CONFIDENTIAL

GARDP Quality Policy

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Revision history

Version	Reasons and Changes	Date
1.0	The GARDP Quality Policy, v1.0 (RD02) replaces the Regulatory Policy v1.0 (RD08) dated March 2019.	21 February 2025

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1. Introduction

GARDP is a not-for-profit organisation committed to the research and development of, and access to, antibiotic products and treatments ("Products") in a way that ensures their quality, safety, and efficacy in compliance with the relevant and/or applicable quality standards and regulatory requirements.

To fulfill its mission, GARDP collaborates with partners including research and development, manufacturing and commercial organizations ("Partners"). GARDP and its Partners are bound by agreements defining their respective responsibilities in order to assure the quality, safety and efficacy of all Products.

2. Purpose

This GARDP Quality Policy ("Quality Policy") outlines the organisational framework and principles meant to ensure the quality of the Products and compliance with relevant and/or applicable quality and regulatory requirements from investigational product research and development (non-clinical, clinical, pharmaceutical) to the manufacture, distribution and supply of the Products ("Product Lifecycle").

3. Scope

This Quality Policy and all related policies and standard operating procedures (SOPs) shall be implemented by GARDP staff and consultants involved in activities at any stage of the Product Lifecycle ("GARDP Contributors"). This Quality Policy and all related policies and standard operating procedures ("SOPs") are administered through a document management procedure and are monitored and updated as required to ensure continued compliance with the Requirements (as defined hereunder).

4. Policy Statement

All activities comprised in the Product Lifecycle, including in particular the research & development, product licensing, manufacture, and distribution of Products by GARDP and/or its Partners must be conducted in compliance with relevant International Codes and Standards[1, 2] and applicable guidelines for good practice (including Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice, Good Distribution practice, Good Pharmacovigilance Practice (together the "Requirements").

To this end, GARDP commits to:

- Provide education, guidance and all the necessary resources to ensure that all GARDP Contributors understand their role in the implementation of the Quality Policy;
- Implement Quality Management Systems (QMS) based on all applicable international regulations, including ICH guidelines, as well as national and regional regulations applicable throughout the Product Lifecycle ; and

- Regularly review the effectiveness of the QMS, evaluating their performance, identifying areas for improvement, and ensuring that it continues to meet the Requirements.

5. Quality management

As stated in paragraph 4, GARDP must implement the appropriate QMS to ensure that:

- all GARDP processes, SOPs and supporting documents are fit for their intended purpose of implementing the required regulatory and ethical guidance and standards.
- a risk assessment, mitigation and implementation process is in place for any changes or incidents that could affect the safety, quality or effectiveness of a Product or process, including the conduct of clinical and non-clinical studies;
- a continuous improvement culture is fostered within GARDP, with regular reviews of QMS processes, identification of opportunities for enhancement, and the implementation of improvements to increase efficiency, effectiveness, and compliance; and
- quality audits of Partners meet the standards set out in this Quality Policy and comply with regulatory requirements.

The QMS is overseen by a designated Quality Assurance (QA) leadership team, ensuring governance, accountability, alignment with GARDP's strategic objectives and compliance with the Requirements.

The QMS are supported by the GARDP policies and SOPs covering relevant functional areas. GARDP ensures that all GARDP Contributors are appropriately qualified and receive ongoing training to maintain their competency and awareness of QMS requirements, industry standards, and regulatory guidelines.

Specifically, GARDP operates within a clinical QMS including regulatory affairs SOPs. GARDP's CMC functions operate within the Drugs for Neglected Diseases Initiative's (DNDi) pharmaceutical quality system.

6. References

1. International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use
2. WHO Health products policy and standards