



Quality Management System requirements for National Inspectorates

Quality Management System



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Background

CDSCO Communication vide file no. QMS/04/RI/2022 dated 31-10-2022 to all State Drugs Controller and Head of Zonal, Sub Zonal & Port Offices for implementation of WHO Technical Series (TRS) no. 1025 Annexure 5- Quality Management System requirements for National Inspectorates

Introduction

This document describes the **quality management system** (QMS) requirements for the operation of **inspection services** within national regulatory authorities (NRA) or other state structures.

Scope

This document outlines the QMS requirements for pharmaceutical inspectorates that are competent for the oversight of GXP operations.

Quality Management System

The concept of a QMS is wide-ranging and covers all matters that are necessary to implement the inspectorate's quality policy and to meet predefined objectives.

The QMS should define the inspectorate's scope and context within the regulatory mandate, as well as covering all functions, processes and activities.

The QMS should at least describe and manage organizational structure, responsibilities, procedures, systems, processes and resources required, to provide value and achieve results for the inspectorate and relevant interested parties.

The legal basis for the establishment of the inspectorate, its mandate, the quality policy and the principles of the QMS should be documented in a quality manual or equivalent document.

The QMS should enable senior ("top") management to best use available resources and systems in order to achieve the inspectorate's targets and quality objectives

Quality Management System.....Contd.

Primary aim

To ensure its ability to **consistently** provide services that meet the organization's **objectives, legal requirements** and interested parties' expectations.

To facilitate **continual improvement** and provide a sound basis for sustainable development to comply with statutory and regulatory requirements.

Context of the Inspectorate

Clear Define
legal basis

establishment
of
Inspectorate
and its
Mandate

statutory and
regulatory
responsibilities
and functions

The inspectorate
should
determine

Scope and
Strategic
direction

to achieve
the
intended
objectives

Structure and
operation of the
inspectorate

impartiality
and
independence
are
safeguarded

deontology,
confidentiality, ethics
and conflicts of
interest should be
obeyed.

Relationship of
the inspectorate

with other
departments
within the
same NRA,

other agencies and
organizations outside
the inspectorate, as
well
as any other
stakeholders

Management and Leadership

- ✓ Formal **commitment** to the **implementation** of a documented quality policy
- ✓ ensure that the **inspectorate's services** and **functions** are aligned with **regulatory requirements** and the NRA's **objectives**.
- ✓ accountable for the **integration of QMS requirements** into the inspectorate's **processes and functions**; for **communicating** the importance of **QMS principles**; and for the **overall effectiveness** of the QMS.
- ✓ promote the application of **risk management principles**.
- ✓ ensure that the pharmaceutical **inspectorate** has **sufficient** and **appropriate resources** at all levels to enable it to meet its objectives.
- ✓ An appropriately **experienced** and **qualified person** should be nominated as a **QMS responsible person**
- ✓ system for **periodic management review** of the QMS **effectiveness**, including process improvements

Management System Planning

Inspectorate should:-

- ✓ Establish **objectives** for **service** and of its **functions**, consistent with the quality policy and regulatory requirements.
- ✓ Considered Principles of **risk management** and **sustainable development** for establishing objectives.
- ✓ Communicate objectives to **personnel at all levels** and update time to time.
- ✓ Availability of **appropriate resources** to meet these objectives.
- ✓ Define **roles** and **responsibilities** and **appropriate timelines** for completion
- ✓ Established systems for **monitoring** and **evaluating** results.
- ✓ Established documented **change management system** to ensure that change requests are assessed, approved or rejected.
- ✓ Change management system should ensure that continual improvement is undertaken in a timely and effective manner.

Resources: Financial, human, facilities and others



Personnel

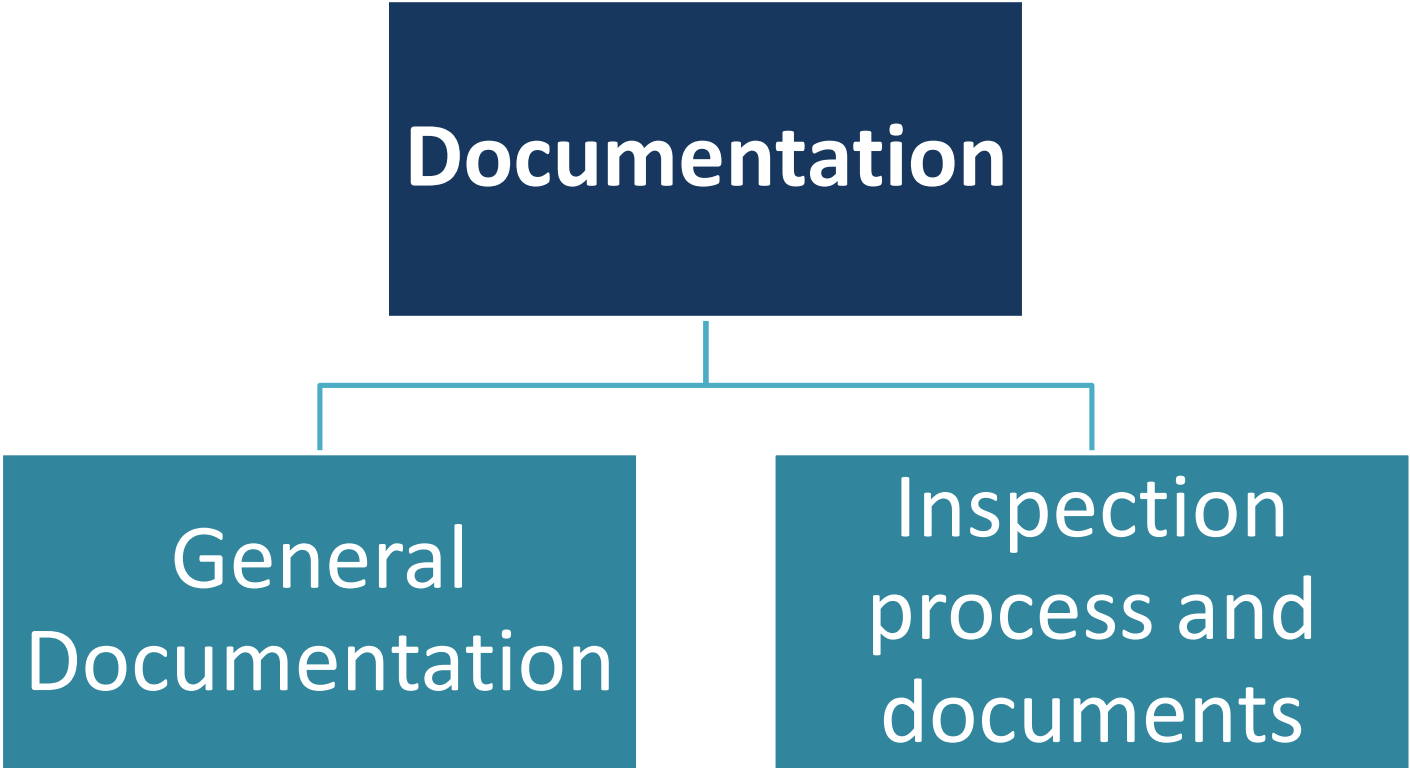
- **expertise** to perform its functions, including inspections
- appropriate **qualifications, including education, training, experience and knowledge** of the inspection process and subject.
- **induction and continuous training** is provided to inspection personnel on administrative, regulatory and technical topics.
- Should be bound by the requirements of the **quality system, obey the inspectorate's code of conduct** and not be subject to any **commercial, financial or other pressures** that might affect their judgement and freedom to act



Infrastructure

- **Necessary infrastructure** and appropriate work environment to enable them perform their functions and meet the quality objectives.
- Infrastructure includes, but is not limited to
- 1. buildings, workspace and associated facilities;
- 2. qualified equipment, including hardware and software;
- 3. transportation resources; and
- 4. information and communication technology.

Documentation



Operational planning and performance evaluation

- ✓ An **annual work plan** should be developed, documented and periodically **reviewed** by senior management.
- ✓ **Quality indicators and methods** should be established, in order to monitor and periodically evaluate the inspectorate's processes and level of improvement and service
- ✓ Inspectorate should implement a **system of periodic and documented internal audits** of its operations

Operational planning and performance evaluation (Management Review)

- ✓ Senior management should review the inspectorate's QMS at planned intervals to ensure
 - ❖ its continuing suitability, adequacy, effectiveness and
 - ❖ alignment with the inspectorate's strategic direction and legislative requirements
- ✓ Management review should be conducted at least once a year

Publications

- The inspectorate should **issue** and **maintain** an up-to-date list of inspected and licensed facilities and organizations, including information on the outcome of inspections
- The inspectorate should ensure that other relevant publications, such as technical guides, GXP guidelines and regulatory requirements, are publicly available.



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Thank You