20 June 2024
Executive Director
EMA/228979/2024

Quality Management Policy

POLICY/0001

Status: Public

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Supersedes: EMEA/MB/355781/2007 Rev 1

1. Introduction and purpose

The European Medicines Agency's (EMA) priority at all times is to ensure that the activities relating to the evaluation and supervision of medicines for the benefit of public and animal health in the European Union are delivered on time and at the high level of quality that the Agency's stakeholders expect, ensuring continued access to high quality, safe and effective medicines.

The implementation of a Quality Management System (QMS) is one of the mechanisms employed to ensure that a structured, comprehensive, efficient and effective approach is consistently used to organise the Agency's work and achieve its priorities and objectives.

This Quality Policy is the document from which EMA's Quality management system is derived.

Acting in full compliance with all relevant statutory laws and regulations, the Agency affirms its commitment to develop, implement and promote a quality culture aiming to fulfil the stakeholders' requirements.

This policy applies to all Agency staff meaning temporary and contract agents, seconded national experts and trainees and includes all other actors involved in the Agency's work, i.e., interims, scientific committee members and experts, contractors, subcontractors, consultants, and similar partnerships managed by the Agency.

2. Policy statement

The Agency's quality objective is to ensure that the Agency operates at consistently high levels of efficiency and cost-effectiveness, and delivers services of the highest quality, reliability and consistency.

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The Agency is committed to:

- Delivering its legal obligations;
- Meeting its strategic goals through efficient and effective operations;
- Striving for excellence in its services by adopting best practices and continually enhancing service level;
- Proactively identifying needs and expectations of its key stakeholders: Patients and consumers, EU Partners, Healthcare professionals, Academia, Pharmaceutical industry;
- Enhance stakeholders' satisfaction by consistently providing the highest quality of service;
- Delivering enduring value to our internal and external interested parties, through continual improvement of EMA's services;
- Managing risks related to the Agency's mission through identification, monitoring, treatment, control and transfer activities where applicable.

3. Roles and Responsibilities

To streamline the implementation and ensure the effective operation of the system, roles and responsibilities are designated throughout the Agency. These assigned roles and responsibilities include:

The **Management Board** oversees the implementation and effectiveness of the quality management system, ensuring alignment with organisational goals and regulatory requirements, while also fostering a culture of continuous improvement and accountability.

The **Executive Director** puts in place the organisational structures and Quality Management System to ensure attaining the Agency's goals and objectives in the most efficient and effective way and is responsible for their effective functioning.

Although the Executive Director is ultimately responsible for effective implementation of the Quality Management System it is, in essence, a shared responsibility that runs through every task and objective for all Agency staff. Specific structures and roles and responsibilities are also assigned throughout the Agency, to ensure effective, systematic and coordinated implementation of the system.

Heads of Divisions and Task Forces, Departments, Services/Offices of the Agency engage in Quality Management System implementation through:

- Establishing, monitoring and reporting management information.
- Analysing and proposing solutions for the continuous improvement of quality.
- Managing risks and the implementation and monitoring of quality assurance.

The **Head of Quality and Risk Management service** supports the Executive Director in implementing the system and manages the activities on a daily basis.

Integrated Quality Management Coordinators (IQM co) are appointed in each division/ task force and advisory function of the Agency and form a network of staff across the organisation that are responsible for facilitating quality and risk management activities throughout the various hierarchical levels of the organisation.

Staff and all other actors involved in the Agency's work must ensure compliance with this policy and be responsible for their activities.

4. Quality Management System

The Quality Management System implemented at EMA shall adhere to the following guiding principles:

- *Focus on performance and efficiency*, while maintaining simplicity of processes and compliance with legal, financial and regulatory requirements.
- *A quality focus and mind-set*. The Agency is committed to quality and excellence, both in terms of delivering high quality results and outputs in its work and cultivating a quality mind-set.
- *Continuous improvement of* systems, structures, processes and procedures, in line with recognised quality standards.
- *Transparency, fairness and independence*. The systems and processes are built to be fair, objective and independent, and so as to produce reliable outcomes and results. Transparency is key to building the trust in the systems and the results. Transparency also underpins communications with both internal and external stakeholders as well as the systems and processes themselves.
- *Evidence and fact-based approach and timely action.* Actions are taken and decisions made, based on sound evidence and reliable, relevant and timely information from trusted sources.
- Fostering Efficiency and Effectiveness through integrated working methods. The system and activities are devised to encourage collaboration and to ensure optimal efficiency and effectiveness through coherent, cohesive, integrated ways of working.
- *Firm commitment to high standards and levels of integrity*. Consistently, from top leadership down to every level, managers set the tone by showing through their attitudes, words, and actions a strong commitment to quality, objectivity, and integrity in all aspects of Agency work.

In order to guarantee the efficient execution, monitoring, and evaluation of the Quality Management System, as well as the ongoing enhancement of processes, resources, and personnel competencies, the Agency has established suitable management and supervision structures.

4.1. Documentation

The Quality Management System shall be supported by a variety of documents to ensure compliance with the Agency's strategic directions, processes, and procedures.

The Agency shall ensure that the Quality Management System documentation is understood, implemented, and maintained at all levels in the organisation.

EMA's document management systems and related procedures shall comply with relevant compulsory security measures, provisions on document management and rules on protection of personal data. The Agency shall ensure that the EMA's document system is secure, efficient, in particular as regards retrieving appropriate information, and complies with applicable legislation.

Records established and maintained shall provide evidence of compliance with regulations, and the effective operation of the Quality Management System.

4.2. Resources

The Agency shall determine and provide the persons, required competency and infrastructure necessary for the effective implementation of the operations and control of its processes.

4.3. Evaluation

The Agency shall determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; when the monitoring and measuring shall be performed; when the results of monitoring and measurement shall be analysed and evaluated and retain appropriate documented information as evidence of the results.

4.4. Management review

To evaluate whether the Quality Management System is performing as intended and producing the desired results as efficiently as possible, the Agency shall conduct management reviews at regular intervals.

4.5. Communication

The Executive Director shall ensure that this policy is effectively communicated, understood and implemented throughout the Agency.

5. Changes since last revision

The policy underwent a thorough review to streamline language and structure, improving readability and accessibility.

6. Entry into force and review

This policy shall enter into force on 1 July 2024.

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Amsterdam,

Emer Cooke
Executive Director