ISO13485 IMPLEMENTATION

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Simone Rudolph-Shortt

0828715740

Workshop Objectives

To enable implementation of ISO13485.

Key points:

- Understand the standard
- Plan the QMS
- Implement the system

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Contents

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International Organisation of Standards

- International Organization for Standardization.
- Set up in 1947, located in Geneva, purpose
  - to facilitate and support international trade by developing standards that people everywhere would recognize and respect.
- ISO achieves this purpose through the participation and support of its member bodies. These member bodies currently come from 146 countries
- developed by technical committees.
- attendees come from many national standards organizations.
- Therefore ISO standards have worldwide support.
- ISO 13485 was developed by ISO Technical Committee 210.
- ISO/TC 210 is responsible for “quality management and corresponding general aspects for medical devices”.

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SABS

Our legislative mandate

The SABS was established by the Standards Act, 1945 (Act 24 of 1945)

SABS exists as a public entity under the Standards Act, 2008 (Act 8 of 2008)

The objectives of SABS are as follows:

- Develop, promote and maintain South African National Standards (SANS)
- Promote quality with respect to commodities, products and services
- Render conformity assessment services and matters connected therewith

International Membership

ISO IEC PASC PACIFIC AREA STANDARDS CONGRESS ARSO SMIIC AFSEC

Accreditation of SABS

sanas South African National Accreditation System

RVA RAAD VOOR ACCREDITATIE

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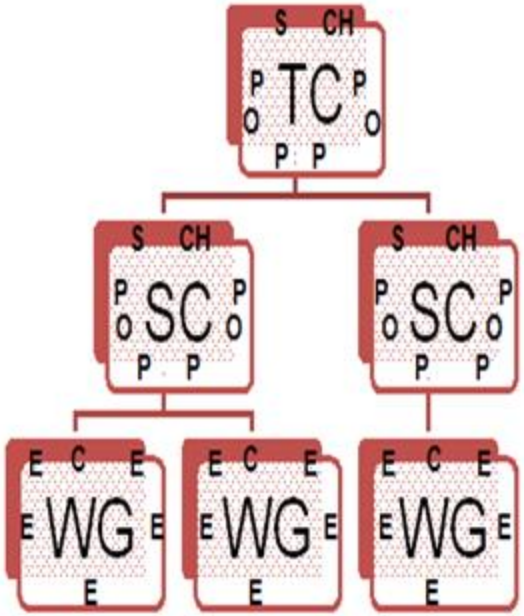
SABS

Guiding principles

- International Principles
- Governance process
- SABS Norm
- Alignment to ISO and IEC programme of work
- Maintenance
  - Reaffirmations
  - Withdrawal
  - Amendments
  - Revisions



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How standards are developed

SABS is the only organisation in South Africa with the mandate to develop, promote and maintain national standards

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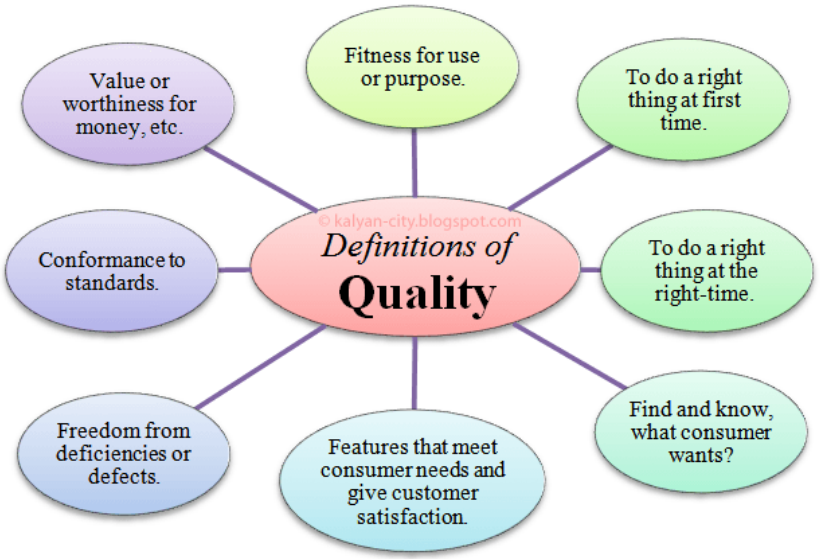
Types of SABS Standards

1. Prescriptive specifications
   - Obligate product characteristics, e.g. device dimensions, biomaterials, test or calibration procedures, as well as definitions of terms and terminologies.
2. Design specifications
   - Set out the specific design or technical characteristics of a product, e.g. operating room facilities or medical gas systems.
3. Performance specifications
   - Ensure that a product meets a prescribed test, e.g. strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy.
4. Management specifications
   - Set out requirements for the processes and procedures companies put in place, e.g. quality systems for manufacturing or environmental management systems.



"Philip Crosby"	• Quality is conformance to requirements.
"Dr Edward Deming"	• Quality is a predictable degree of uniformity and dependability, at low cost and suited to the market.
"Dr Juran"	• Quality is fitness for use/purpose.
"R J Mortiboys"	• Quality is synonymous with customer needs and expectations.

QUALITY MEANS ….

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QC, QA , QMS

- Quality Control
  - Inspection / test activities
- Quality Assurance
  - Planned activities to provide confidence that the product or service fulfils requirements for Quality
- Quality Management System
  - all organisational processes to assure quality

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A quality management system (QMS)

- defined as a collection of business processes that focus on meeting customer and regulatory requirements on a consistent basis
- Purpose is to ensure that, every time a process is performed, the same information, methods, skills and controls are used and applied in a consistent manner.
- A procedure is a documented method for completing something with steps and instructions for each aspect of the task to ensure the activities of the organisation consistently realise high quality products and services, which in turn brings many benefits, including satisfied customers, regulators, management, and employees

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1. PURPOSE / SCOPE OF QMS

ISO 13485

- Developed to
  - establish a quality management system that is oriented towards the design, development, production, and installation of medical devices and related services.
  - demonstrate **ability to supply** medical devices and related services that meet
    - **customer expectations**
    - **comply with regulatory requirements.**
  - evaluate **how well the organization is able to**
    - **meet customer expectations**
    - **comply with regulatory requirements.**

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ISO 13485

- ISO 13485 is a **process standard** and therefore for product compliance to requirements there is also a need to comply with all relevant product and service oriented technical standards and regulations.
- The **process approach** considers the interaction between processes, and the inputs and outputs that tie these processes together. The output of one process becomes the input of another

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ISO13485

- It specifies requirements for a quality management system (QMS) that can be used by an organization involved in one or more stages of the **life-cycle** of a medical device.
- It is emphasized that the QMS requirements specified in this International Standard are **complementary to the technical requirements** for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

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KISS "KEEP IT STREAMLINED SIMPLE"

Define the system	Plan it
Determine documentation	Say it
Procedures for processes	Do it
Check & Test procedure	Check it
Management review	Review it
Certification	Go for it

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Management Responsibility

Provide evidence of commitment

Ensure quality policy is appropriate, effective, complete, communicated and maintained

Ensure measurable, consistent quality objectives are established at relevant levels

Plan system implementation

Ensure planning is performed to meet requirements and objectives, including during times of QMS change

Assign R&R

Ensure responsibilities, authorities and interrelationships are established

Appoint a management representative to manage the QMS and report on performance

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Quality Management Principles

- **Process** approach
  - A desired result is achieved more efficiently when activities and related resources are managed as a process
- **System** approach to management
  - Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives

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Quality Management system

- Transform **inputs** of resources into a **output** of product or service which meet the organization's objectives with
- satisfying the customer's quality requirements,
- complying to regulations

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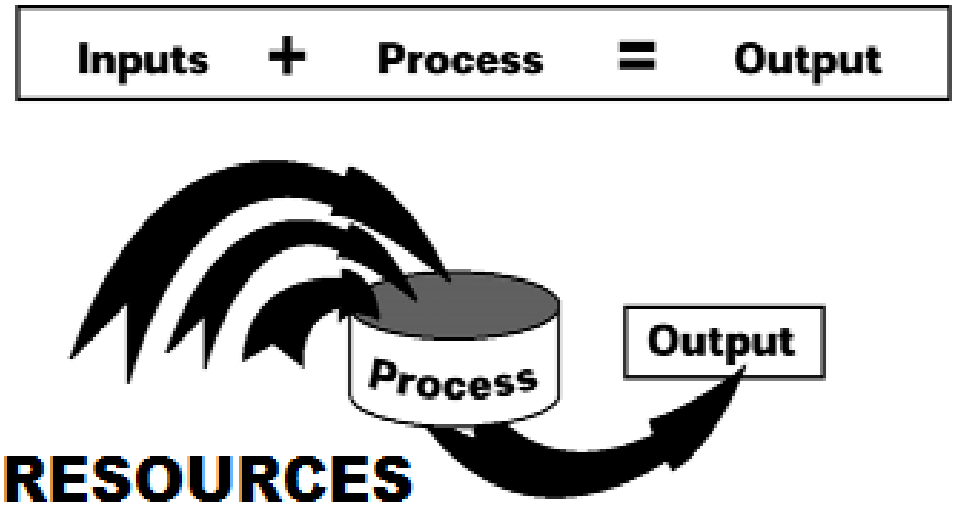
- RESOURCE INPUTS (6M)
  - Man
  - Materials
  - Machine
  - Methods
  - environMent
  - Money



2. MANAGEMENT COMMITTMENT

7 Principles to Quality Management

1. Customer
2. Leader
3. People
4. Process
5. System
6. Supplier
7. Facts
8. Improve
9. Risk

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- Leaders establish unity of purpose and direction of the organization.
- They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

- Quality POLICY
- Quality Objectives
- Management Review

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Top Management shall

- take **accountability and responsibility** for the effectiveness of the Quality Management System and ensure that it meets its purpose
- Based on the context and strategic direction of the organization, ensure that **Quality policies and objectives are established** for the Quality Management System.
- Ensure that the Quality Management System **works together with the organisation's business processes;** This will in-turn ensure that the requirements of the customer are met and this enhances customer experience.

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cont

- **Promote process approach**. This is where top management's own commitment and understanding on the principles of QMS is required so that they imbibe these principles in their working and encourage use of processes across the organization.
- **Communicate the importance of conforming to the QMS and its requirements**.
- **Provide adequate resources** needed for the QMS; Top Management needs to create effective organizational structures and provide right internal environment that motivates people towards achievement of organisation's goals and objectives.

Cont

- **Engage, direct and support persons** to contribute to the effectiveness of the Quality Management System. This requires top management's direct involvement in all stages of QMS including planning, reviewing the results and suggesting improvements. The top management needs to show commitment towards processes to motivate others also to implement and improve processes.
- **Promote a culture of process improvements**, take initiatives to develop new products and introduce new tools, to improve efficiency and productivity.

Cont

- **Support other relevant management roles** to ensure that all roles as required for effective implementation of QMS are available in the organization.
- **Maintain a consistent focus on customer requirements, meeting of regulatory or statutory requirements and enhancing customer satisfaction.** All the requirements shall be determined and met and confirming products or services provided to the customer.
- **Determine and address any risks** that may hinder an organization's ability to provide conforming products/services, or which may have a negative effect on customer satisfaction.

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Top Management

- Video

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Top Management Commitment

- To gain and support for the implementation
- Assign key member of management to lead the project
- Assign the management representative
- Top management must understand the implications of their decision and the need for their personal involvement.
- Estimate resources; people, time, and costs for the project (Implementation and certification)
- Procure the necessary resources for planning, implementation and certification
- Management to understand the key concepts and requirements though a briefing or training
- Plan the ISO 13485 implementation as a PROJECT

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RESOURCES

Assigning	a manager as project leader
Appointing	a Management Representative
Developing	an implementation plan
Ensuring	adequate time, infrastructure, effort
Approving	ISO 13485 training or communications
Appointing	a conformity assessment body

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3. CONSULTANTS / EXPERTS

Benefits of a Consultant / QARA expert

- The benefits of using a reputable and experienced ISO Consultant who has good knowledge of the relevant ISO standards and industrial sector are that you
  - will achieve Certification with an effectively implemented management system and
  - operated by people that understand how to continue to achieve continual improvement.

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ISO 17021, the definition of **consultancy**

- is the 'participation in designing, implementing or maintaining a management system' and cites examples such as the preparation of manuals and procedures, or giving specific advice or instruction towards the development and implementation of a management system

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QMS support

- 1. Illustrate the concepts concerning quality management paying special attention to the understanding and adoption of quality management principles, ensuring that the design and implementation of the QMS is suited to the organization’s culture and specific business environment.
- 2. Involve all relevant individuals in the QMS realization, advising and supporting the organization in identifying the appropriate processes needed for its QMS, define the relative importance and interaction of those processes and assist the organization in identifying documentation essential to ensure the effective planning, operation and control of its processes.

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QMS support

- 3. Once the processes have been identified, evaluate their effectiveness and efficiency to stimulate the organization to look for opportunities for improvement and assist in promoting a process approach and continual improvement of the QMS within the organization.
- 4. Assist in identifying the training needs to enable the organization to maintain the QMS.
- 5. Where applicable, assist the organization in identifying the relationship between its QMS and any other relevant management system (e.g. environmental or occupational health and safety) and facilitate the integration of such systems.

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Consultants guidance and expertise on :

- SAHPRA license applications submissions and requirements – which guidance docs are available etc
- Global regulatory requirements , standards , technical dossiers etc
- Auditing of processes to various standards eg lab- iso15189/GCLP/ ISO 13485
- Registration / Marketing Authorisation Applications to Regulatory / Government Agencies
- Better Communications between industry and regulatory bodies/agencies
- Pharmacovigilance for clinical trials

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role of regulatory consultant / expert

- adds value to the organization by understanding existing processes and how to improve them
- brings expert knowledge on regulations and standards and how to implement
- instills peace of mind and assurance in the organization
- give feedback to organization on state of the art i.t.o regulatory and quality tools
- -emains objective and doesn't take shortcuts

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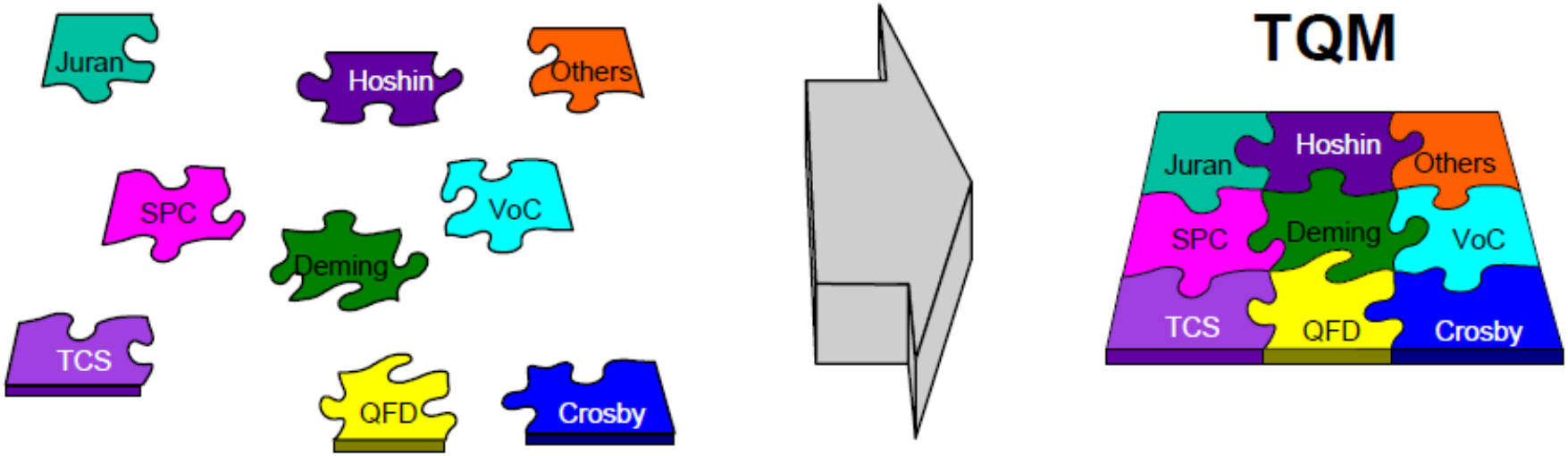
4. IMPLEMENTATION PROCESS

Total Quality Management

- **MUCH more than a "program of the month," an *integration* of the work of many gurus (Deming, Juran, Crosby, ...)**
- **Total Quality Mindset**



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OVERVIEW

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1. REQUIREMENTS

Regulatory

SAHPRA

NRCS

ICASA

- **Websites**
- **Act, Guidelines, Forms, Fees**

Processes

Main

Anxillary

Support

BUSINESS

Size, Sites

Complexity

Divisions

Budget

No of people , R&R

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2. INFORMATION

STANDARD

- **Training**
- **consultant**

SOP & Format

- Hard Copy
- Electronic

Product (group, family), GMDN, GMDN descriptor, CE/ISO certificates

- Declaration of Quality / Conformity

Operations

- Linked to processes

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Introduction

- Document control often confused with various types of information management
- Document control = right document, right place, right time
- Control means change is subject to rules
- Two document types:
  1. DOCUMENT CONTROL
     - Content is directive and can change
  2. RECORD CONTROL
     - Content is historical and cannot change

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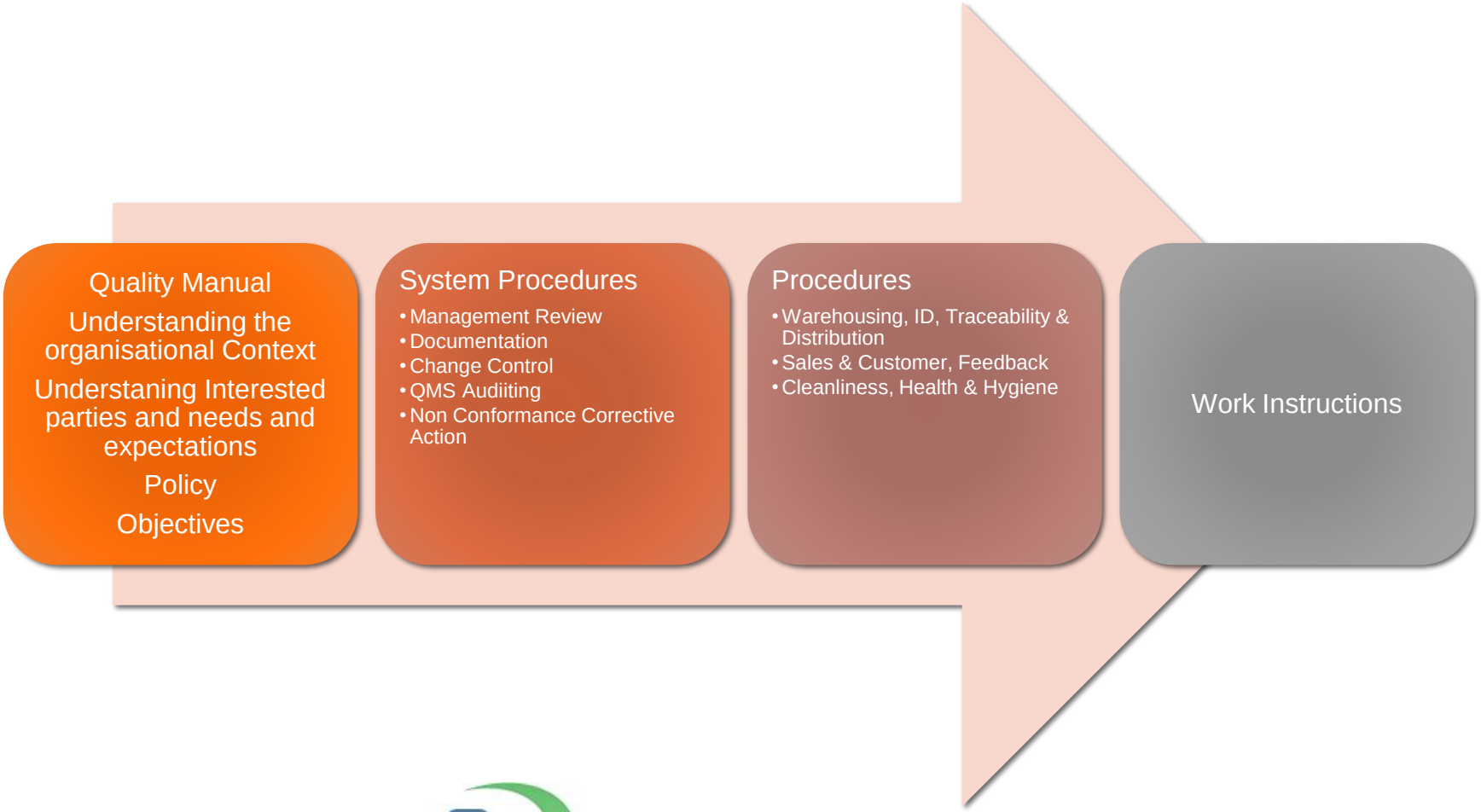
DOCUMENTATION



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Document Control

Document management

- Controls the life cycle of documents in your organization
  - how they are created, reviewed, published, disposed of or retained.
- an effective document management system should reflect the culture of the organization that is using it
  - The tools should be flexible
  - enough to allow you to tightly control a document's life cycle, if that fits your enterprise's culture and goals, but also to let you implement a more loosely structured system, if that better suits your enterprise.

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FORMAT

Paper

- referred to as the ‘Legal’ original document
- does not face the risk of a virus attack
- no software maintenance:

Electronic

- more effective:
- Saves Cost
- Easy to Secure:
- time saving
- Reduce Clutter
- easy to update

Paper

1. ‘Legal’ original document
- Electronic documents can be tampered with easily.
- Some require original, hard-copy documents that have their integrity maintained
- Paper documents preserve the originality of documents, electronic documents aren’t so guaranteed

2. virus attack
- electronic documents can be wiped off by viruses

3. no software maintenance
- Unless there are changes in a document, there’s no need to update a paper document for any reason

Negative; changes require process of re-printing, re-storing, and increasing the cost of running the business

Electronic

THE ADVANTAGE OF CHOOSING ELECTRONIC DOCUMENT OVER PAPER DOCUMENT

- We are living in an increasingly digital world where everything we do is online.
- Technology is becoming so common that we can fit lots of information into our pocket, courtesy of our smartphones. This is why electronic documents are needed.
- An electronic document is a media content stored and used in an electronic format. Electronic Document provides advantages that surpasses those of traditional paper documentation systems on many levels.

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Electronic

1. More effective

- to build an effective team- can't achieve if you use paper documents.
- team can work faster without being restricted because of inaccessibility to documents
- team would more productive, which helps the business grow faster in the long run.

2. Electronic documents Saves Cost

- Paper-based is more expensive -spend money on printers, ink, cartridges, paper, and stationery.
- Electronic documents need money to buying some equipment and subscription fees for cloud-based storage

3. Easy to Secure

- Can be secured with a password
- Viewing highly-sensitive information by setting access controls and giving permission to certain people

Electronic

4. Time saving

- the simplicity of searching for documents within seconds

5. Reduce Clutter

- Scanning documents to keep paper documents
- Can substitute keeping stacks of paper in file cabinets for storage in the cloud or on your computer
- Can access them from anywhere
- Unlimited storage space in the cloud—no disposal of paper

6. Easy to update

- updates or changes - reupload to the cloud
- not the case for paper documents

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END OF DAY 1

Q&A

Video – System vs Processes vs SOPS

Considerations

- First and foremost, make your SOP easy to read, understand, and use. If not, it won't be utilized and, thus, won't be effective.
- Make your SOP actionable. Your audience should know exactly what actions to take to meet the specific task or goal.
- Make your SOP specific and measurable. This will ensure that you can evaluate the effectiveness of a process while adjusting as necessary.

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Procedures metadata

Standard contents;

- Purpose
- Scope
- Responsibilities
- Process
- Records

The data that describes other data, providing a structured reference that helps to sort and identify attributes of the information it describes

Information used to describe content. The most basic forms of file and folder metadata employed by nearly every operating system are names, paths, modification dates, and permissions

There are three main types of metadata: descriptive, administrative, and structural

Procedure Writing

Example: The objective of this procedure is to detail the steps to be followed when performing test or process … The scope describes where (e.g. facility), what (e.g. products, systems or activities affected) and to who (e.g. department, division or title) this document applies

- Step 1: Begin with the end in mind – Output – what to achieve
- Step 2: Choose a format (structure, metadata)
- Step 3: Ask for input / collect information
- Step 4: Define the scope (defines the areas covered by the procedure
- Step 5: Identify your audience (R&R - identifies who is responsible and what is required to be performed)
- Step 6: Write the SOP include Acronyms and Definition – states the exact meaning of complicated terms, abbreviations, acronyms, or words used in the procedure
- Step 7: Review, test, edit, repeat - Procedure – the step-by-step instructions needed to be performed.

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3. PREPARE

Focus on standard requirements	Identify interested parties	Define core business process/es	Organisational Structures	Define products and processes
List **Gap Analysis** **Training** **Consultants** **Experts**	regulators, suppliers, principles, customers, communities	Manufacturing Distribution Marketing	LH, AR, Mgt Rep	Sterile, non Sterile Storage conditions Packaging

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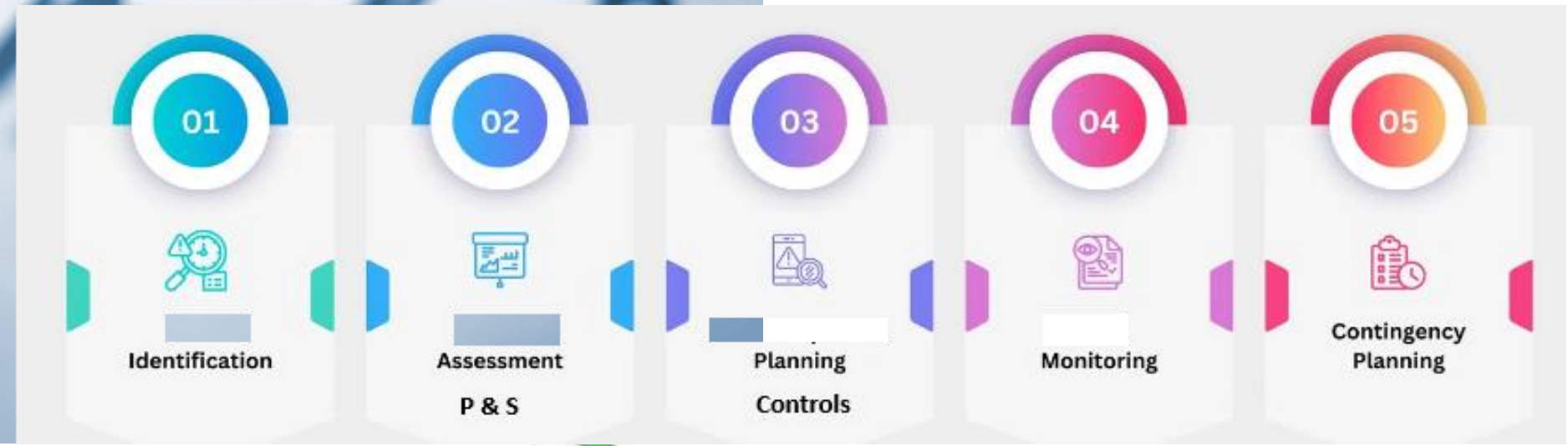
APPLY a RISK BASED APPROACH

- adapting the quality management activities to the level of risk.
- Objectives:
  - Avoid unnecessary activities
  - Avoid quality management bureaucracy
  - Focusing resources on “critical” aspects.

RISK management



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Risk based approach

4. PLAN

Map processes, sub-processes and support processes

Create Quality Manual

Decide documentation needs

- Procedure
- Definition
- Instruction
- form

Control of documents & records procedure

- Format
- Review and Approve
- Retention & Storage

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4. PLAN

- Set a deadline
- Draw up a timeplan
- Include tasks with responsibilities
- Conduct reviews
- Action changes (redo Risk analysis) or implement actions
- Plan for IA and Management review

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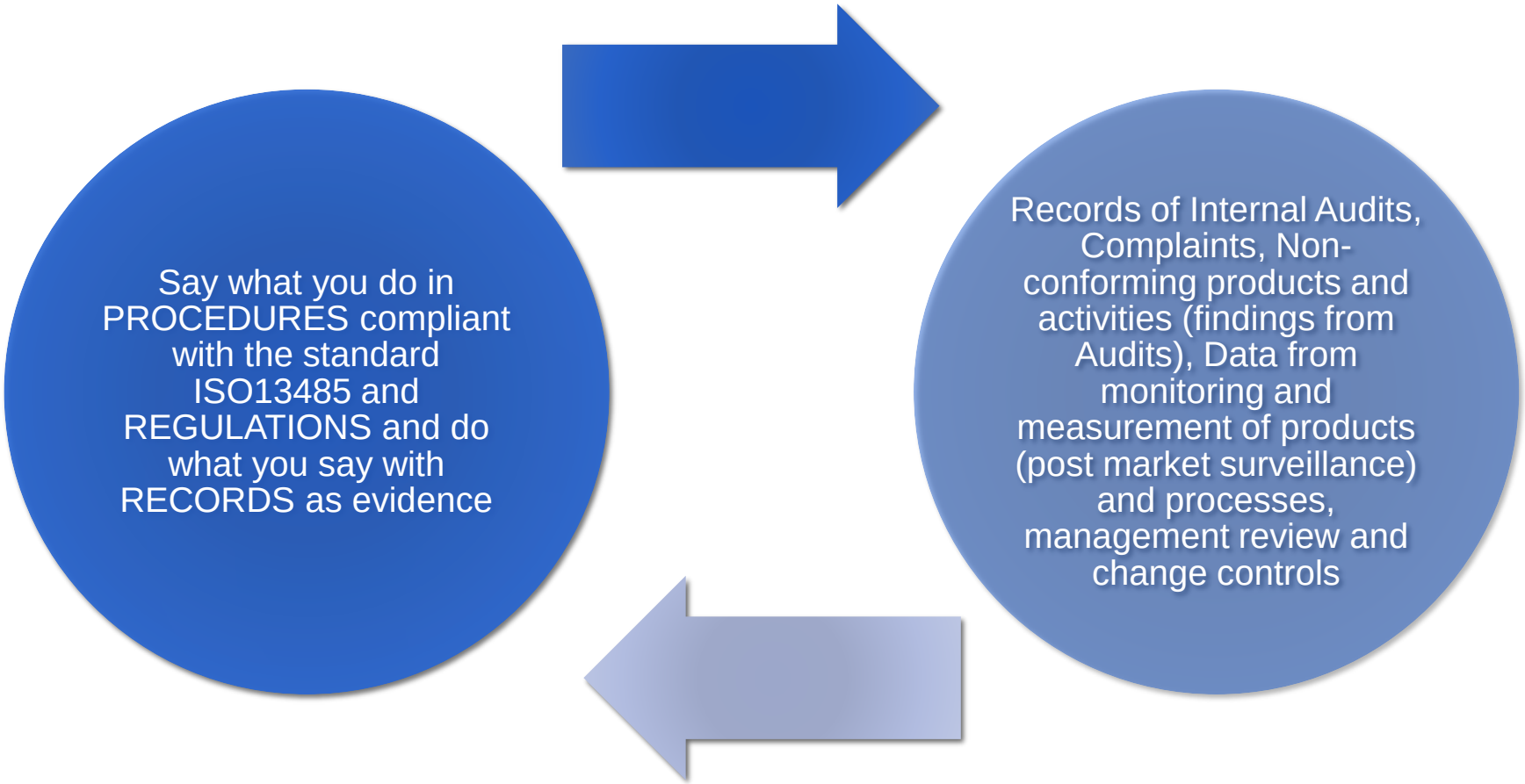
5. CREATE

Systems	Change control, management review, regulatory controls
Operation	Controls: cleanliness infrastructure & environment (pest, waste and hygiene controls), External provides (purchasing & suppliers), D&D, Validation, Identification & Traceability, preservation, QC
Improvement; Monitoring & measurement	of products & processes, Audits, Data Analysis, CAPA

6. RECORDS



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7. CERTIFICATION

Contract an accredited CONFORMITY ASSESSMENT BODY

- Stage 1, documents
- Evidence, stage 2
- CERTIFICATION

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Video – what is ISO13485

5. GUIDANCE

ASPECTS

1. Leadership
2. Knowledge
3. Scope
4. Process
5. Implement
6. Training
7. Certification application
8. Operate QMS
9. Internal Audit
10. Management Review
11. Corrective Action
12. Stage 1
13. Stage 2
14. Certification

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1. LEADERSHIP– FIRST QMS Principle

Understand, Communicate and drive the benefits of ISO 13485 implementation with;

1. Reputation enhancement

- Certification provides client and customers confidence
- Marketing tool
- Increases opportunity and growth

2. Improves customer satisfaction

- Achieving customer needs and expectations
- Increases services to new customers
- Increased revenue.

3. Process Improvement

- Process approach to discover opportunities for improvements
- Identification and elimination of waste within and between processes, reduce errors, and avoid rework—
- Facilitates greater efficiency and cost savings

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cont

Understand, Communicate and drive the benefits of ISO 13485 implementation with;

4. Improved decision-making

- Use of evidence-based decision making
- Using data and facts for decisions
- Understanding and visibility of the performance of the business

5. Continual improvement culture

- Drives increased effectiveness and performance

5. Employee engagement

- Enables involvement towards success of the company.
- Employees understand their roles which leads to increased efficiency and productivity

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2 - 4

2. **KNOWLEDGE: Identify requirements;** Understand and agree the legal and regulatory requirements, customer requirements considering the needs and culture of the company and interested parties.

3. **Define the SCOPE;** idea of what needs to be done, and the boundaries of implementation. Use the quality policy and quality manual as 1st to develop for your QMS.

4. **PROCESS Definition**; The ISO 13485 standard defines mandatory procedures, determine what processes and procedures to be defined in order to ensure adequate and consistent quality. Define all the company's processes, and the interaction with each other. These interactions are often where problems become evident.

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- **5) IMPLEMENT processes and procedures;** Documentation of existing processes and procedures to ensure consistent quality that meets requirements
- **6) TRAINING and awareness programs;** every employee in your organization understands how the QMS works, and where they fit into the mix. All personnel need to be trained on the basics of ISO 13485, so they get an idea of the purpose of implementation and they need to be aware of any changes to be made in the processes they are a part of.
- **7) Choose a CERTIFICATION body.** The right certification body can make all the difference, because this is the company that comes in after your implementation to audit your Quality Management System and determine whether or not it conforms to ISO 13485 requirements. In addition, they will also decide how effective your QMS is, and whether it shows continual improvement.

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8 -

- **8) OPERATE the QMS / Measure the system.** This is when you will collect the records that will be required in audits to show that your processes meet the requirements set out for them, that they are effective, and that improvements are being made in your QMS as needed. Certification bodies need this to happen over a certain length of time, which they will identify, in order to ensure that the system is mature enough to show compliance.
- **9) Conduct INTERNAL AUDIT ; to** tell you whether or not the processes are performing as planned, and if not, you'll have the opportunity to take corrective action to resolve any issues you find.
- **10) Conduct MANAGEMENT REVIEW ; S**upportive of the company's ISO 13485 implementation in the ongoing maintenance of the Quality Management System. Examine data from the QMS activities to make sure that all processes have the resources they need to continue to be effective, and to improve over time.

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11 - 14

- **11) Take CORRECTIVE ACTION;** root cause of the problems discovered during internal audits, measurements, and management review, and necessary action to correct the problems at the source. Crucial step in the continual improvement which is a key aim of ISO 13485.
- **12) Perform the STAGE 1 certification audit;** to review your documentation and verify that – at least on paper – all of the ISO 13485 requirements have been addressed in your QMS. Audit report detailing the areas of compliance, as well as those in which you have problems. You will then be given an opportunity to implement the necessary corrective actions to resolve the problems. This is often done during the same timeframe given for the initial operation of the Quality Management System.
- **13) STAGE 2 certification audit; .review** at the records you have collected through the operation of QMS processes Include those from management review, internal audits, and corrective actions. Audit report that outlines their findings, including their determination as to whether or not the QMS appears to be effective, and if it complies with the requirements of the ISO 13485 standard
- 14) **CERTIFICATION**

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Video

6. ISO13495

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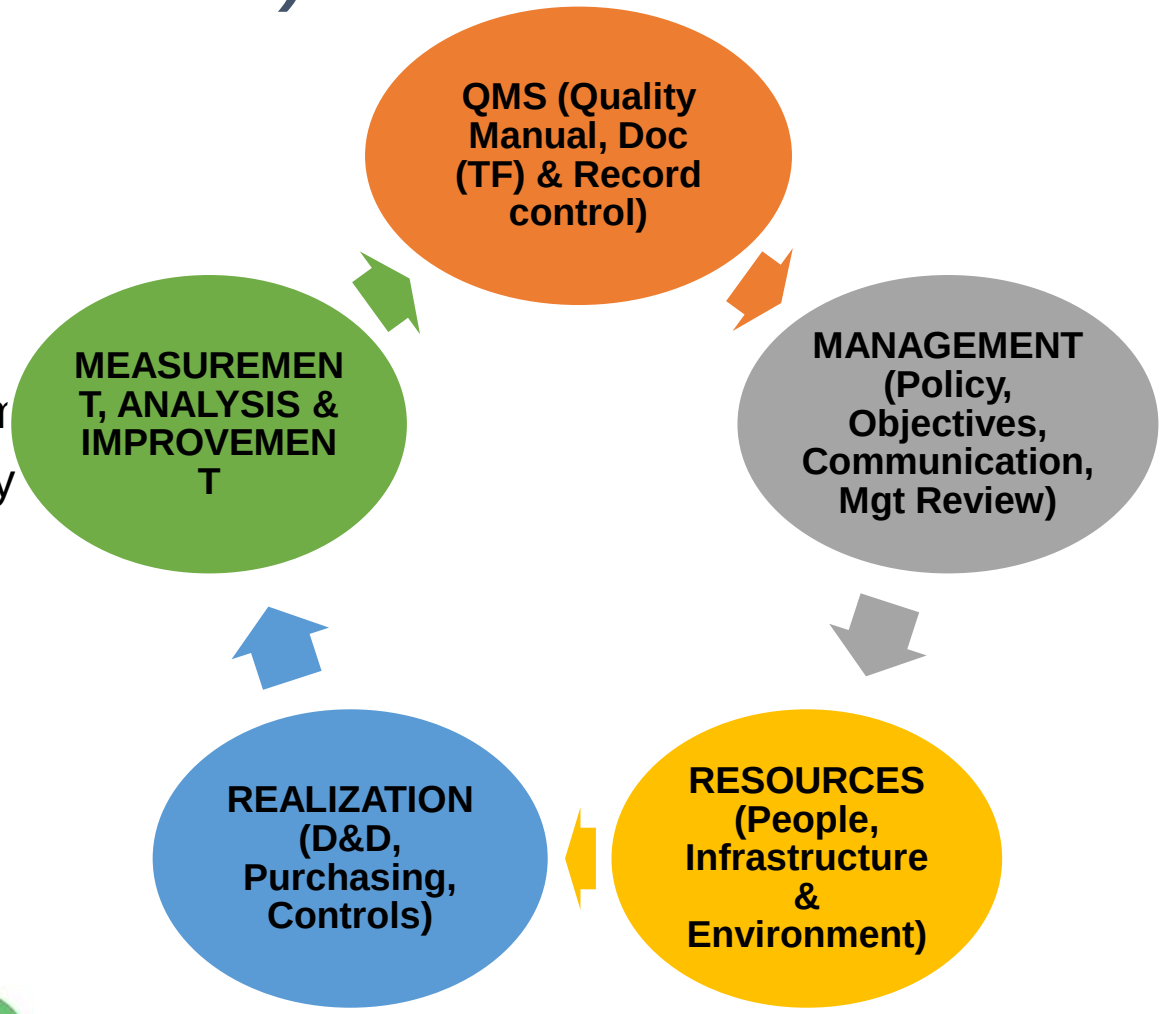
ISO13485 (contents)

- Foreword
- Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Quality management system
- 5. Management Responsibility
- 6. Resource Management
- 7 Realization
- 8 Monitoring, Measurement and Improvement



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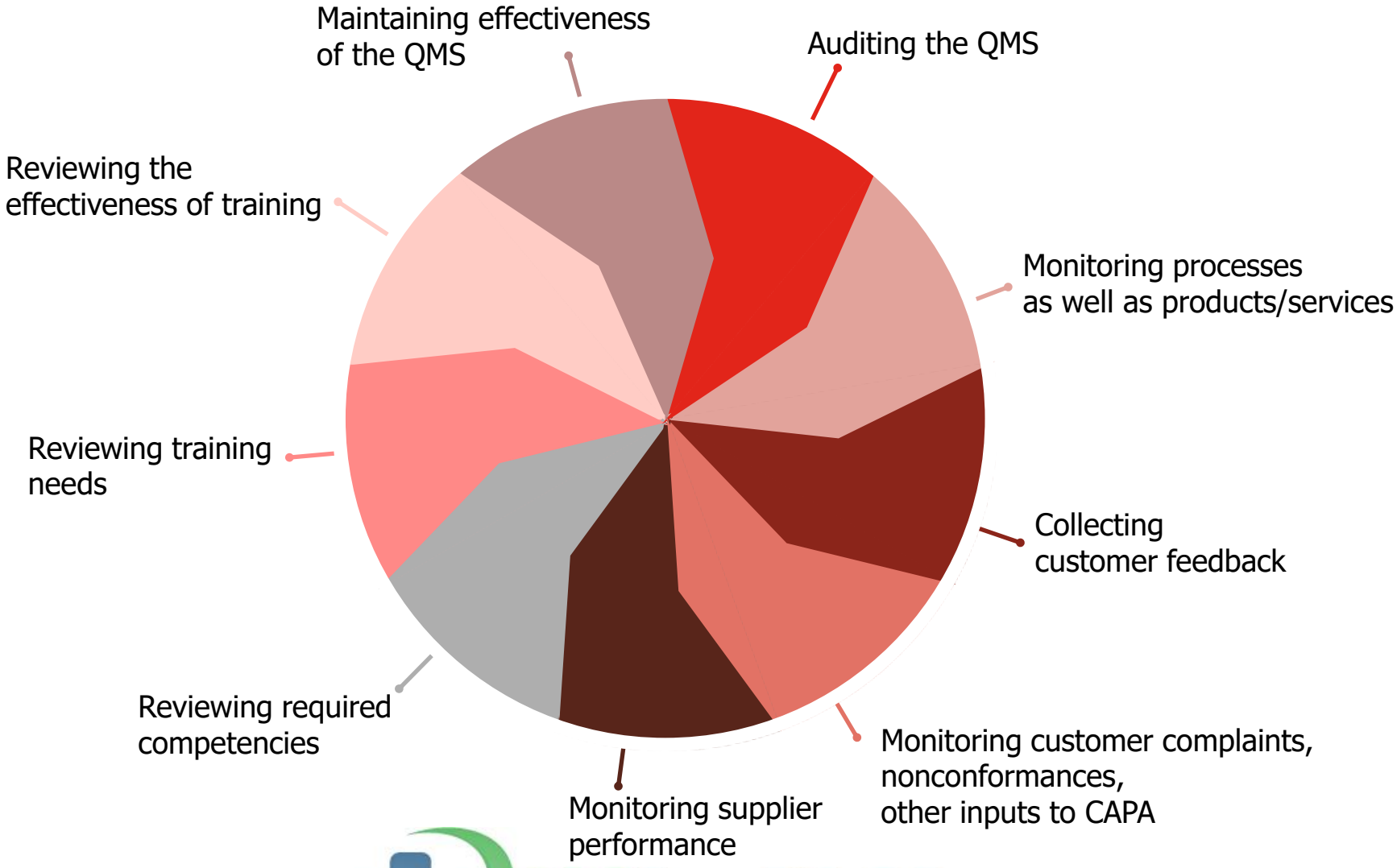
Improvement



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REQUIREMENTS

- ISO 13485 is **based on the ISO 9001:2000 quality management standard**. Both standards are organized in the same way and use a similar numbering system. In addition, most of the ISO 13485 requirements are taken directly from ISO 9001 without modification.
- ISO 13485 includes **a special set of requirements** specifically related to the supply of medical devices and related services.
- In general, ISO 13485 is made up of two kinds of requirements:
  - old ISO 9001 requirements
  - new requirements that are **specifically related to medical devices and associated services**.

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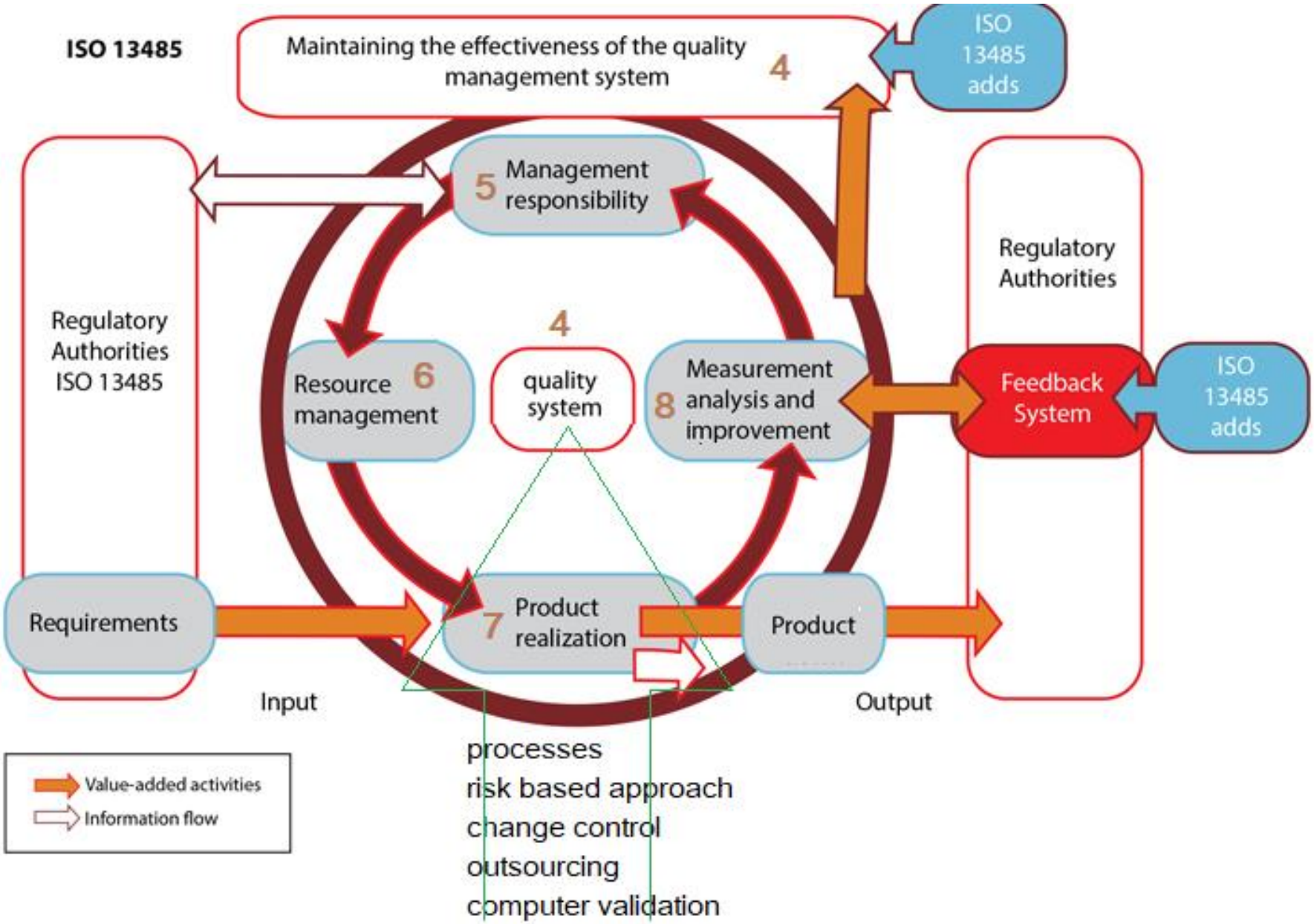
ISO 13485
Maintaining the effectiveness of the quality management system
4
ISO 13485 adds
5 Management responsibility
Regulatory Authorities ISO 13485
Regulatory Authorities
4
Resource management 6
quality system
8 Measurement analysis and improvement
Feedback System
ISO 13485 adds
Requirements
7 Product realization
Product
Input
Output
Value-added activities
Information flow
processes
risk based approach
change control
outsourcing
computer validation

5. MANAGEMENT RESPONSIBILITY

5.1. Management commitment
5.2. Customer focus
5.3. Quality Policy
5.4. Planning
5.4.1. Quality objectives
5.4.2. Quality management system planning
5.5. Responsibility, authority and communication.
5.6. Management review

5.2 Customer focus & 5.3 Quality Policy

- **5.2 Customer focus**
- Top management shall ensure that customer requirements are determined and are met

- **5.3 Quality policy**
- Top management …
- a) is appropriate to the purpose of the organization,
- b) includes a commitment to
  - comply with requirements
  - maintain the effectiveness of QMS
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization,
- e) is reviewed for continuing suitability.
-

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5.4 Planning

- **5.4.1 Quality objectives**
- Top management ….

quality objectives, including those needed to meet requirements for the product are established at relevant functions and levels within the organization.

Objective:

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5.4.2 Quality management system planning

- Top management …….
- a) the planning of the quality management system is carried out in order to meet
  - SYSTEM REQUIREMENTS
  - QUALITY OBJECTIVES
- b) the integrity of the quality management system is maintained when changes to the quality system are planned and implemented

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5.5 Responsibility, authority and communication

- 5.5.1 Responsibility and authority
- Top management ….
  - responsibilities and authorities
    - Defined . Documented. Communicated
  - establish the interrelation of all personnel who manage, perform and verify work affecting quality
  - ensure the independence and authority necessary to perform these tasks.
    - nomination of specific persons
- 5.5.2 Management representative
- 5.5.3 Internal communication

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5.6 Management review

- 5.6.1 General
- Top management …
  - review organization's QMS
  - at planned intervals

    suitability, adequacy, effectiveness
  - include
    - assessing opportunities for improvement
    - the need for changes to the QMS, including the quality policy and quality objectives.
- Records from management reviews shall be maintained

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8.5 Improvement

- 8.5.1 General
- The organization shall **identify and implement any changes** necessary to **ensure and maintain** the continued suitability, adequacy and effectiveness of the quality management system as well as
- medical device safety and performance through the use of ..
- the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.

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7. CERTIFICATION VS ACCREDITATION

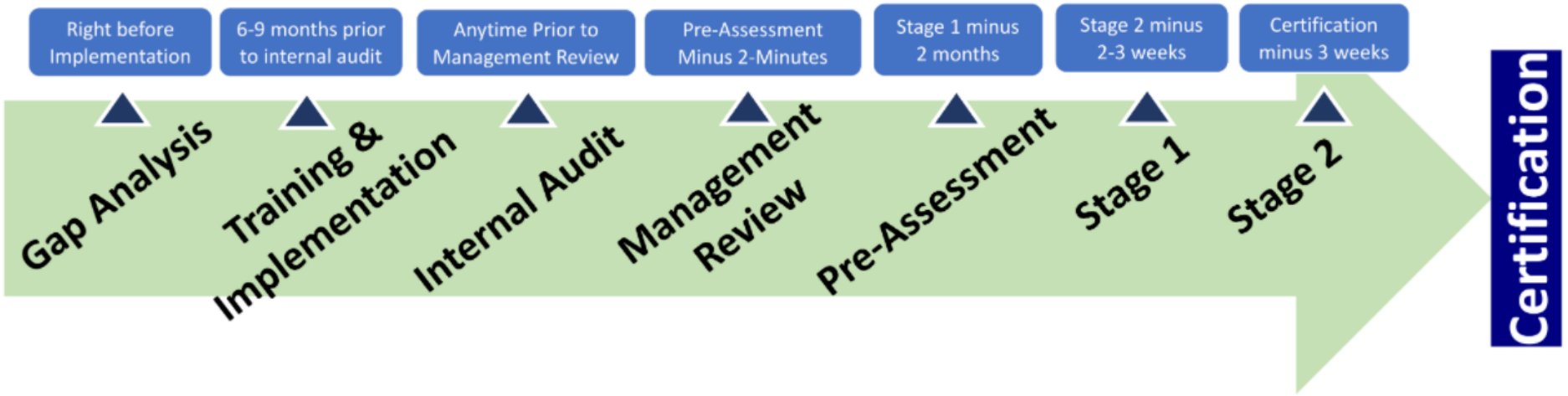
Certification vs Accreditation

- Certification - confirmation of certain characteristics of an object, person, or organization or to a standard
  - provided by some form of external review, education, or assessment.
  - E.g. professional certification, where a person is certified as being able to competently complete a job or task, usually by the passing of an examination.
  - Certification, or registration, to a standard is the outcome of a successful assessment by an independent third party.
- Accreditation - a process in which certification of credibility, authority, or competency is presented.
  - Organizations that certify third parties against official standards are themselves formally accredited by the standards bodies "accredited certification bodies".
  - The accreditation process ensures;
    - competence to test and certify third parties

Certification Process

- Purchase and understand the standard (use guidelines & consultants)
- Establish a team and analyze the business and business needs
- Determine training needs
- Document the system.
  - Quality manual
- Develop and implement procedures
- Application for certification / accreditation.
- Establish the records for review
- Assessment by an accreditation body that is certified to perform accreditation / certification

Application, stage 1 and stage 2



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Successful tips

- Commitment and right attitude.
- Understanding of the concept set forth in the standard, and use the standard to define your management system.
- Determine the application and implications of the standard applicable to your company.
- Project Manage a Gap Analysis and use the standard as a tool for improvement.
- Use tools e.g. **process mapping and risk assessment** (FMEA) to understand the processes and risks that affect your organization's ability to realize its business strategy.
- Select a credible certification / accreditation

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END OF DAY 2

Q&A