The ISO 13485: 2016 QMS

A Framework for a Safe, Efficient, and Effective IVD Medical Device(s)

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Agenda

- The Scope, and Principles of ISO 13485:2016
- Concise overview of General Clauses, and examples of some Specific Requirements
- Process-, and Risk-based Approach
- Monitoring, Safety and Effectiveness
- Data Integrity of IVD medical device/s in its lifecycle, and example of a CAPA to a critical gap in data integrity
- Identification, Traceability, similarity and summary of differences
- Conclusion/s

QMS and the ISO 13485:2016 QMS

Def. QMS: A formal system that documents the structure, processes, roles, responsibilities, and procedures required to achieve effective quality management

SAFE

EFFICIENT

EFFECTIVE

The Scope of ISO 13485:2016

Any organization involved in one or more stages of the IVD/ medical device/s lifecycle

Ability to provide IVD/medical device

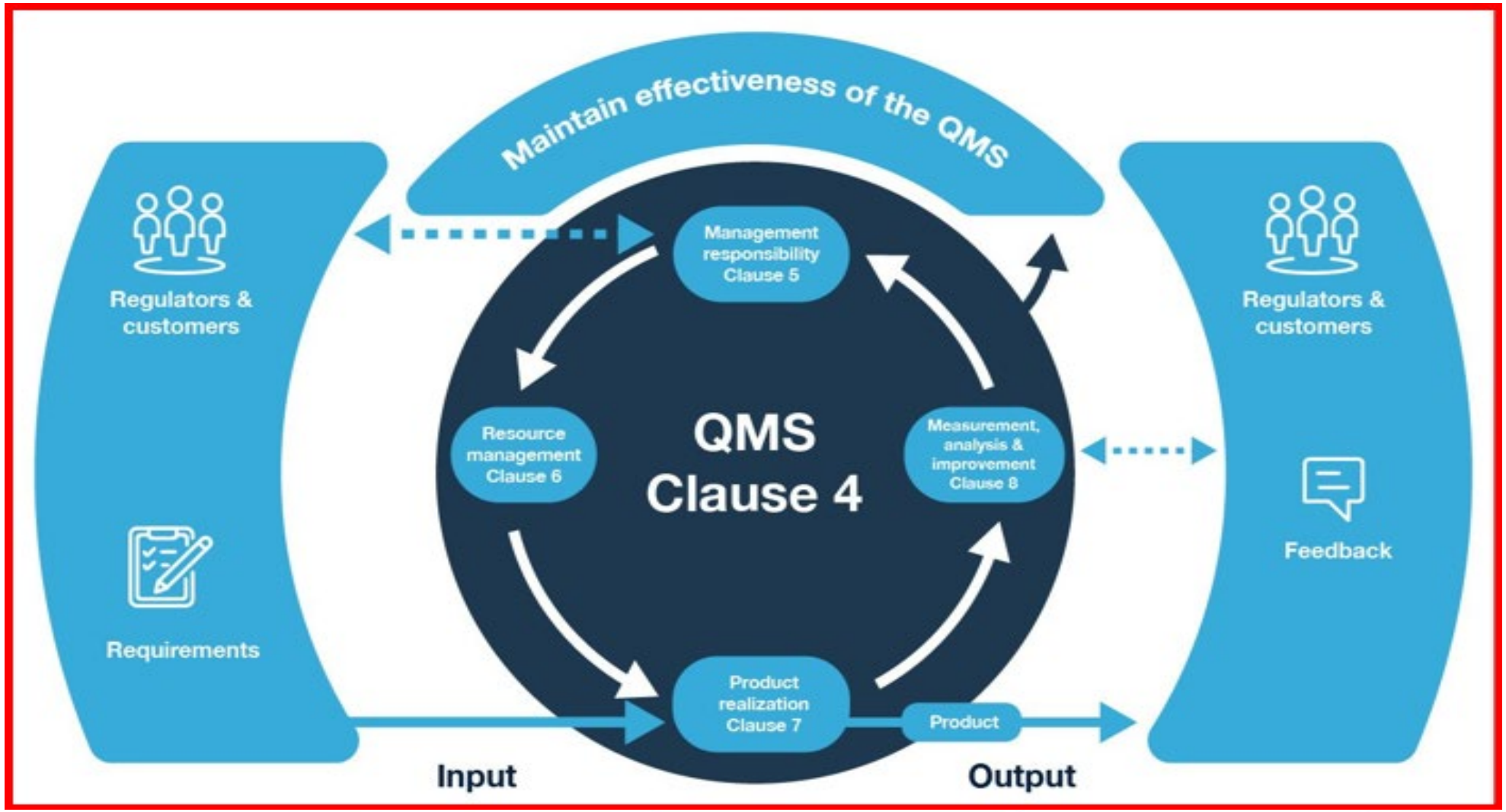
Related services consistently meeting customer/s and applicable regulatory requirements

Principles of ISO 13485: 2016

A concise overview of General Clauses, and e.g. some Specific Requirements

1. Scope
2. Normative references
3. Terms and Definition
4. QMS/QMS documentation,
5. Management Responsibilities,
6. Resources Management,
7. Product Realization,
8. Measurement, Analysis and Improvement,

QMS ISO 13485: 2016



Clause 4.1 General Requirements

4.1.2 Process approach

- Determine the processes needed for QMS and the application of these processes throughout the organization taking into account the roles undertaken

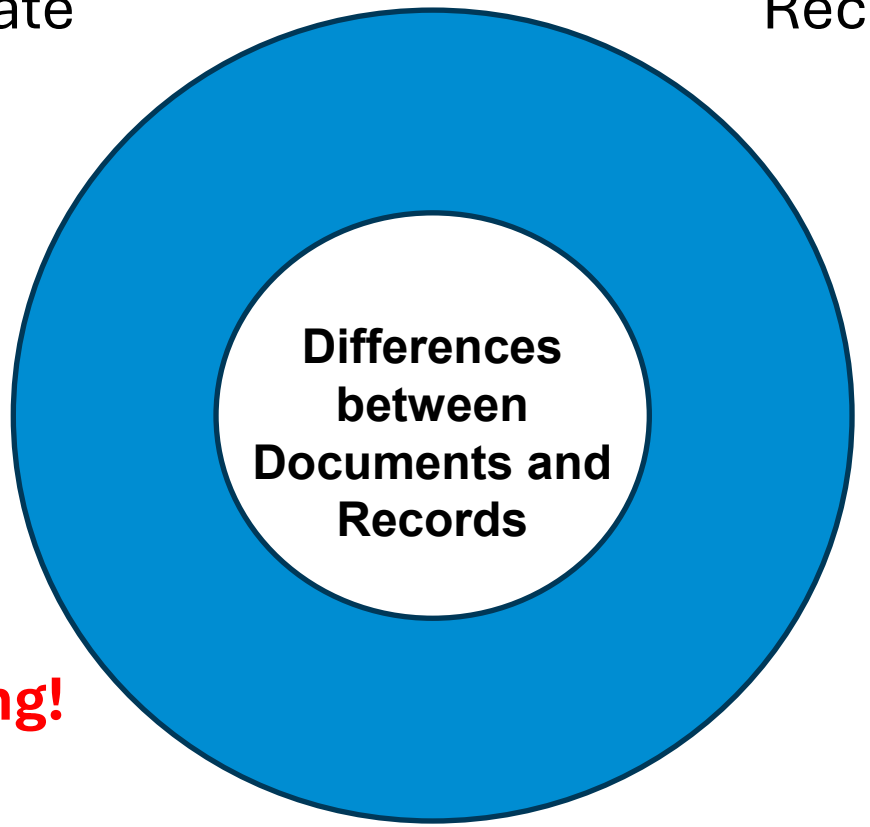
- Apply a risk-based approach to the control of the appropriate processes needed for the quality management system

4.1.3 For each QMS process- monitoring its effectiveness

Documentation, and records

Documents communicate Information through

Policies- what to do
Procedures-how to do it
Processes-how it happens



Records capture information on worksheets, labels and charts

Records capture facts or objectives; batch records, printouts

Regular Updating!

X

NO Updating!

4.2.4 Control of documents/ 4.2.5 Control of records

Resources Management → Product Realization

Competence, Training/s

People

Infrastructure

Processes

Overall work environment

Planning of Product Realization

Customer-Related Processes

Design and Development

Purchasing

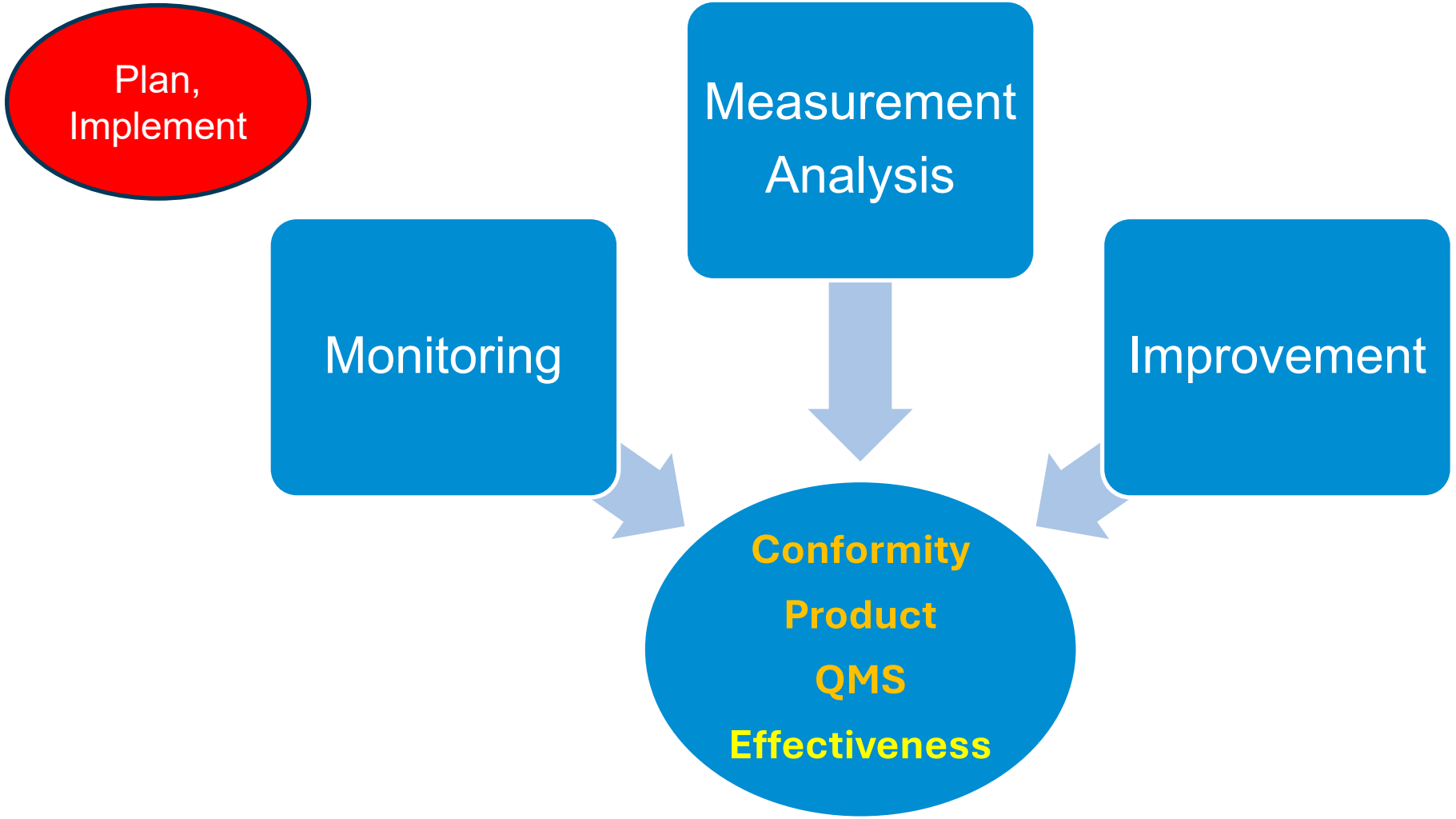
Production and Service Provision

Control of Monitoring and Measuring Equipment

Supplier's evaluation/ selection/ reevaluation

Process validation, Production control

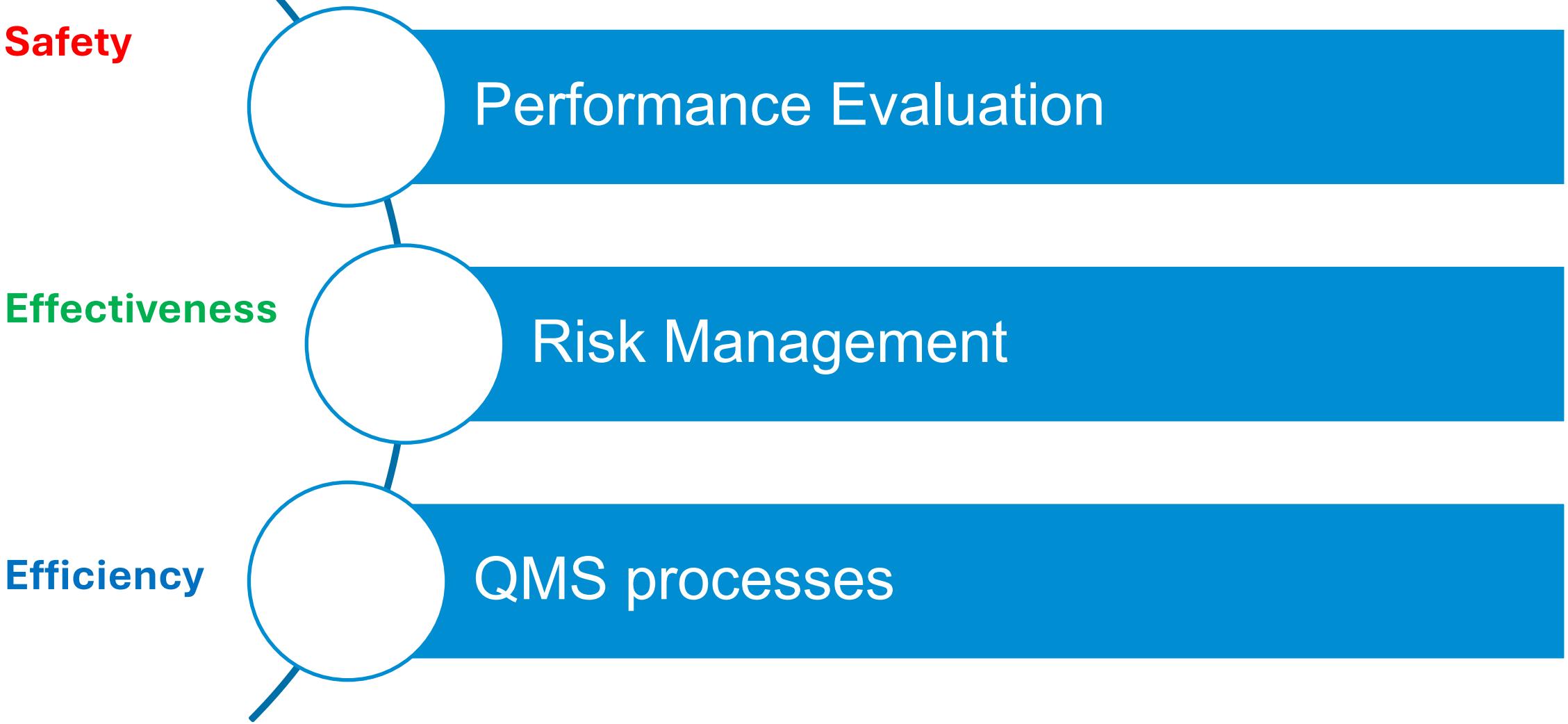
Measurement, Analysis, and Improvement



Monitoring and Measurement

Feedback/ Customer satisfaction	Internal Audits	Nonconforming product	
Complain handling	Process Monitoring, Measurement	Actions before-after delivery Rework	CAPA
Reporting to RA	Product Monitoring, Measurement	Improvement	

Diversity of Monitoring, and Safety, Effectiveness, Efficiency of IVD



Diversity of monitoring leading directly to Safe, Effective, and Efficient IVD medical device/s manufactured under ISO 13 485:2016 requirements

- Design and Development Control
- Production Control
- Supplier/s Monitoring
- Outsourced Process/es Monitoring
- Internal Audits, Management Review/s
- Feedback

Common challenges related to ISO 13485:2016 implementation

- Lack of Management Commitment
- Documentation and Record Keeping
- Training and Competence
- Understanding and Interpreting Requirements
- Risk Management
- Validation of Processes
- Internal Audits

Data Integrity- Monitoring, Measurement, Analysis, and Improvement

Data integrity refers to the accuracy, completeness, consistency, and reliability of data throughout the IVD medical device lifecycle crucial for ensuring product safety, efficacy, and regulatory compliance

Data validation and verification,

Access control, Data encryption

Audit Trails and Logs

Regular Backups, and Recovery Plans

Data versioning, and timestamps, Data quality assessment

Data Governance Framework,

Error Handling Mechanism

Data Integrity- IVD tests for Neglected Diseases NTDs under ISO 13485:2016 requirements

Human Error

- Manual data entry mistakes
- Incorrect information recorded

System Error

- Incomplete data recording, data loss
- Missing entries in batch records
- Incomplete test results
- Errors in data handling, Insufficient backup

Noncompliance with ISO 13 485: 2016

- Lack of traceability; inadequate traceability of data; verification failure of accuracy of data e.g. Data of Performance Evaluation shown inconsistency of results- failure checking ID reagents

A critical gap in data integrity of IVDs production for NTDs

Incomplete or inaccurate data recording during the manufacturing process

- Incomplete data entries- potential data integrity

Root Cause Analysis: Human Error; Manual data entry mistakes can lead to incorrect information records, potentially affecting the quality and reliability of the IVD tests

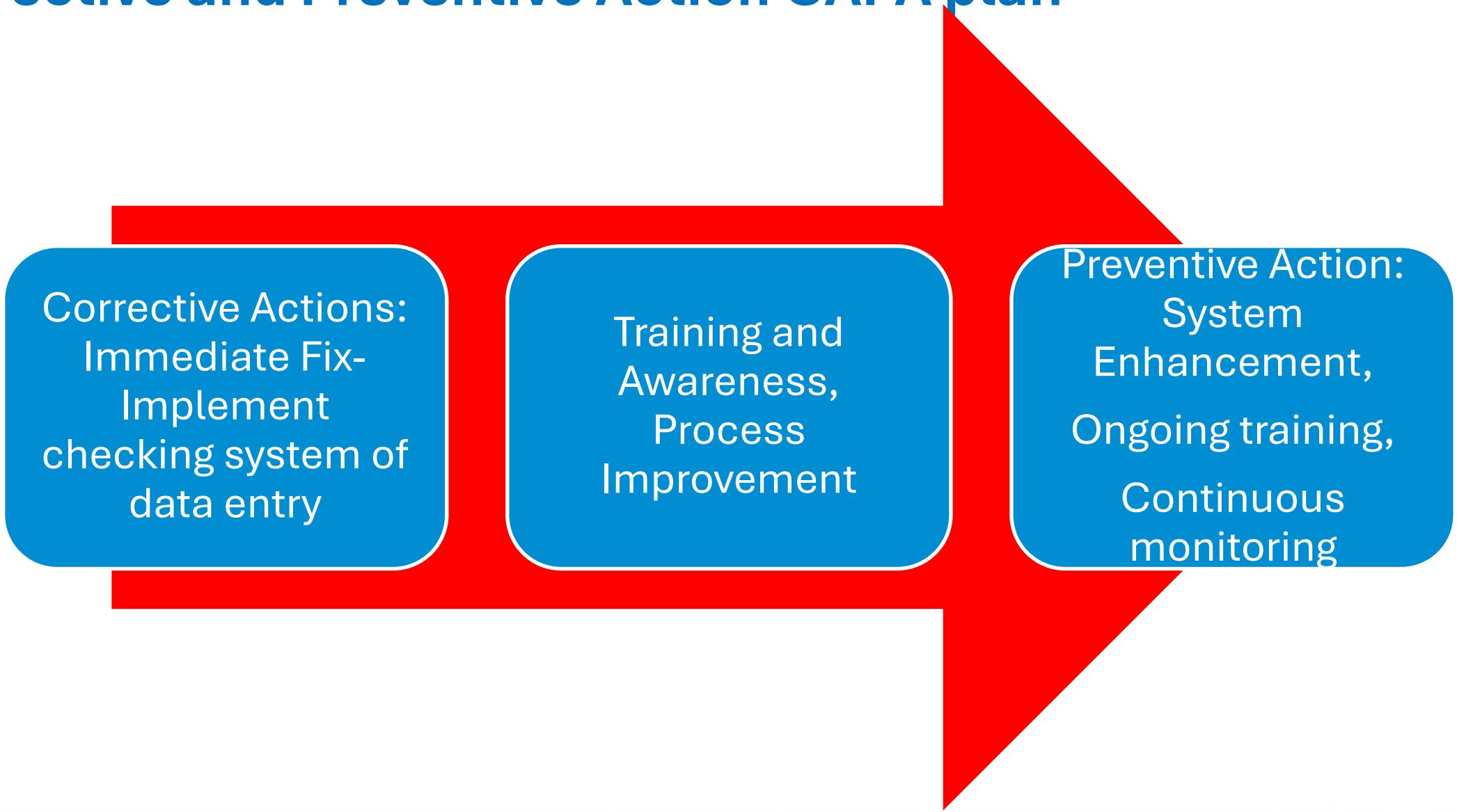
Temperature Logs of Reagents

Stability, Effectiveness

System Failures: technical issues with data management systems can lead in data loss leading to gaps in the production records

Contributing Factors Inadequate training on the importance of data integrity and lack of clear SOPs for critical data entry and record

Corrective and Preventive Action CAPA plan



A critical gap in data integrity of IVDs production for NTDs

E.g. Chagas Stat-Pak immunoassay possible gaps

- **Lack of specific data**

Inconsistent Reagent Quality

Variability in the quality of reagents during manufacturing can lead to inconsistency of test performance

Improper Storage condition

Failure to maintain proper storage condition- no data recorded- can affect stability and efficacy of the test

Inadequate calibration of equipment

Inadequate data recorded can lead to errors in test performance

Corrective and Preventive Action CAPA plan

Corrective Action

Ensuring all reagents meet quality standards; entry-specific data,

Controlling temp, humidity level- records

Regular calibration schedule, specific data recorded

Training and Awareness, Process Improvement

Preventive Action

Adequate SOPs, protocols

Control system

Ongoing training

Identification, and Traceability

Identification ensures each IVD device can be uniquely recognized and distinguish from other devices

Labelling with essential information such device name, intended use, manufacturer details

Batch/Lot no

Expiration date

Labelling-crucial for identification, ensures users have all necessary information for safe, effective use

UDI

UDI; identifies within the healthcare supply chain, and provides a standardized way to identify IVD medical devices throughout their life cycle

Traceability

Traceability ensures history, application,
and the location of each IVD device
can be tracked
through entire lifecycles
* Supply Chain-extent of traceability
to the entire supply chain ensures all suppliers,
subcontractors comply with
Traceability requirements

Comprehensive records of production, testing,(R&D if appl.) distribution

Tracking raw materials, components

Finished products

Batch, Lot tracking

Ensures each batch or Lot can be traced back

Summary of differences:

Scope; Identification focus on uniquely recognizing each device

- Implementation: Labelling and UDI
- Objective: Identification aims to ensure each device can be distinguish and use correctly

Scope: Traceability involves tracking the device's history and movement through the supply chain till the end of production and the lifecycle of IVD

- Traceability requires detailed record-keeping and supply chain management
- Traceability aims to ensure the device's lifecycle can be monitored, and any issues can be traced back to their source

enhance the safety, quality, and regulatory compliance of their IVD device

Conclusion/s

ISO 13 485:2016 ensures that the design, development, production, and distribution process of IVDs are consistent and controlled, leading to higher quality, and safer products through enhanced quality and safety

While certification isn't required, aligning with ISO 13 485:2016 helps meet regulatory compliance facilitating smoother approvals and market access

The standard provides a systematic approach to identifying, and mitigating risks throughout the product lifecycle with an application of a risk management approach ensuring patients and user safety

Implementing ISO 13 485:2016 can streamline process with operational efficiency, reduce waste, and increase product

Conclusion/s

Compliance with ISO 13 485:2016 can enhance market access globally and increase competitive advantage as many countries recognize this standard. It also builds credibility and trust with stakeholders, including regulators, customers, and end-users

Adhering to a globally recognized quality standard can significantly enhance the manufacturers reputation, building trust and confidence among stakeholders

For WHO Prequalification of IVDs, demonstrating compatibility with ISO 13 485:2016 requirements can be a strong foundation, showing a commitment to quality and safety even if full certification isn't pursued

References:

- EN ISO 13485:2016 Medical devices — Quality management systems, International Organization for Standardization, 01 March 2016
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Thank You