Scientific Integrity and Innovation: A Macroprocess Model for Quality Management in Biomedical Laboratories

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Biomedical research, especially when conducted in non-regulated environments, requires a quality management system that ensures traceability, scientific integrity, regulatory compliance, and institutional accountability. The lack of an effective system can lead to serious consequences such as the loss of scientific credibility, retraction of studies, and funding difficulties. However, many laboratories face challenges in structuring and applying these requirements in an integrated, continuous, and auditable manner. This article proposes a macroprocess model that organizes, operationalizes, and monitors the requirements of the WHO's Quality Practices in Basic Biomedical Research (QPBR) Manual, adapting it to the practical/operational reality of laboratories. The model is structured into seven macroprocesses covering everything from institutional guidelines and personnel management to process digitization, data control, and results management. Each macroprocess is broken down into practical actions linked to key performance indicators and supported by a Standard Operating Procedure (SOP) that guides its step-by-step implementation. Operated in a digital environment (Miro), the model allows for both visual and collaborative tracking as well as evidence repository and continuous monitoring functions. In addition to serving as a technical guide, the model is a strategic tool for quality governance, promoting an organizational culture based on best practices, ethics, biosafety, and continuous improvement. It thus contributes to compliance with national standards and international guidelines while strengthening the credibility of scientific production in contexts of funding, publication, and international cooperation.

Keywords: Quality Management in Research. Laboratory Macroprocesses. Scientific Traceability.

Science has established itself as the main driver of human progress, and the efficiency and reliability of biomedical research are crucial to translating discoveries into tangible social benefits. However, the rapid expansion of research organizations introduces not only innovative opportunities but also threats to scientific integrity, requiring a cultural transformation that confronts entrenched biases and incorporates new evidence-based standards. As Ioannidis [1] warns, disruptive interruptions in the modus operandi of scientific investigation must be well-founded to avoid compromising its validity.

In this context, quality management emerges as a critical pillar to ensure methodological reliability, participant safety, and ethical excellence in biomedical research. Paradoxically, its implementation in university laboratories still faces resistance, being perceived as a hindrance to creativity and a source of excessive bureaucracy [2]. This tension reveals a central challenge: how to align regulatory rigor with investigative agility without compromising innovation.

The robustness of scientific results is intrinsically dependent on data management, especially in long-term trials where follow-up losses can invalidate conclusions. Friedman and colleagues [3] demonstrate that high discontinuity rates require sensitivity analyses to preserve credibility, reinforcing that international standards, such as the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines [4], are not only mandatory for drug approval but also serve as shields against ethical risks [5-7].

To unify global efforts, the World Health Organization (WHO) published in 2006 the Quality Practices in Basic Biomedical Research (QPBR) Manual, translated in Brazil by Fiocruz in 2010

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[8]. This guide serves as a compass for ethical and methodological standardization, proposing reproducible guidelines that transcend borders [9]. However, its operationalization in non-regulated contexts remains fragmented, lacking adaptive models that convert principles into auditable actions. It is within this gap that our proposal is inserted: a macroprocess management model, structured based on the QPBR Manual, aimed at transforming abstract requirements into measurable operational flows. By linking WHO guidelines to performance indicators, evidence repositories, and controls, the model not only addresses historical challenges related to integrity [10], but also catalyzes a cultural shift where ethics, biosafety, and continuous improvement become the foundation for building an institutional culture focused on quality.

Materials and Methods

Step 1 - Definition of Macroprocesses

In this step, the fundamental macroprocesses of quality management were identified and organized, based on the grouping of requirements outlined in the QPBR Manual. Each macroprocess was broken down into operational actions and linked to monitoring indicators, enabling the structuring of a systemic and applicable view for continuous monitoring.

Step 2 - Use of a Digital Modeling Tool

A digital tool was incorporated to support the modeling and operationalization of the system. The collaborative platform Miro was used as a visual environment for building the model, allowing graphical representation of the macroprocesses and their breakdowns, in addition to serving as a dynamic repository of information and conformity records.

Step 3 - Presentation and Structuring of the Model

This step involved organizing the model for presentation and validation, taking into account criteria such as practical applicability, adherence to the QPBR Manual, alignment with institutional guidelines, and feasibility of implementation in real laboratory contexts.

Step 4 - Development of the Standard Operating Procedure (SOP)

A specific SOP was developed for applying the model, guiding practical implementation, evidence recording, indicator monitoring, and continuous updating.

Results

The model was developed with the aim of clearly structuring and linking the main quality management macroprocesses applicable to research laboratories, as illustrated in Figure 1.

Presentation and Structuring of the Model

The presented model integrates these issues with their respective practical applications in the laboratory context, promoting a functional and systemic visualization of the operational responsibilities linked to each area to meet quality requirements. The conceptual structure of the model was organized based on seven strategic axes, defined as Institutional Guidelines, People Management, Operational Management, Research Project Management, Data Management, Results Management, and Information Technology Management. These axes encompass three layers of breakdown: (i) organizational requirements, (ii) operational requirements, and (iii) results requirements.

Axis Institutional Guidelines represents the internal regulatory framework that guides the operation of biomedical research laboratories regarding quality and its interfaces. This structure includes institutional policies, manuals, technical standards, codes of conduct, and operational guidelines, which form the basis for quality governance. These instruments ensure coordination

Figura 1. Model for the implementation of normative quality management requirements in laboratories:

between administrative, technical, and operational aspects, allowing the laboratory to operate in compliance with ethical, regulatory, and scientific standards. This macroprocess is also responsible for integrating quality requirements into cross-sectional areas such as infrastructure, biosafety, environmental management, institutional communication, scientific integrity, and risk management. Two key indicators linked to this macroprocess are Accreditation/Recognition/Authorization and Certifications and Accreditations. The first indicates that the laboratory is formally authorized by competent regulatory bodies to perform specific activities, such as handling genetically modified organisms (GMOs) or biological risk agents, demonstrating compliance with legal requirements. The second demonstrates the laboratory's alignment with national and international quality standards, reflecting the degree of institutionalization, maturity, and reliability of the quality system. Both indicators function as seals of excellence and institutional legitimacy, contributing to the laboratory's recognition by funders, regulatory agencies, and the scientific community.

Within biomedical research laboratories, the People Management axis goes beyond human resources administration and is understood as a structuring pillar of quality. This macroprocess ensures that employees work with technical competence, institutional responsibility, and alignment with organizational objectives, in accordance with good practices required by regulated and high biological risk environments. Promoting continuous team development is central to this process. The implementation of training programs, validation of technical knowledge, and updating of training records ensure that laboratory activities are performed with accuracy, reproducibility, and scientific integrity. Simultaneously, competency and responsibility mapping, through tools such as functional matrices and codes of conduct, promote organizational clarity, action traceability, and adherence to regulatory requirements. Another critical component of People Management is structured internal communication, which goes beyond operational information exchange. Two indicators reflect the effectiveness of this macroprocess. The Number of Trainings/Events measures investment in the technical and scientific improvement of employees, indicating continuous preparation of the team in relation to quality and biosafety requirements. The Number of Bulletins/Reports/Benchmark indicates the degree of active and structured institutional communication, promoting the circulation of strategic information, visibility of actions, and encouragement of experience exchange among teams and units.

Operational Management is one of the central pillars of the quality system in biomedical research laboratories, responsible for ensuring technical accuracy, routine standardization, and documentary control of laboratory activities. This macroprocess

covers everything from the implementation of internal controls for critical activities to the systematic performance of preventive maintenance and equipment calibration, which are fundamental to guaranteeing the reliability of generated data. A highlighted focus is document management, which includes both prescriptive documents, such as standard operating procedures (SOPs), work plans, and technical instructions, as well as descriptive documents that record the practical execution of these instructions. This structure guarantees traceability, reproducibility, and transparency of processes, crucial aspects for auditable and highly regulated environments. Beyond the technical axis, Operational Management also interfaces with cross-sectional regulatory and institutional support areas, such as Waste Management, through compliance with specific legislation, and Biosafety, which requires conformity with internal standards, infrastructure requirements, and official certifications. This shows that operational activities go beyond the technical plan, involving interaction with legal, environmental, and institutional security aspects. Two indicators are directly associated with this macroprocess: the Proficiency Test Approval Rate, which evaluates the laboratory's technical capacity through external comparative assays; and the Document Compliance Rate, which checks the adequacy, updating, and traceability of documents linked to laboratory routine. Both indicators form part of the monitoring system for the institution's technical and documentary quality. In summary, Operational Management is the backbone of quality execution in the laboratory, supporting the entire biomedical research cycle with safety, standardization, and technical responsibility.

The Research Management macroprocess aims primarily to ensure that scientific investigations are conducted in a structured, safe, and technically grounded manner. This macroprocess ranges from technical support for drafting and reviewing research documents, such as projects, protocols, and terms of reference, to the use of digital tools aligned with information technologies that enable efficient management of the different phases of the research cycle. An essential component of this macroprocess is risk analysis, which is introduced as a preventive practice in the planning of each study. This analysis allows for the prior identification of possible operational, methodological, or ethical failures, contributing to risk mitigation, protection of the team and environment, and robustness of scientific results. The associated indicator, Percentage of Projects with Documented Planning and Risk Analysis, measures the proportion of research projects that start with a formal plan duly recorded and accompanied by a validated risk analysis.

Results Management represents the stage in which research achieves its scientific and institutional purpose: the production of reliable, relevant, and socially applicable knowledge. This macroprocess is responsible for ensuring that data generated throughout the project are critically analyzed, technically validated, and communicated with integrity, guaranteeing scientific transparency and institutional responsibility. The model highlights four breakdowns that compose this macroprocess. The first relates to compliance with good research practices, ensuring that studies have been conducted according to ethical standards, validated technical protocols, and standardized operational criteria. The second axis concerns the execution of periodic critical analyses and evaluations based on results, which guide strategic decisions and allow methodological corrections throughout the research cycle. The third axis involves formal study closure procedures, which ensure the existence of complete final reports, describing conduct, methodology, changes, results, critical discussion, and conclusions, promoting traceability and final documentation of the research. Finally, the macroprocess includes institutional support for scientific publication, ensuring clear policies on authorship, peer review, respect for data integrity, and encouragement of the dissemination of negative results, in line with open science principles. The associated indicator, Percentage of Projects in Compliance with Good Practices, measures the proportion of research fully complying with the ethical, technical, and documentary requirements

defined institutionally. This indicator directly reflects the quality and credibility of produced results, being fundamental for audits, scientific publications, accountability to funders, and strengthening the institutional reputation of the research unit.

In the context of biomedical research laboratories, Data Management represents one of the pillars of scientific credibility and regulatory compliance. This macroprocess ensures that data generated throughout research is preserved, accessible, traceable, and protected against loss or unauthorized alteration. Its structure is anchored in three central and complementary components. The first component refers to data preservation, which involves the existence of adequate and secure infrastructure for storing raw data, technical forms, and critical records. This preservation covers both physical means (such as dedicated cabinets and archives) and digital environments (internal servers, institutional repositories, and secure clouds), ensuring record maintenance according to traceability and audit requirements. The second component is information integrity and recovery, translated into the implementation of reliable backup and restoration procedures. These measures ensure the full recovery of data in case of technical failures, accidents, or cyberattacks, protecting accumulated scientific knowledge and maintaining continuity of laboratory activities. The third component is the chronological recording of experimental data, which requires sequential, continuous, and dated documentation of all observations, measurements, and procedures performed. The associated indicator, Percentage of Data with Traceability and Backup, measures the proportion of data sets that have complete, chronologically organized records stored with secure recovery mechanisms.

Information Technology Management is configured as an essential macroprocess in contemporary biomedical research laboratories, providing the necessary digital infrastructure to ensure security, traceability, integration, and efficiency of scientific, administrative, and operational processes. This component goes beyond the traditional technical support role, positioning itself as a strategic axis supporting quality. Its actions include implementing and using reliable, validated, and authorized computerized systems for secure management of data, processes, and laboratory workflows. Compliance with information security standards is ensured through validation of critical software, access management based on responsibility profiles, and adoption of good digital protection practices, which guarantee data integrity and change control. The role of IT in supporting the systematization and visualization of operational flows stands out, through tools such as process mapping systems that facilitate planning, transparency, and data-driven decision-making. Furthermore, IT drives the digital culture in the laboratory environment, promoting adoption of advanced technologies such as artificial intelligence (AI), applied to analysis of large data volumes, protocol optimization, and automation of critical routines.

The central indicator of the proposed model is the Internal Quality Audits, conceived as a systematic and structured mechanism for monitoring compliance and effectiveness of all macroprocesses comprising a quality system in biomedical research laboratories. Due to its transversal nature, this indicator allows an integrated evaluation of the implemented practices, from people and project management to data preservation and communication of scientific results, aligning with the requirements of the PQPB Manual, institutional standards, and good laboratory practices.

Its systematic application enables the identification of deviations, promotion of corrective actions, and proposal of continuous improvements, strengthening not only regulatory compliance but also the organizational and scientific maturity of processes. By integrating all macroprocesses under a single verification criterion, the indicator helps reduce operational risks, increase data reliability, and reinforce the scientific integrity of activities developed in the laboratory environment. Therefore, it is a key component for the sustainability and credibility of the quality management system in biomedical research.

Conclusion

This model overcomes the dichotomy between methodological rigor and creative agility by integrating ethical-regulatory compliance, research ethics principles, good clinical practices, robust data management, and biosafety. By enabling real-time evidence generation, it transforms quality once seen as an obstacle into a strategic foundation. This strengthens national scientific credibility with funders and international partners, fosters an institutional culture of integrity, and translates excellence into concrete impact for health research.

It is recommended that future validations include case studies across different types of institutions, as well as the systematic measurement of the model's impacts through performance indicators and internal audits. The continuous improvement of the model, along with its dissemination and adaptation, may consolidate a more integrated, auditable, and sustainable approach to quality management in biomedical research.

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