in this training to learn the basics of a QMS and what it means to be ISO 13485 registered and how it will affect your job as a manufacturer of medical devices.



Lets start with some fundamentals



ISO (International Organization for Standardization) is a network of standards organizations from some 180 countries with a central office in Geneva, Switzerland, that coordinates the system.

ISO develops a variety of standards for product features like film, fasteners, etc.., as well as management systems to help operate an organization.

The ISO 13485 Quality Management System is the most popular management system for medical devices that ISO publishes.

ISO is a non-governmental organization whose members are in both the public and private sectors.

ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

Although global, they must allow for compliance to laws in every local geography.

What is a Management System?

Your organization is made up of several Management Systems, which operate within your overall Business Management System. Example:

- Financial (FMS)
- Quality (QMS)
- Environmental (EMS)
- Safety (SMS)
- Energy (EnMS)
- IT (MIS) etc.

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A Management system refers to what an organization does to run a business, manage its processes, or activities so that its products or services meet the organization's objectives, such as:

• Satisfying the customer's quality requirements,

• Complying to regulations, or

• Meeting quality objectives

Student's Guide with space for notes

ISO 13485:2016
Employee Training Overview

Committed to Continual Improvement

Topics Covered

1. Fundamentals	2. Basics of a QMS and ISO 13485	3. Establishing your QMS	4. Managing the ISO 13485 QMS
• Who is ISO? • What is a Management System? • Plan Do Check Act • Process approach • Risk Management	• What is an QMS? • What is ISO 13485? • Benefits of certification • Elements of ISO 13485:2016	• Key Elements • Documenting your QMS • Implementing the QMS in your Organization • Training People • Auditing the QMS • Certification	• Key elements of an ISO 13485 QMS • ISO 13485 registration

Section 1 - Fundamentals

- Who is ISO?
- What is a Management System?
- P-D-C-A Continual Improvement Cycle
- Process approach
- Risk Management

Who is ISO?

ISO is the International Organization for Standardization

- ISO develops Standards for use worldwide.
  - Many are product based (types of coatings or hardware)
  - Some of these are **Management Systems Guidelines** for common operations in an organization like the Quality Systems, Environmental Systems, Safety Systems, Financial System, etc..
  - ISO 13485 is a familiar standard for Quality Management System (QMS) for Medical Devices.
- Global standards are needed so everyone can be equally measured.
  - Different countries can compare "apples to apples"
- ISO Standards always defer to state, local and federal requirements.
  - Different statutory and regulatory requirements will apply.

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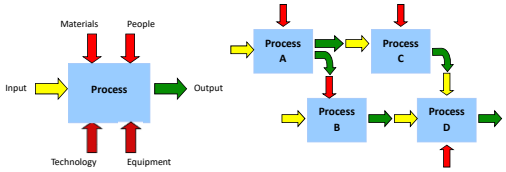
Plan-Do-Check-Act Example

Plan	Do	Check	Act
• Set Goal – Lose weight • Metrics – 10# per month until you reach your target weight • Set up exercise schedule, nutrition	• Implement the plan • Exercise, eat wisely, portion control	• Validate – Step on the scale – Are you meeting the goal? • No – Why not? • Yes – Great! Can you improve?	• Adjust plan • Keep improving by raising the bar (Continual improvement)

Process Approach



- Look at your business as a ***series*** of interacting processes, not departments.
- If you break down the process, you can improve them for consistent results – like a recipe.
- Requires that your processes are controlled and managed for continual improvement.

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Process Approach Example

A bakery is a system of processes

Quotation Process

Design Process

Purchasing Process

Production Process

Quality Process

- Understanding what your customers want
- Develop your recipe to meet these requirements
- Select Providers, Buy ingredients, etc..
- Mix Ingredients, Bake bread, etc..
- Determine risks and opportunities
- Audit: Test results – were they burned?
- Corrective Action: Adjust oven, etc..

All of the processes directly / indirectly impact each other

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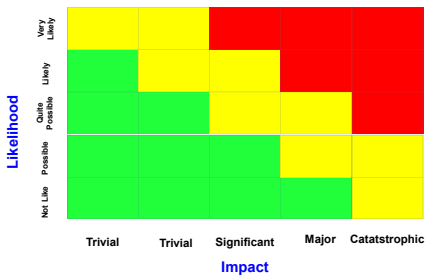
Risk Management – An informal risk management system aimed at improvement



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Includes Quizzes to test knowledge

b. Is about consistently meeting requirements aimed at enhancing customer satisfaction

c. Outlines the levels of quality performance you must achieve

8. ISO 13485 identifies the requirements for an

a. Energy Management System

b. Environmental Management System

c. Quality Management System

d. Quality Management System - Medical devices

9. ISO 13485 is a national standard put together by the ASQC

a. True, b. False

10. Benefits of implementation include

a. Market recognition / expansion

b. Improved communication

c. Financial return on investment / improved operating margins

d. Clearly defined operational process requirements

f. All the above

11. Each employee should understand their own roles and responsibilities within the QMS.

a. True; b. False

12. Within the 5 clauses of ISO 13485 there are some 30 elements that are required to be met.

a. True; b. False

13. Only management personnel are involved in a third-party audit by a registrar.

a. True; b. False

14. Prior to a registration audit, it is necessary to run the ISO-based QMS for a minimum period of:

a. One year

b. Six months

c. Three months

d. Two weeks