ISO 9001:2015

and

ISO 13485:2016

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QMD-003

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Instructions:

This manual is used as a template in developing your Quality Management System covering both the ISO 9001:2015 and ISO 13485:2016 international standards.

The specific additions for ISO 13485:2016, Medical Devices – QMS for regulatory purposes are highlighted in yellow.
To provide the correlation between the requirements of ISO 13485:2016 and those of ISO 9001:2015, each procedure and instruction contains the paragraph 3.1.2 (also highlighted in yellow) that reflects the corresponding clause numbers.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QM-001 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

Table of Contents – (this page)

Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its context, Your Company determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Your Company meets the requirements of both the ISO 9001:2015 and ISO 13485:2016 international standards. The system addresses the design, development, production, installation, and servicing of the company's products and it incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standards.

This manual is used internally to guide the company's employees through the various requirements of the ISO standards that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

A top management representative approves the manual.

President: _____ Date: _____

Section A Scope or the Quality Management System

General

To determine and establish the scope of the QMS, Your Company determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company.
The scope is available and maintained as documented information stating the products and services covered by the QMS.
Your Company applies all the requirements of ISO 9001:2015 when they are applicable within the determined scope of the QMS.
As developed with procedure P-400 for Organizational context, include the scope of your QMS here:

_____

_____

Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
In the event that any requirement is not applicable at Your Company, justification for any instance where a requirement cannot be applied is documented.
Your Company has determined that the following requirement(s) is/are not applicable to the operations at this site:

_____.

As determined with procedure P-400, identify the requirement(s) that do not apply and document the justification here:

_____

_____

Section B References

a. Reference.

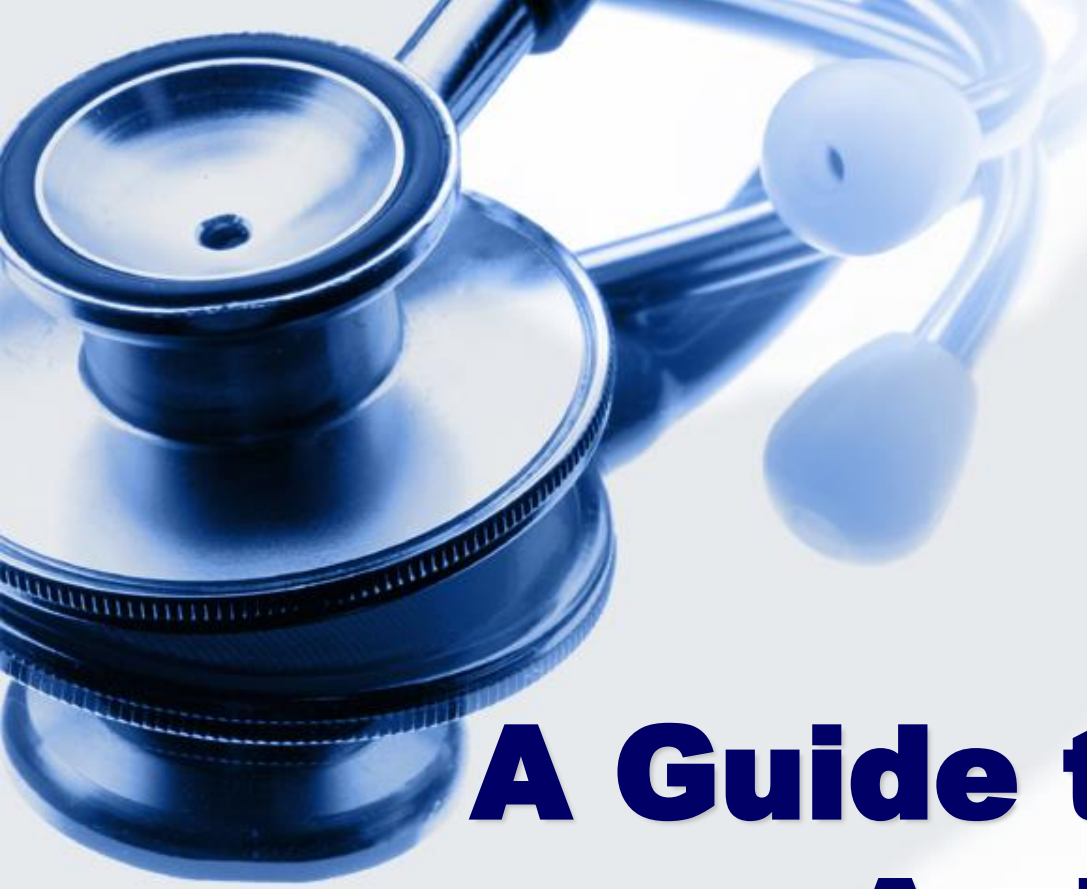
- ISO 9001:2015 Quality management systems requirements
- ISO13485:2016 Medical devices – Quality management systems - Requirements for regulatory purposes

b. Normative reference.

- ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary.

c. Definitions.

- Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.



A Guide to Internal Auditing

ISO 13485:2016

Introduction: Why are you here?

- To learn more about ISO 13485:2016
- To be able to evaluate you own area and make improvements.
- To understand the audit process.
- To be able to participate in the audit process.

Performing an Internal Audit

»Techniques

More about audits and auditing techniques

• Auditees must be made comfortable during interviews and there are techniques that are used by auditors to make it easier.

• Experienced auditors learn to read body language and other non-verbal clues.

• The auditor will question the auditee, listen to the answers, and anticipate the answer to the question.

• It is necessary to listen critically, analyze the answer, record the information and at the same time prepare the next question.

Internal Audits: Conclusion

The Internal Audit process is one of the most important in ISO 13485 or any ISO based standard.

Conduct internal audits to determine if the QMS:

- Conforms to planned arrangements for quality management .. this includes both the requirements of the ISO standard and your own operational requirements.
- Has been properly implemented and is maintained.
- Provide information on results of audits to the management group.

INSERT YOUR COMPANY NAME HERE

ISO 9001:2015 – with – ISO 13485:2016 - Quality Management Systems - Internal Audit Checklist

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This checklist helps audit a Quality Management System against both ISO 9001:2015 and ISO 13485:2016. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements. You will see questions on the checklist that refer to the standards and for each clause provisions are made for additional questions.

While the editions of the standards do not line up when comparing the contents and requirements, the ISO 13485:2016 requirements over ISO 9001:2015 are highlighted in yellow and the relevant ISO 13485:2016 clause number appears with the audit question. The auditors are expected to keep in mind that while ISO 13485:2016 requires specific procedures for some QMS processes, the ISO 9001 standard does not require such mandatory procedures; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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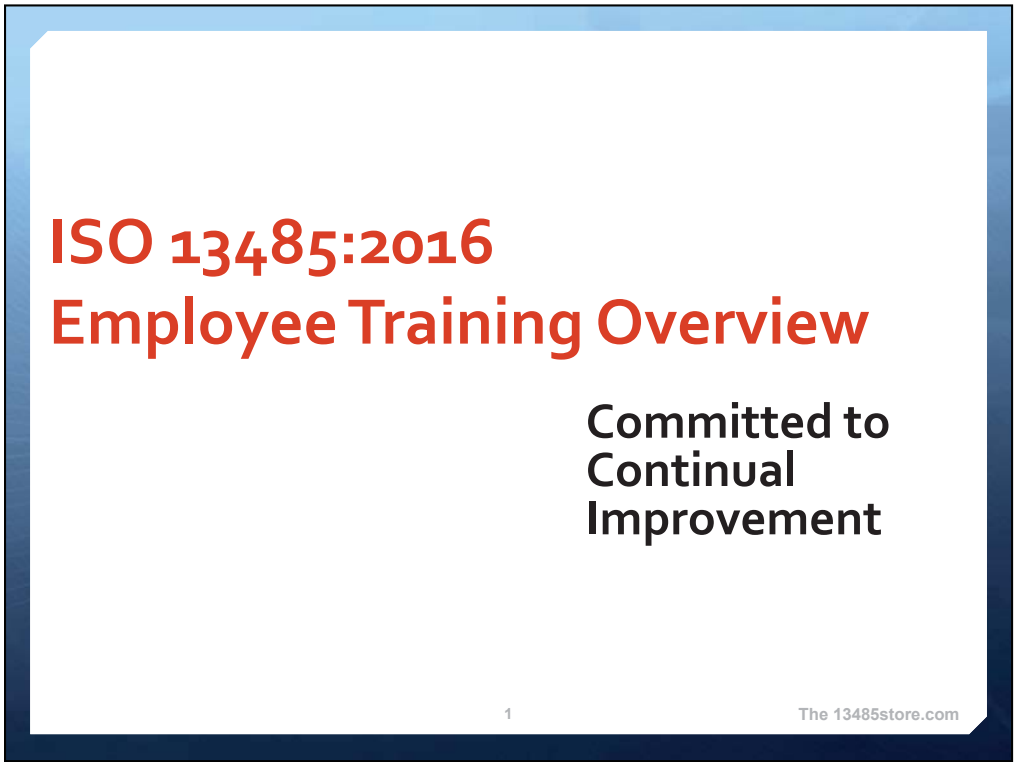
	• Available to relevant interested parties?		
	Additional Questions		
5.3	**Organizational roles, responsibilities, and authorities**		
	Does the top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company?		
	5.5.1 Have you document the interrelation of personnel whose work affect quality?		
	Does top management assign the responsibility and authority for:		
	• Ensuring that the QMS conforms to the requirements of ISO 9001:2015 standard?		
	• Ensuring that the processes are delivering their intended outputs?		
	• Reporting on the performance of the QMS on opportunities for improvement and for reporting to top management?		
	• Ensuring the promotion of customer focus throughout your company?		

	• Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?		
	5.5.2 Has top management appointed a management representative with responsibility and authority for:		
	• Ensuring that QMS processes are documented?		
	• Reporting to top management on the performance of the QMS and the need for improvement?		
	• Ensuring the promotion of awareness of regulatory and QMS requirements?		
	• Maintaining the integrity of the QMS when changes are planned and implemented?		
	Additional Questions		
6	**PLANNING**		
6.1	**Actions to address risks and opportunities**		
6.1.1	When planning for the QMS, does your company consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed?		
	5.4.2 a) Does top management ensure the planning is		

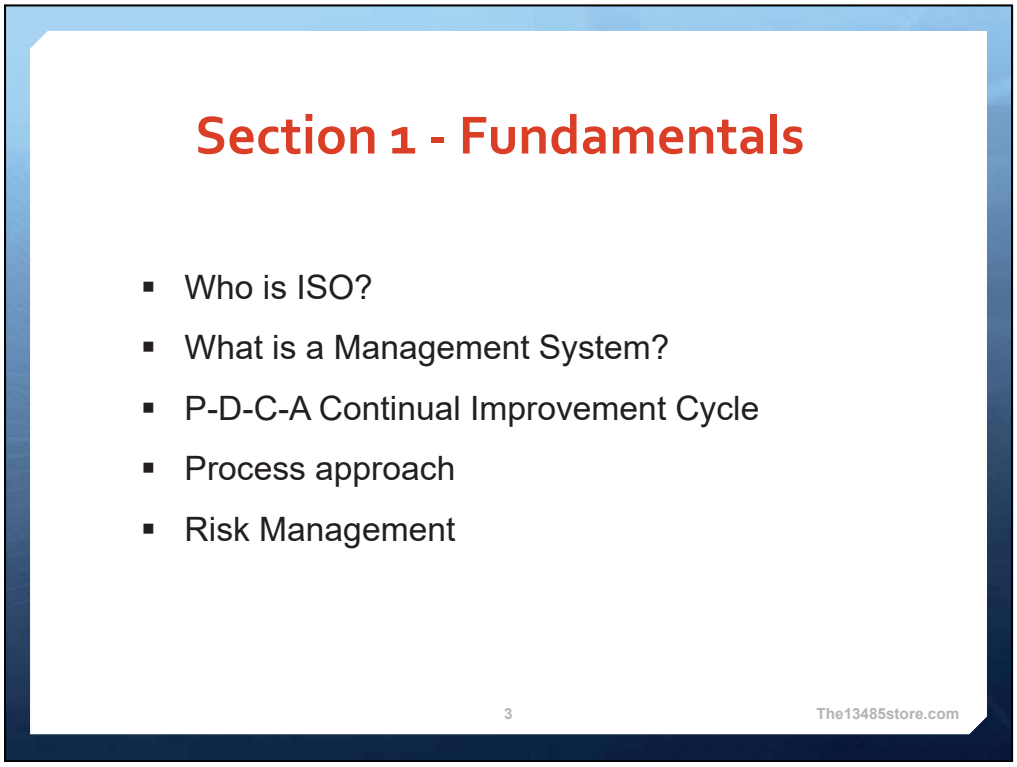
	carried out to meet the requirements? 5.4.2 b) Is the integrity of the QMS maintained when changes are planned and implemented		
	Is this performed to:		
	• Give assurance that the QMS can achieve its intended results?		
	• Enhance desirable effects?		
	• Prevent, or reduce undesired effects?		
	• Achieve improvement?		
6.1.2	Does the company plan:		
	• Actions to address these risks and opportunities?		
	• How to integrate, implement the actions into the QMS processes and evaluate their effectiveness?		
	Do you take actions to address risks and opportunities that are proportionate to the potential impact on the conformity of products and services?		
	7.1 Have you document one or more processes for risk management and do you maintain records?		
	Additional Questions		

Trainer's Guide with Speakers Notes

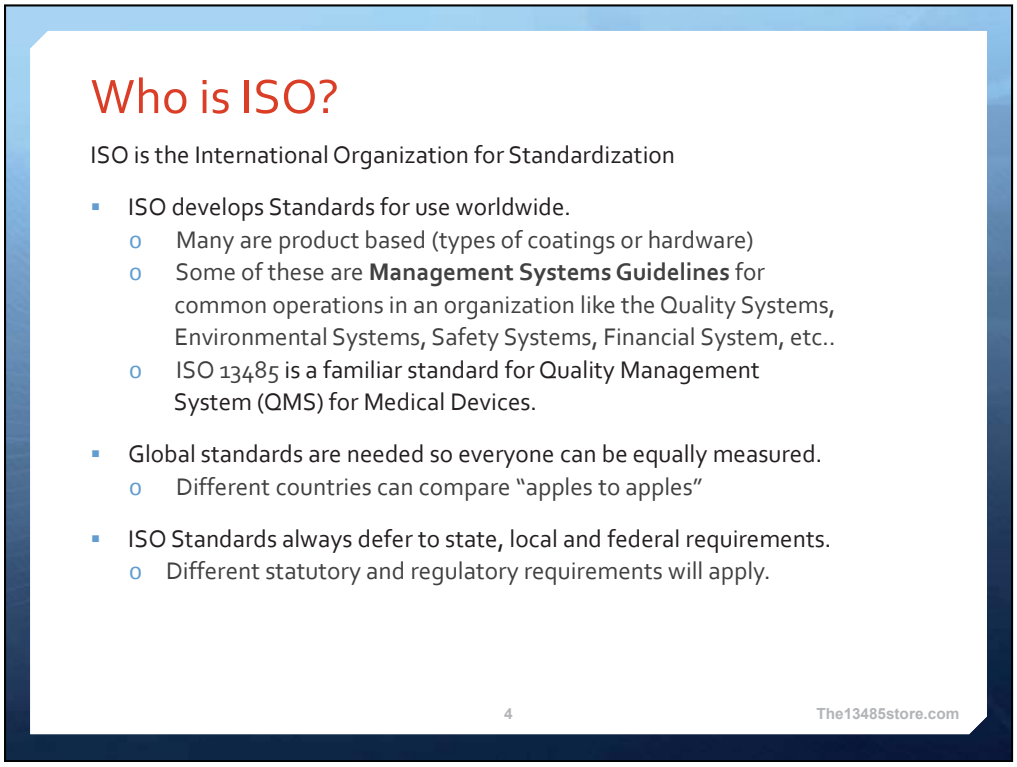


Every employee in your ‘Medical Device’ company has an important role to play in your Quality Management System (QMS)s.

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.

5

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.

What is a Management System?

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

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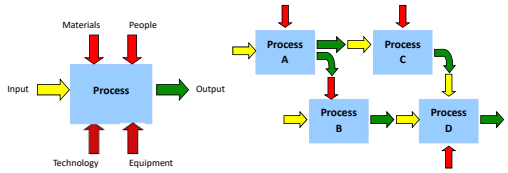
- IT (MIS) etc.

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)

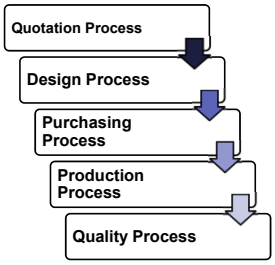
Process Approach



- 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.

Process Approach Example

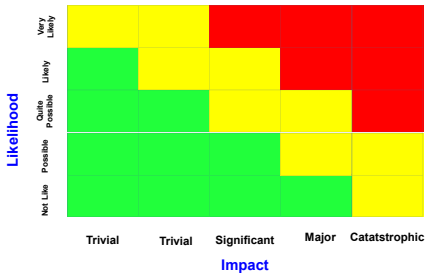
A bakery is a system of processes



- 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

Risk Management – An informal risk management system aimed at improvement



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