Regulatory, quality and clinical affairs

NX-451 – What to know when working with medical devices

Session 8

Kim Rochat

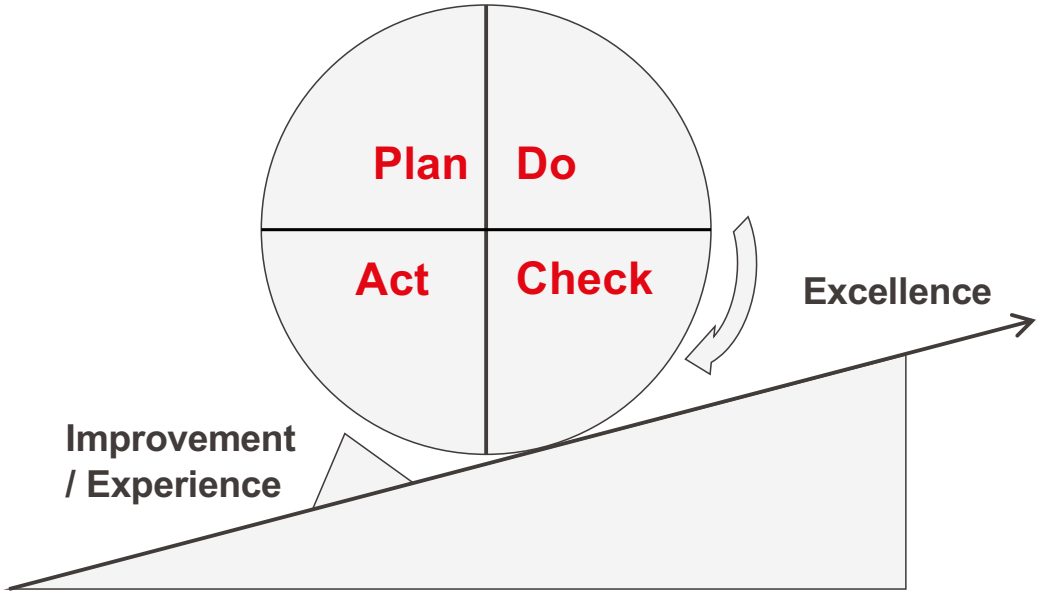
last update 2025-04-09

Quality management – Principles

Quality Management (QM) is the systematic process of ensuring that products, services, and processes consistently meet customer expectations, regulatory requirements, and industry standards.

- **Planning**
  - Define objectives
  - Specify processes and resources to achieve objectives
- **Assurance**
  - Provide confidence that requirements will be fulfilled
  - Prevent defects by following controlled processes and standard procedures.
- **Control**
  - Fulfilment of requirements
  - Detect and correct defects through inspections, testing, and monitoring.
- **Improvement**
  - Increase ability to fulfil requirements
  - Ongoing efforts to enhance processes,

Quality management – Methodological approach



Plan
Define what has to be done

Do
Execute what was planned

Check
Verify what has been done conforms to expectation

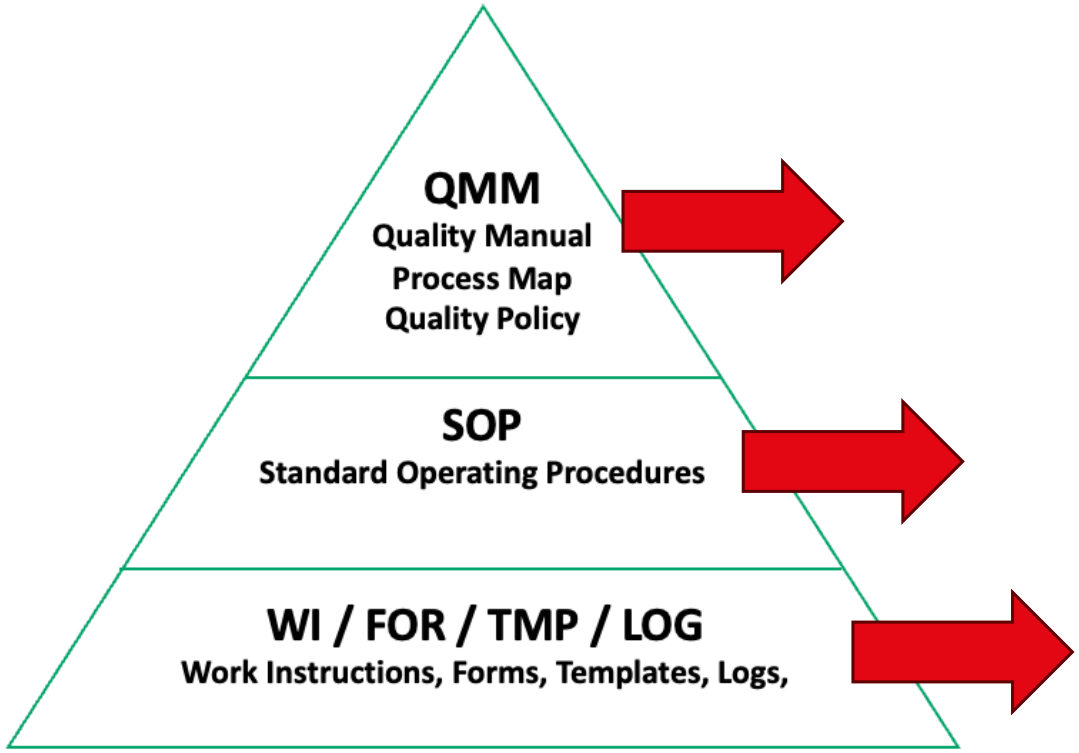
Act
Correct, improve, continue

- We say what we do
- We do what we say
- We verify we did what we said

⇒ We are reliable

Quality management – QMS

The Quality Management System is a compilation of documents that defines how the company is organized and operates as well as the compilation of documents that documents the performance of the activities (evidences).



The **quality manual** is a mandatory document that outline the scope of the QMS, present the policies, processes, and responsibilities.

The **standard operation procedures** (SOP) defines specific process and provide guidance to the employees on specific activities.

The **records** materialized the performance of activities and processes within the organization.

Quality management – ISO 13485

ISO 13485 – Content of the standard

4 Quality management system
4.1 General requirements
4.2 Documentation requirements

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

6 Resource management
6.1 Provision of resources
6.2 Human resources
6.3 Infrastructure
6.4 Work environment and contamination control

7 Product realization
7.1 Planning of product realization
7.2 Customer-related processes
7.3 Design and development
7.4 Purchasing
7.5 Production and service provision
7.6 Control of monitoring and measuring equipment

8 Measurement, analysis and improvement
8.1 General
8.2 Monitoring and measurement
8.2.1 Feedback
8.2.2 Complaint handling
8.2.3 Reporting to regulatory authorities
8.2.4 Internal audit
8.2.5 Monitoring and measurement of processes
8.2.6 Monitoring and measurement of product
8.3 Control of nonconforming product
8.4 Analysis of data
8.5 Improvement (CAPA)

Quality management – ISO 13485

ISO 13485 – Standard's structure

4. Quality Management System
5. Management responsibility
6. Resources management

→ **Management System** with
- QMS Organization
- Responsibilities
- Resources

⇒ The system works!

7. Product realization

→ **Design and manufacturing** of the product / Service with
- Requirements, Design, V&V
- Control of manufacturing processes and suppliers

=> Product is up to spec!

8. Measurement, analysis and improvement

→ **Improvement System** with
- Collection of feedbacks
- Management of non-conformities
- Post market activities

⇒ Organization achieves its objectives!

Quality management – Management system

Management responsibility (5.x)

Commitment to quality shall be established

- Management commitment shall be documented and demonstrated
- Customer focus shall be ensured, especially in identification and implementation of their requirements
- A quality policy shall be defined and communicated
- Quality objectives must be set and followed

Responsibility, authority and communication shall be set

- Responsibilities and authorities shall be formalized (i.e organization chart)
- Quality Management Representative shall be appointed
- Internal communication process shall be defined
- Management reviews shall be held periodically

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Quality management – Management system

Management commitment (5.x)

Quality Policy

Company's vision

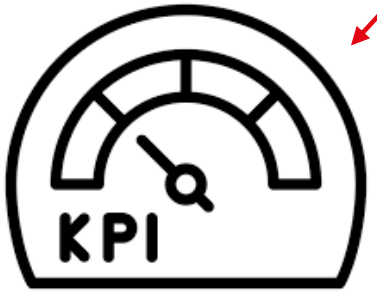
Company's objectives

Company's quality policy

Quality statement

Company objectives (examples)

- Ensure 100% compliance with regulatory requirements
- Achieve a customer satisfaction score of at least 85% in annual surveys.
  Reduce customer complaints related to product defects by 10% per year
- Close 100% of audit findings within the required timeframe.



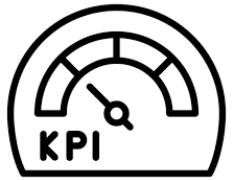
Measurement of quality

KPI – Key Performance Indicator

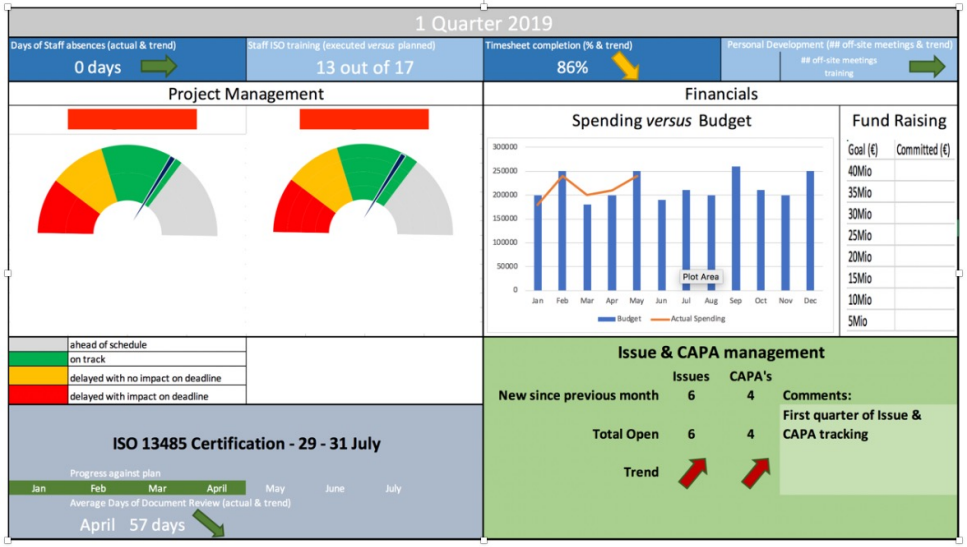
Example of quality policy: https://www.vermontprecisiontools.com/app/uploads/2023/05/ISO-13485-Quality-Policy.pdf

Quality management – Management system

Management commitment (5.x)



→ **Measurement of quality**



Processus / indicateurs	Type	Source	Fréquence	Trimestre 1				Trim				
				Jan	Fev	Mar	Avr					
Management												
Taux d'occurrence des réunions planifiées	Qualitatif	Chef. Clin.	1x/trimestre		☺							
Nombre de projets en gestion	Quantitatif	Chef. Clin.	1x/mois	4	3	2	4					
Ressources humaines												
Taux de rotation (%)	Quantitatif	Admin. RH	1x/trimestre		2							
Ratio formation (heures fo / heures travail)	Quantitatif	Admin. RH	1x/mois	0.01	0.02	0.01	0.2					
Ressources matérielles												
Nombre maintenance correctives	Quantitatif	Serv. Tech.	1x/mois	1		2	1					
Nombre maintenance préventives	Quantitatif	Serv. Tech.	1x/mois		2			2	1		1	
Accueil patient												
Nombre patient accueillis	Quantitatif	Accueil	1x/mois	182	160	145	172	240	223	112	175	183
Durée d'attente moyenne	Qualitatif	Accueil	1x/mois	☺	☺	☺	☹	☹	☺	☺	☺	☺
Traitement												
Nombre d'actes de faible complexité	Quantitatif	Inf. chef	1x/mois	150	115	100	122	210	160	80	126	152
Nombre d'actes de haute complexité	Quantitatif	Inf. chef	1x/mois	20	42	40	43	20	60	32	40	20
Taux de transfert vers soins intensifs	Quantitatif	Inf. chef	1x/mois	12	3	10	7	10	3	0	9	11
Incidents												
Nombre d'incident nouveaux	Quantitatif	Inf. chef	1x/mois	2	1	0	0	3	1	2	1	2
Nombre d'incident ouverts	Quantitatif	Inf. chef	1x/mois	1	2	1	0	3	3	3	0	1
Achats												
Nombre de livraisons	Quantitatif	Admin.	1x/mois	12	8	9	5	6	4	11	6	3
Nombre de non-conformités	Quantitatif	Admin.	1x/mois	1	2	0	0	2	1	2	4	2
Amélioration												
Nombre d'événements nouveaux	Quantitatif	AQ	1x/mois	2	6	5	4	3	5	0	2	3
Nombre d'événements ouverts	Quantitatif	AQ	1x/mois	1	7	12	9	4	4	3	2	1
Vitesse de traitement	Qualitatif	AQ	1x/mois	☺	☺	☹☹	☹☹	☺	☺	☺	☺	☺

Either “graphic visuals” including KPIs (key performance Indicators) and objectives

Or simple table including KPIs and objectives and ”semi visuals – colors”

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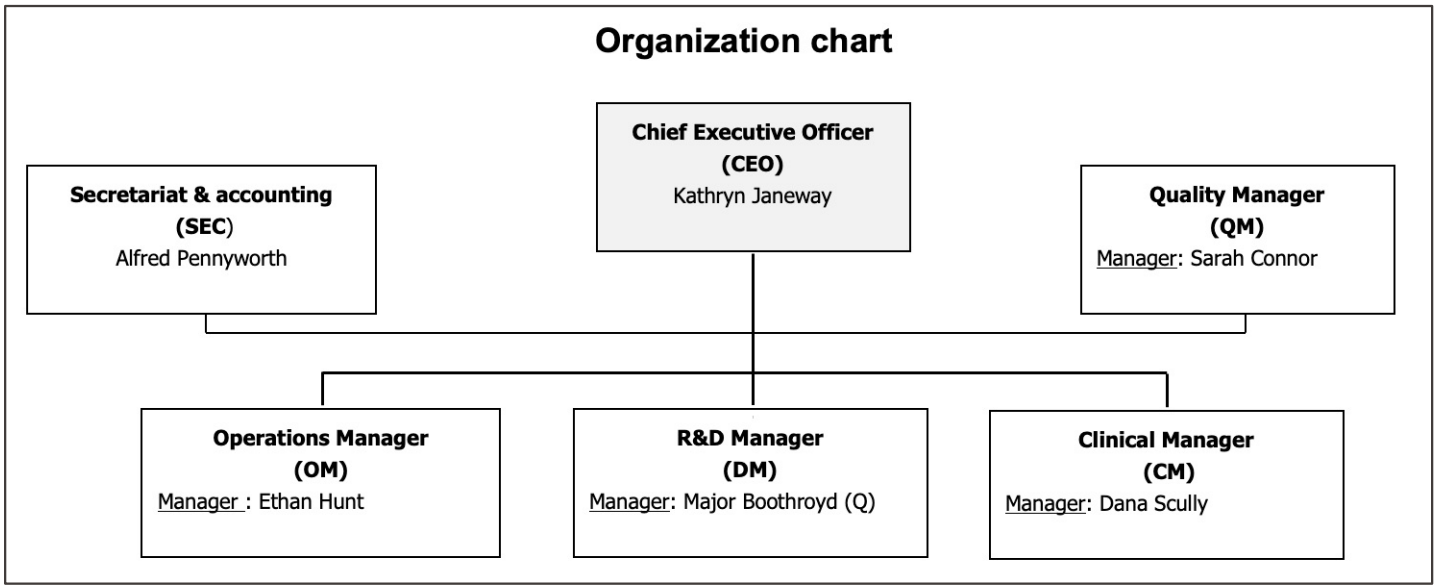
Quality management – Management system

Responsibility, authority (5.x)



Job description

- Job Title
- Reporting line
- Key responsibilities
- Key duties
- Qualification and skills

Quality Management Representative (QM)

- QMS Documentation & Structure – Ensure all necessary processes are documented and maintain the QMS architecture.
- Reporting & Improvement – Provide top management with updates on QMS effectiveness using KPIs, ensuring alignment and improvement.
- Regulatory Awareness & Compliance – Promote awareness of regulatory and QMS requirements across the organization, essentially "selling" QMS internally.

Quality management – Management system

Management review (5.x)

A management review is a formal evaluation process where top management assesses the performance and effectiveness of the Quality Management System

The standard requires that:

- The organization shall document procedures for management review.
- Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness.
- The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
- Records from management reviews shall be maintained.

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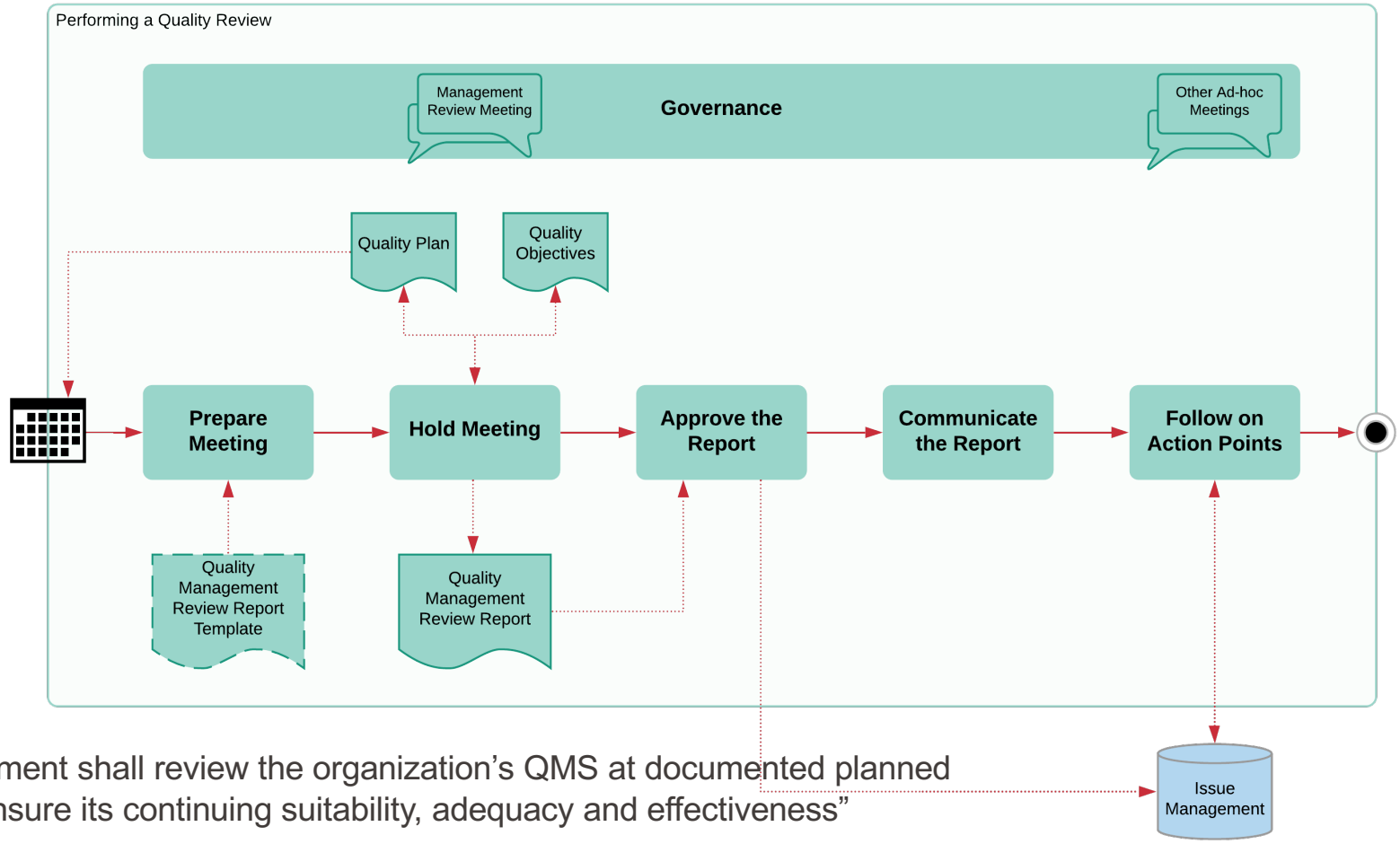
Quality management – Management system

Management review (5.x)



"Top management shall review the organization's QMS at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness"

Quality management – Management system

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Management review (5.x)

Typical **inputs** of the management review:

- Follow-up actions from previous management reviews
- Feedback (customer satisfaction)
- Complaint handling
- Reporting to regulatory authorities
- Result of Audits (internal and external)
- Monitoring and measurement of processes (KPI)
- Monitoring and measurement of product (Default)
- Corrective action / Preventive action
- Changes that could affect the quality management system
- Recommendations for improvement
- Applicable new or revised regulatory requirements

Typical **outputs** of the management review:

- Improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Changes needed to respond to applicable new or revised regulatory requirements
- Resource needs

Quality management – Management system

Management review (5.x)

Frequency => shall be at planned intervals

- Yearly at least, usually 2 times per year
- At least one before 1st certification
- Frequency must be justified at the light of the variability of key indicators

Attendees:

- CEO
- Upper management
- QA manager

Organization

- QA manager usually prepares the material in the initial ”life” phase of the QMS
- Later, the various material is prepared by the relevant process owners
- Usually in the form a meeting, online or on site
- Result in a documented report that conclude on the capacity of the QMS to fullfil regulatory requirements

Quality management – Management system

Resource management (6.x)

Resource management processes ensures the company determines and provide the necessary resources to ensure its operations. It focus mainly on:

- Management of human resources
  - Determination of the necessary competences
  - Provision of the adequate personal
  - Provision of necessary trainings or actions to maintain the level of competences
  - Maintain awareness of the importance of activities and impacts on processes and products.
- Management of infrastructure
  - Ensuring adequate buildings, workspaces and associated utilities
  - Provision of necessary process equipment (both hardware and software)
  - Provision of supporting services (such as transport, communication, or information systems)

Quality management – Management system

Resource management (6.x)

As part of the infrastructure management, the ISO 13485 has specific requirements on Work environment and contamination control.

Work environment

- Determination of what is adequate work environment, in particular what is needed to ensure the product is not negatively impacted (i.e. temperature, humidity, electrostatic sensitivity, cleanliness, etc.)
- Implementation of necessary monitoring capabilities to ensure the work environment is adequately controlled.
- Provision of necessary training to ensure employees do not impact negatively the work environment (i.e. health, cleanliness and clothing).

Contamination control

- Ensuring contaminated or potentially contaminated products do not negatively impact the work environment (i.e. returning products).
- For sterile devices, ensuring the level of microorganisms or particulate matter is control to prevent drift in sterilization process.

Quality management – Management system

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Clean Room

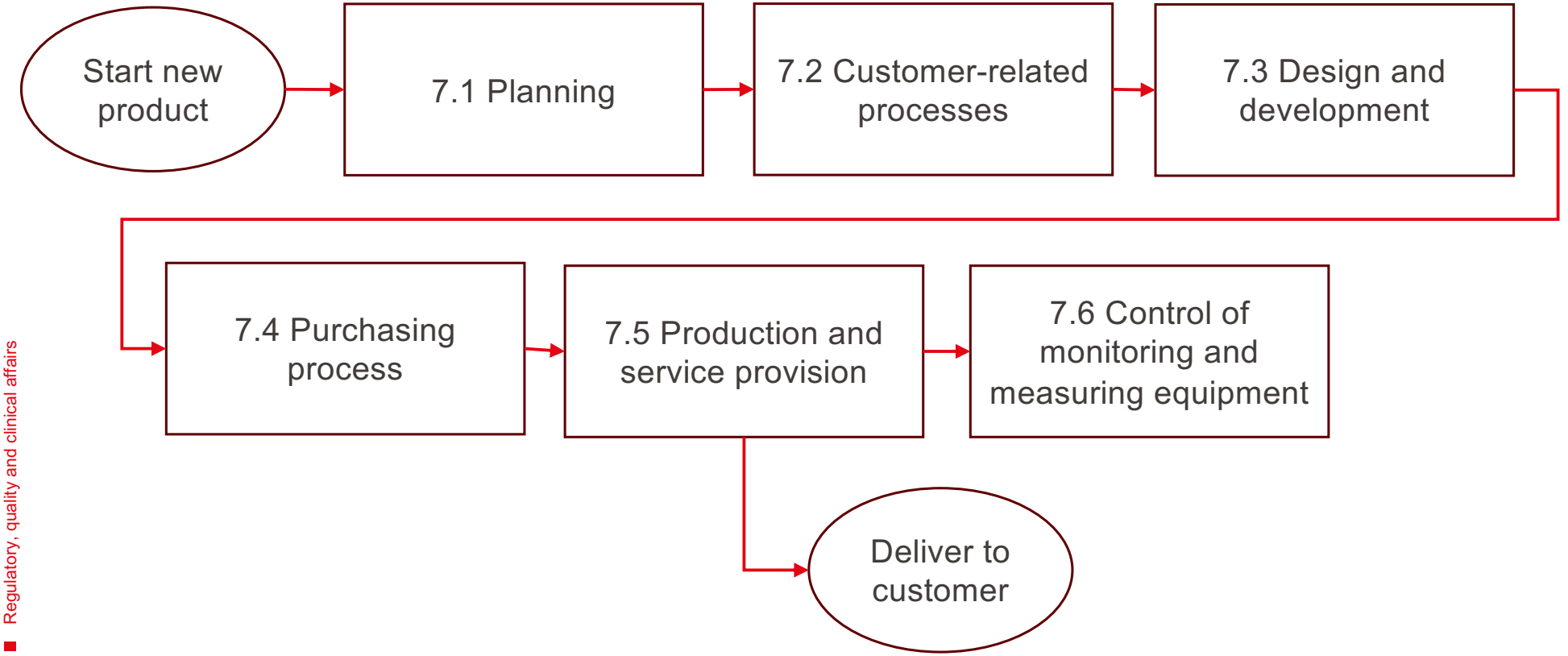
Clean rooms are controlled work environment that typically include:

- **Air Filtration** – Prevent airborne particles.
- **Positive Pressure -** Keeps air flowing outward, so unfiltered air from outside doesn't enter.
- **Strict Entry Protocols -** People must wear protective clothing to avoid bringing contaminants in.
- **Temperature & Humidity Control -** Maintained at specific levels for stability.
- **Smooth, Non-Porous Surfaces -** Walls, floors, and equipment are made of materials that don't shed particles and are easy to sanitize.
- **Bacteriological controls** – Periodic measurement of microorganism presences

Quality management – Management system

Product realization (7.x)

The product realization process covers all steps of product life-cycle



Quality management – Management system

Planning process (7.1)

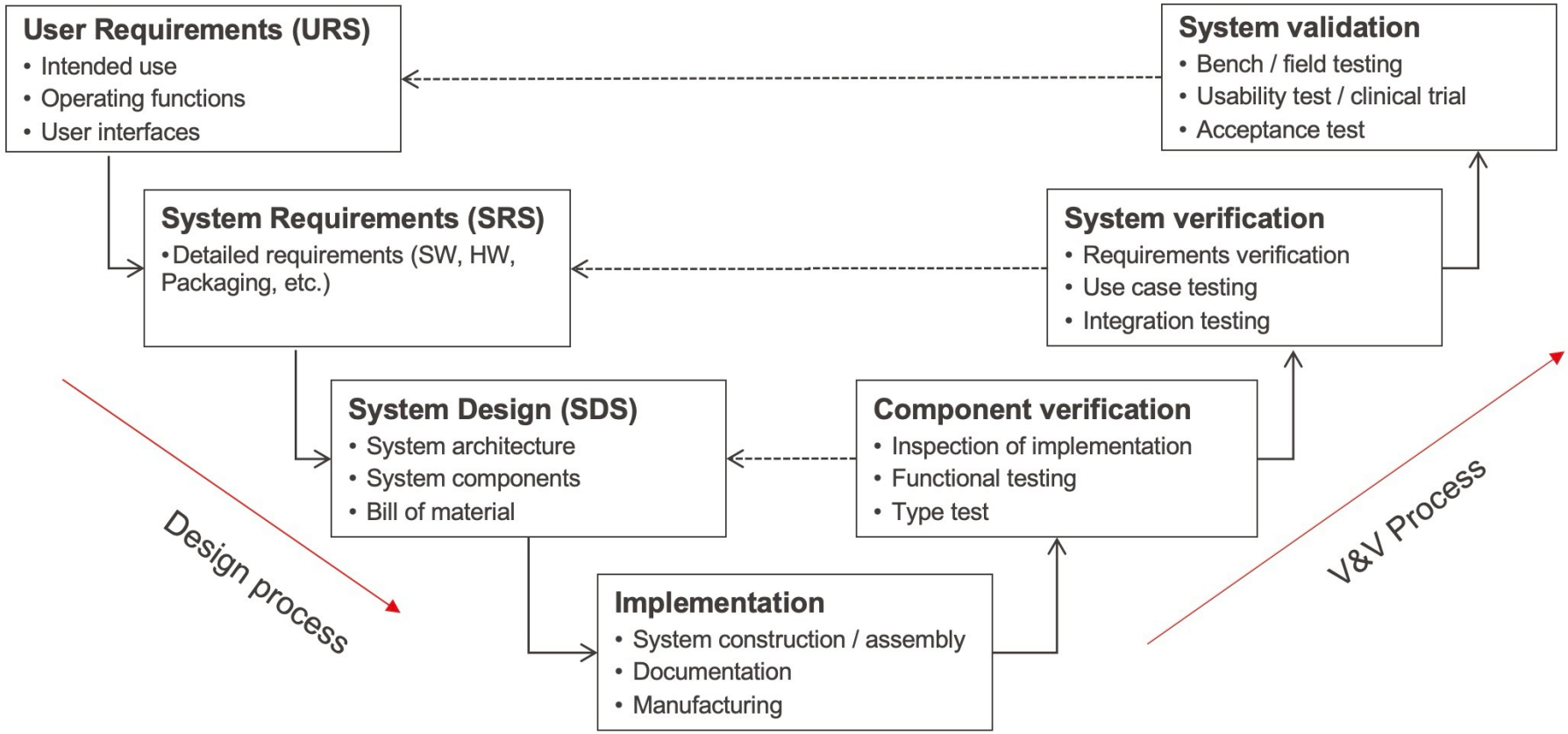
- Define quality objectives and product requirements
- Definition of processes and controls
- Elaboration of the project plan

Customer-related processes (7.2)

- Determination of customer requirements for the product.
- Evaluation and review of requirements
- Communication with clients and stakeholders (i.e. customer feedback, complain, enquiry, advisory notices, etc.)
- Provision of production information (i.e. input to marketing)

Quality management – Management system

Development process (7.3)



Quality management – Management system

Purchasing process (7.4)

- Selected suppliers shall be qualified and regularly evaluated…
  - based on the supplier's capability
  - based on the performance of the supplier
  - based on the effect on the quality of the medical device
  - proportionate to the risk associated with the medical device
- Purchasing information shall be defined and shall include a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the product to meet specified purchase requirements.
- Incoming inspections / verifications of purchased items shall be implemented based on on the supplier evaluation and to the risks associated with the purchased product.

Quality management – Management system

Example of supplier qualification criteria

Class A *Critical items*	Class B *Non-critical items*	Class C *Non-controlled items*
Criterion: • Critical parts, component materials supplied or subcontracting services applied or used on our medical devices. • Sub-contractor is responsible of a critical step in the manufacturing process or in charge of the whole manufacturing of a part or product.	**Criterion:** • Non-critical components used on our medical devices or item not directly embedded in our product. • Subcontracting services that are not part of the production process or where we have 100% controls on deliveries.	**Criterion:** • Office supplies
Control methods: • Formal assessment as per process below. • Written quality agreement with the supplier • Certified QMS, yearly supplier audit • Written purchase orders • Incoming quality control as per specific working instruction. • Certificate of conformity	**Control methods:** • Written orders • Visual incoming quality control • Certificate of conformity	**Control methods:** • No formal purchasing methods • No formal incoming inspection

Based on the nature of the supplied product specific method of control will be applied such as:

- Specific evaluation
- Quality Agreement
- Supplier audits
- Verification of Certification of Conformity
- Incoming inspections

Quality management – Management system

Production and service provision (7.5)

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification.

Production controls include:

- Procedures, work instructions and methods for the control of production;
- Qualification of infrastructure, validation of processes as applicable
- Monitoring and measurement of process parameters and product
- Defined operations for labelling and packaging;
- Product release, delivery and post-delivery activities

→ batch record or individual product record required

Specific requirements apply for cleanliness of the product, sterile medical devices, traceability, equipment installation and validation of processes, management of customer property, preservation of product

Quality management – Management system

Control of monitoring and measuring equipment (7.6)

The company shall ensure that monitoring and measuring equipment

- used in production are calibrated or verified, or both, at specified intervals
- are adequately identified and their status is controlled
- protected from damage and deterioration during handling, maintenance and storage
- safeguarded from adjustments that would invalidate the measurement result

Monitoring and measuring equipment are critical in production, as they ensure that products are manufactured accurately, consistently, and meet all quality and regulatory requirements. They typically:

- ensure Product Quality and Conformance
- support Process Control
- provide Data for Improvement and Traceability

Quality management – Management system

Measurement, analysis and improvement (8.x)

The measurement, analysis and improvement processes serve to monitor the company's performance and to initiate necessary actions to correct or improve the operations.

Overall, these processes are used to:

- demonstrate conformity of product(s)
- ensure conformity of QMS;
- maintain the effectiveness of QMS.

Specific processes are defined such as:

- Monitoring and measurement with feedback collection, complaint handling, reporting to authorities, internal audit, Monitoring and measurement of processes and product
- Control of nonconforming product and rework
- Analysis of data
- Improvement process

Quality management – Management system

Notified body audits and Internal audits

Audit definition:

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

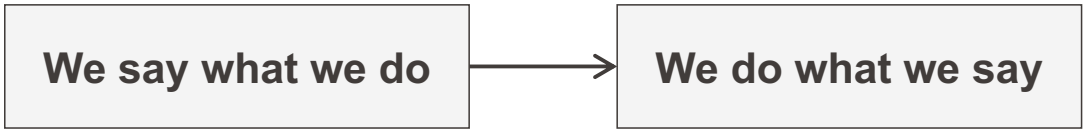
Audit criteria definition:

Set of policies, procedures or requirements used as a reference against which audit evidence is compared

Objectives of the audits:

- Perform an independent assessment of a situation or a process in order to provide factual information on its performance, compliance, relevance, etc.
- Demonstrate compliance to specific requirements
- Identify opportunities for improvements

⇨ Collect and formalize information on company processes and products. They gather objectives evidences



Quality management – Management system

Notified body audits and Internal audits

Audits can be performed by multiple parties:

- Internal audits
  - Typically performed by company personnel with the framework of an internal audit program. They may also be called first party audit
- Supplier audits
  - Typically performed by customer personnel or representative within the framework of a quality agreement. They may also be called second party audit.
- Third party audits
  - Typically performed by Notified body or Competent authorities for legal, regulatory and similar purpose such as certification, inspection.

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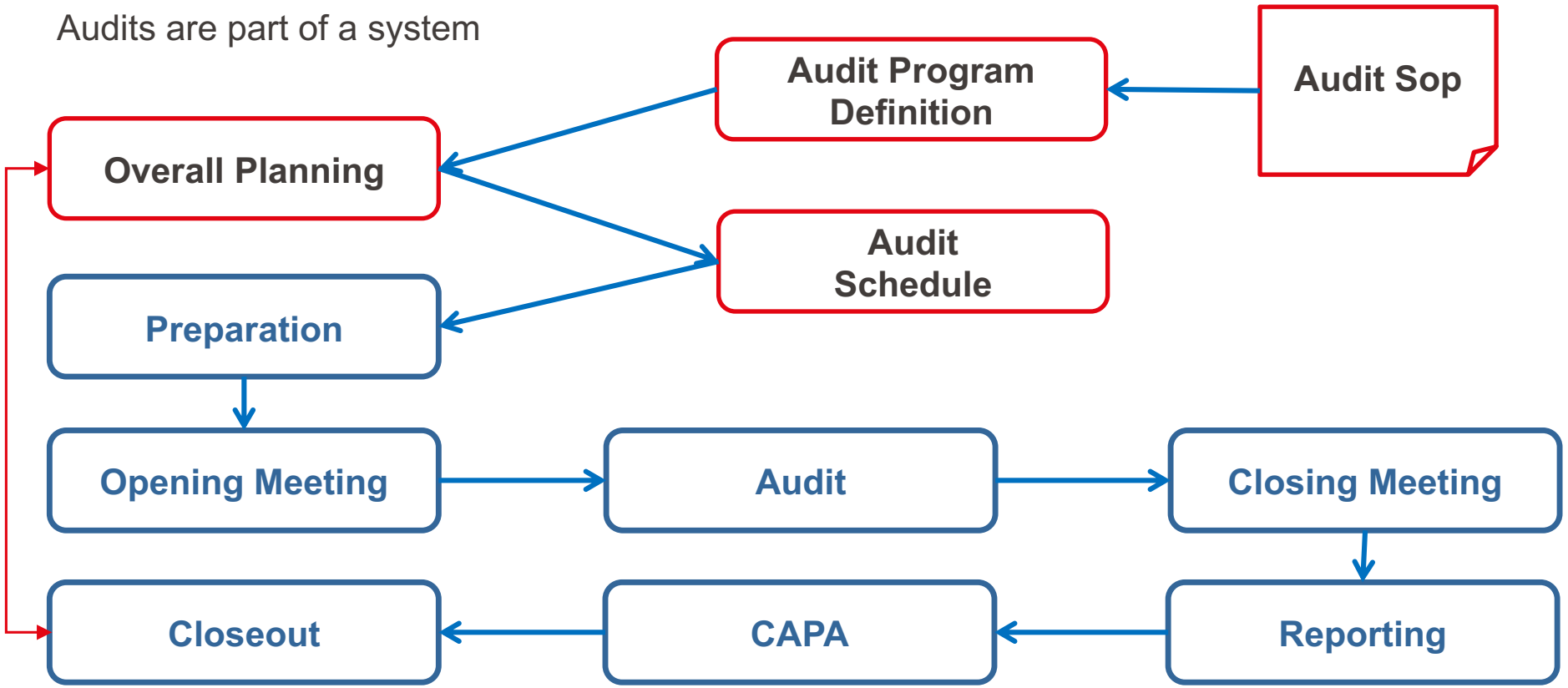
Quality management – Management system

Notified body audits and Internal audits

Audits are part of a system



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Quality management – Management system

Improvement system

Improvement system purpose is:

- To collect and analyse information to identify actual and potential product and quality problems
- To investigate product and quality problems and take appropriate and effective corrective or preventive action
- To verify or validate the effectiveness of corrective and preventive actions
- To communicate corrective and preventive actions to the appropriate people
- To provide information for management review
- To document activities

It mainly drives 3 types of actions:

- Correction (fix or repair, often immediate actions)
- Corrective Action (Corrective Action = action to eliminate the cause(s) of a nonconformity)
- Preventive actions (action to eliminate the cause(s) of a potential nonconformity)

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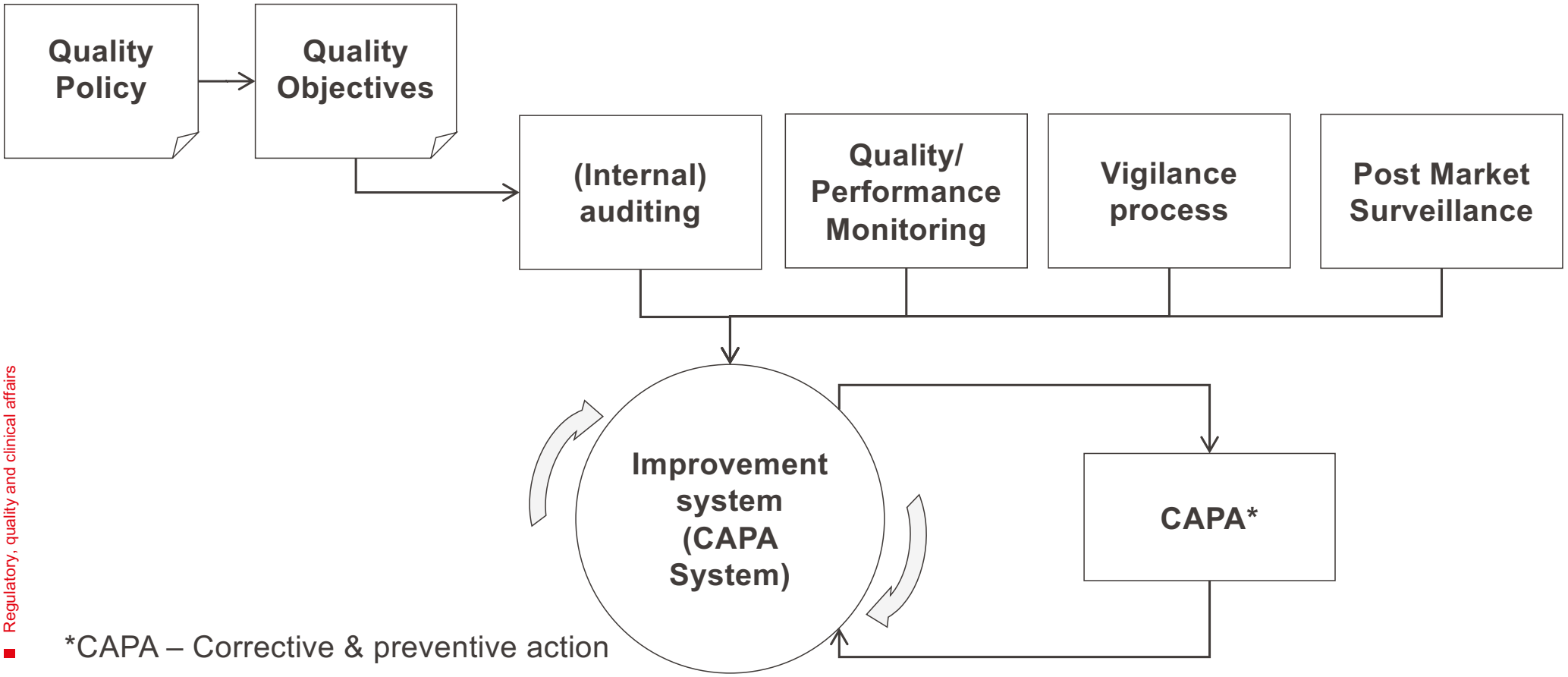
Quality management – Management system

Improvement system

The improvement system is used to identify and fix nonconformities and maintain compliance



*CAPA – Corrective & preventive action

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Improvement system

Types of Nonconformities in ISO 13485

- Product Nonconformity - When a medical device does not meet design, safety, or performance specs.
- Process Nonconformity - When a manufacturing or quality process isn't performed according to procedure.
- System Nonconformity - When the quality management system (QMS) fails to meet ISO 13485 or internal quality manual requirements.
- Documentation Nonconformity - Missing, incomplete, or outdated records or procedures that violate document control requirements.

Actions within improvement system

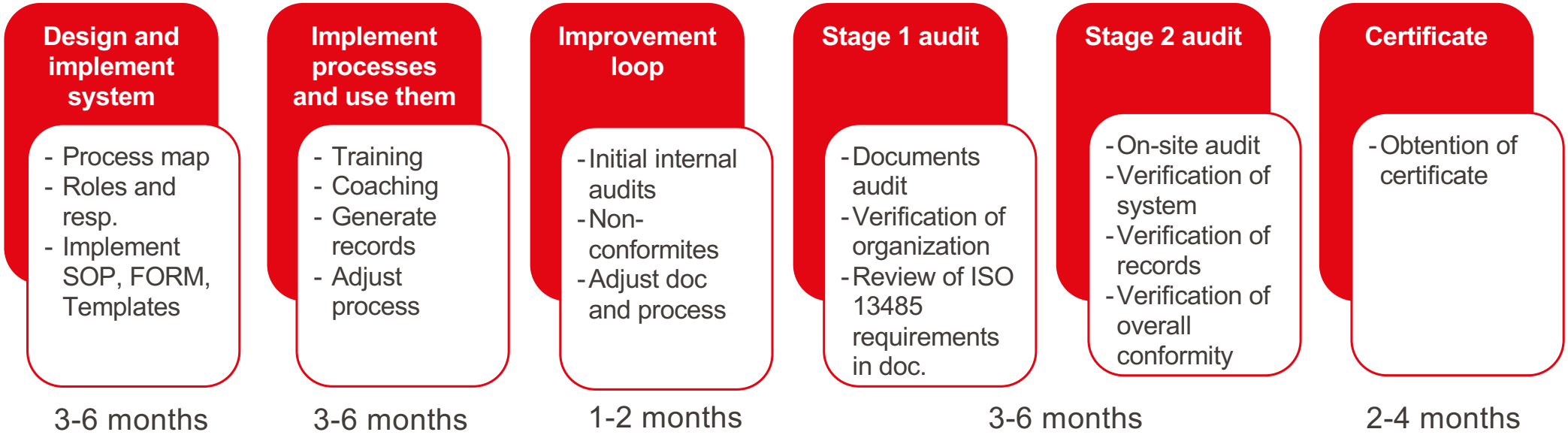
Quality management – Management system

Typical processes / operating procedures in a QMS

Process	MDR Art. 10 requirements
General Management and Management review	10.9 c) j)
Human Resource Management	10.9 d)
Infrastructure Management	10.9 g)
Computer Software Validation	10.9 g)
Device Design and Development	10.9 a) b) g) h)
Risk Management	10.9 e)
Storage Management and manufacturing	10.9 g) h)
Purchasing and management of suppliers	10.9 d)
Documentation Control	10.9 g)
User feedback and Complaint handling	10.9 k)
Vigilance	10.9 j) k)
Clinical and Post Market Surveillance	10.9 f) i)
Clinical investigation	10.9 b)
Improvement system	10.9 k)

Quality management – Management system

QMS implementation sequence and duration towards certification



The duration and effort will typically depend on:

- Organizational environment
- Organization's varying needs
- Organization's particular objectives
- Products the organization provides
- Processes the organization employs
- Organization's size and organizational structure
- Applicable regulatory requirements

Quality management – In a nutshell

- **Ensure Product Safety, Quality, and Compliance** - Quality assurance ensures that products consistently meet regulatory requirements, are fit for their intended use, and are safe for end users.
- **Promote a Process-Driven Approach** - Organize work into defined, repeatable processes that drive efficiency, consistency, and clarity across the organization.
- **Apply Risk-Based Thinking** - Identify and control potential risks early to prevent issues, protect users, and ensure business continuity.
- **Drive Continuous Improvement** - Use data, feedback, and root cause analysis to make informed changes that enhance quality and performance over time.
- **Ensure Documentation and Traceability** - Maintain clear, controlled records to support compliance, decision-making, audits, and accountability.
- **Monitor, Measure, and Act** - Use metrics and controls to track quality, detect deviations, and implement corrective actions when needed.

Q&A


ELBONIA
I'VE BEEN SENT TO TEACH YOU "TOTAL QUALITY MANAGE-MENT."
IN THE OLD DAYS, QUALITY WAS JUST AN EMPTY WORD MEANING 'GOOD."
QUALITY EQUALS GOOD (1950)
EVENTUALLY IT EVOLVED INTO A COMPLICATED METHOD FOR TRANS-FERRING YOUR MONEY TO BUSINESS CONSULTANTS.
S. Adams
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