CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE

QUALITY POLICY

The mission of Clinical Validation from Biopharmaceutical Findings (CVBF) is to provide scientific, methodological and regulatory support for innovation in the pharmaceutical and biotechnological fields, with a specific focus on clinical research.

The institutional aims of CVBF are:

- to support the integration of the Italian pharmaceutical system into the European dimension;
- to support the development of products intended for the treatment of special populations (e.g. patients with rare diseases, children);
- to promote access to and rational use of medicines in compliance with current legislation and the Good Clinical Practice (GCP) standards;
- to participate in integrated national and European research projects in its areas of expertise;
- to promote educational activities and, in particular, provide training on topics of CVBF interest.

Taking into account the nature and purpose of CVBF, and the desire to provide reliable services and, at the same time, implement new projects that are technically and scientifically rigorous and efficient, the Management has established and maintains a Quality Management System (QMS) in accordance with the UNI EN ISO 9001:2015 standard.

Established on 27 December 2000, CVBF operates as a Contract Research Organisation (CRO) at national and international level and is committed to ensuring:

- the qualified implementation of the acquired services and projects;
- the satisfaction of stakeholders and clients;
- the rational and efficient use of available resources;
- compliance with contractual, legal and regulatory requirements applicable to the sector (e.g. ICH, AIFA, EMA).
- the continuous improvement of quality performance.

The Management undertakes to: define the strategic vision and objectives for quality; promote an organisational culture based on quality and transparency; actively involve staff and enhance individual skills; make available the resources necessary for the implementation, maintenance and continuous improvement of the QMS; periodically monitor the effectiveness of the system through management reviews and periodic measurement of the achievement of results.

CVBF adopts a process-based approach, which allows activities to be planned, managed and controlled in a systematic and interconnected manner in order to: identify processes, with their roles and responsibilities; ensure the efficiency, traceability and quality of the information produced.

CVBF applies a risk-based approach, in line with the principles of ISO 9001:2015, integrating quality management with information security management. In this way, the organisation identifies the risks present in each process and adopts prevention and control measures proportionate to the severity of the identified risks.

The Management entrusts Dr Maria Rita Fagone with the responsibility of the Quality Management System, in the role of Quality Assurance Manager (QAM), and appoints Dr Mariagrazia Felisi as Management Representative for Quality in order to ensure the proper maintenance of the QMS.

The staff involved in the management and maintenance of the QMS, belonging to the Quality Assurance, Risk Management & Auditing Unit, undertakes to: monitor the application of the QMS and report the results to the Management; promote, through communication, training and awareness-raising activities, awareness of the role of each individual in the quality and safety management; coordinate the risk assessment, continuous improvement and internal audit activities.

Bari, 04/11/2025

Signature of the Chief Executive Officer

Donato Bonifazi