Quality Management System for National Regulatory Authorities

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Background

- Several World Health Assembly resolutions, including WHA67.20 (2014), mandate WHO to provide support to its Member States in strengthening national regulatory systems for medical products.
- It recognizes that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes.
  - that regulators are an essential part of the health workforce and.
  - that inefficient regulatory systems themselves can be a barrier to access to safe, effective, and quality medical products.

Objectives

Describe principles for implementing a **QMS** to support **planning, execution, monitoring,** and **evaluation** (M&E) of the performance of all applicable functions and activities of an NRA

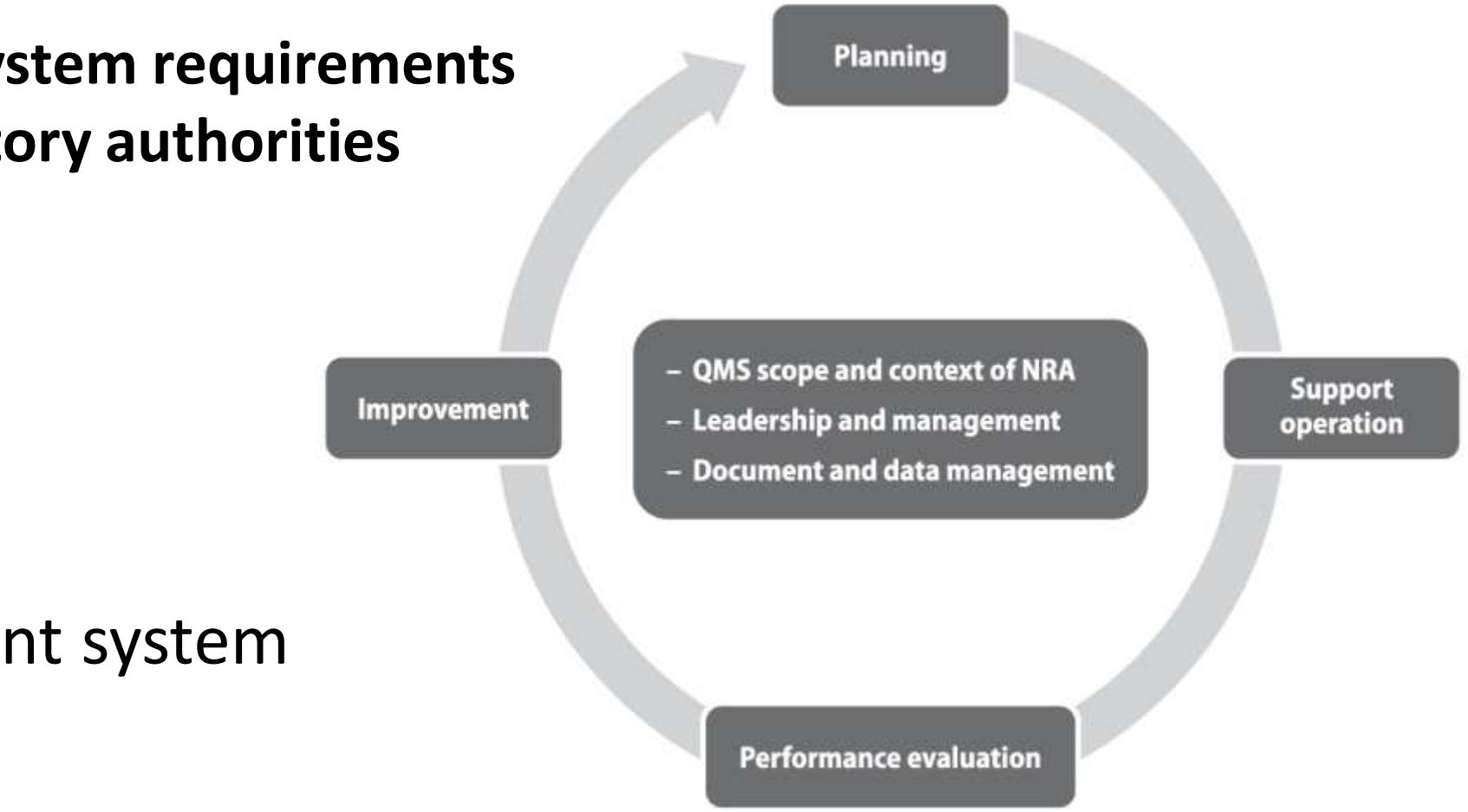
Provide requirements for the QMS to **support** and **facilitate systematic linkages** and **integration** of different **processes** and **systems** of the regulatory functions and activities within an NRA.

Provide requirements that NRAs should consider for evaluating the performance of the QMS and measures that the NRA should implement for continually improving the QMS.

Scope

- This is an overarching guideline that should be applied across all regulatory functions and activities, including registration and marketing authorization; vigilance; market surveillance and control; licensing establishments; regulatory inspections; laboratory access and testing; clinical trials oversight; national lot release; and others, as applicable to the implementing NRA.
- The guideline can be used for other regulatory activities that are mandated by the national laws and regulations to ensure public health safety, by assuring the quality, safety and effectiveness of medical products.
- This guidelines is applicable for centralized, decentralized(federal governance system) or discrete structure of NRA.

Quality management system requirements for national regulatory authorities



1. Quality management system concepts

Quality management system requirements for national regulatory authorities

The QMS requirements that are described in this guideline are based upon the quality management principles presented next, as provided in ISO 9000:-

- Customer focus
- Leadership
- Engagement (involvement) of people
- Process approach
- Improvement
- Evidence-based decision-making
- Relationship management

Quality management system requirements for national regulatory authorities

Introduction

legislative mandates and scope (functions) of the NRA; • standards and guidelines used in QMS implementation;

• QMS implementation history; integration (as applicable) with other management and software systems for personnel performance appraisals, finances and accounting, environment, occupational health and safety, workflow, customer relationship management, ministry of health policies and strategic action plans; •identification of the functions and processes that are already covered by other QMSs.

Scope of the quality management system

NRAs to document the processes that are covered by the implemented QMS.

- All processes and activities that are done by the NRA as mandated by national laws and regulations should be included in the QMS. Implementation can be done at once or in phases.

Organizational context of the national regulatory authority

To provide guidance regarding what should be indicated when describing and documenting the setup of the NRA with its regulatory system, functions and activities within the QMS.

- This extends to the model type (discrete, decentralized or centralized) and to the relationships with other institutions providing regulatory services for medical products and other health technologies.

Leadership, management and organization

what should be expected from top management for effective implementation of the QMS.

It also includes the roles, responsibilities and authorities that should be part of the implemented QMS.

Document and data management

Applicable to internally generated documents and to those of external origins, including data

- Applicable to internally generated documents and to those of external origins, including data. The requirements include development, review, approval, distribution, version and access control, storage, retrieval and disposition of documents.

Planning

- Planning requirements for achieving the set objectives, managing risks and opportunities across the NRA, and planning changes to the QMS for continuous improvement.

Support and resources

- input resources (technical and non-technical), personnel and infrastructure needed for effective implementation of the QMS.
- It also provides guidance on documenting operational linkages of processes and systems for effective and efficient QMS implementation..

Operation

Requirements for QMS implementation in core processes and activities that are within the mandates of the NRA.

Quality management system requirements for national regulatory authorities

Performance evaluation

- Methodologies and recommendations regarding what should be implemented by the NRA to facilitate accurate, objective and efficient performance monitoring, analysis and evaluation of operations indicators, QMS effectiveness, resources and customer satisfaction.

Improvement

- NRAs to implement in the QMS to support continuous improvements based on collected, analysed and evaluated data.

Quality management system implementation methodology

Supporting factors for quality management system implementation:-

Potential mechanisms that can support QMS implementation include:

- establishing effective coordination and communication mechanisms
- receiving high-level support from top management for QMS implementation
- establishing high-level ownership and commitment by top management for QMS implementation and maintenance
- including QMS implementation roadmaps in NRA strategic plans by top management when submitting to an oversight body (council, board, committee or ministry of health) for approval, as applicable
- including QMS implementation by the NRA in the national health strategic plans;

Quality management system implementation methodology

Supporting factors for quality management system implementation:-

Potential mechanisms that can support QMS implementation include:

- including responsibilities and authorities for contributing to the QMS in every staff job description and human resources performance appraisal
- creating and implementing training plans for QMS personnel, based on NRA competence frameworks
- engaging all customers and stakeholders for communication and awareness
- implementing applicable ICT tools for internal and external implementation of QMS and communication of quality policy awareness
- embedding assigned QMS personnel within regulatory processes, with the dual responsibilities of regulatory job functions and QMS responsibilities to support and maintain the QMS in the respective regulatory unit;

Quality management system implementation methodology

Situational analysis of quality management system implementation status in the national regulatory authority:-

- Regardless of the size of NRA, the scope of regulatory functions and the NRA organizational model (i.e. discrete, decentralized or centralized), for gap and situational analyses should be considered when implementing QMS and when planning for continuous improvement of a QMS that is already implemented. NRAs should first identify existing gaps and determine the level of implementation of the QMS.

Quality management system implementation methodology

Gap analysis for developing a roadmap for quality management system implementation:-

- identify gaps and define activities to be done for QMS implementation,;
- The planning, prioritization and implementation should be as practical as possible and be determined by the NRA, taking into consideration the availability of resources and priorities for the provision of regulatory products and services.

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency

Quality management system implementation methodology

Quality management system development and implementation roadmap:-

- The roadmap will be used to identify activities to be done; required resources; competencies of personnel; responsibilities and authorities; timelines (time frame); and prioritization based on the needs of the NRA with respect to the regulatory products and services as mandated by national laws and regulations.

Quality management system development and implementation roadmap:-

Steps	Activity	Responsible
1	Assign resources (personnel, financial, equipment and infrastructure).	Top management
2	results from self-benchmarking to determine the status of the QMS and submit report to top management, noting activities and areas that require actions.	Assigned staff/ Consultant
3	Prioritize activities based on availability of resources (internal and external); risks of non-implementation; and regulatory products and services, as mandated by national laws and regulations.	Top management
4	Allocate responsibilities and authorities with timelines for development, review, approval, implementation, and monitoring and evaluation of prioritized QMS requirements.	Top management and assigned staff/ Consultant
5	Validate the prioritization of QMS requirements, timelines, responsibilities and authorities with NRA staff, through collection of input and feedback to promote ownership of QMS implementation.	Top management and assigned staff/ Consultant
6	Consolidate the feedback and input into an activity/ action plan, as a roadmap for QMS implementation for the NRA.	Assigned staff/ Consultant
7	Integrate the QMS roadmap (activity/action plan) into the NRA organizational activity/action plans, the NRA strategic plans, and the ministry of health strategicplan/policy, as applicable.	Top management

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Thank You