

Quality Policy

The Quality Policy is EURO-PHARMA's commitment to its stakeholders through the application of a QMS in accordance with UNI EN ISO 9001:2015 and UNI EN ISO 13485:2021 and in compliance with the applicable mandatory regulations.

The general objective that oversees the Quality Policy is the realisation of high-quality products. Realisation is understood as the design, production management and marketing of finished products.

EURO-PHARMA defines annual improvement objectives against which the validity and effectiveness of its quality management system can be measured and evaluated and provides appropriate means and resources.

The objectives that EURO-PHARMA sets itself are:

- I. Maintain an effective quality management system consistent with the requirements of UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2021 and applicable regulatory requirements;
- II. Ensure the maintenance of the highest level of quality of products and business processes in order to meet customer needs;
- III. Develop strategic products in order to improve image and growth in the market, assessing risks and opportunities, aiming to meet the needs of the medical class and patients;
- IV. Communication to the medical profession, in particular hospital specialists and local health authority, through a medical-scientific information structure. The people involved in the medical-scientific information are up-to-date and competent and their feedback from the field contributes to the continuous improvement of the products. This system increases the satisfaction of specialists and the benefits of their patients;
- V. Increasing turnover by enhancing the development of medical information carried out in the Italian territory, the territorial expansion of the company and the entry into new foreign market areas;
- VI. The careful selection and promotion of the company to the outside world, such as: participation in national and international congresses/fairs, dissemination of institutional scientific content via social media (in compliance with current regulations);
- VII. Training of staff in order to make them acquire the skills necessary to achieve the objectives for quality;
- VIII. Pursue assiduous and constant collaboration with suppliers in order to activate relationships marked by continuous and joint growth;
- IX. Periodic review of the quality policy to assess its suitability ensuring continuous improvement;

review	date	reason	drafting and verification	approval
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X. Compliance with medical device requirements according to EU Directive 93/42/EEC and New Regulation 745/2017.

The Management of EURO-PHARMA promotes the culture of Quality, involving and requiring constant commitment from all those who work in the company and for the company, with the aim of making everyone aware of their role and responsible in achieving the Quality objectives of continuous improvement and good management by applying "risk based thinking". The work of raising awareness and involvement of all personnel is carried out through meetings, internal communications, training meetings and anything else deemed appropriate and effective.

To this end, EURO-PHARMA undertakes to:

- Implement and maintain an active Quality Management System in light of UNI EN ISO 9001:2015 and UNI EN ISO 13485:2021 and applicable regulatory requirements;
- Adapt its Quality Management System to the fulfillments required by the entry into force of MDR745/17 with regard to DMs and the maintenance of requirements from EU Directive 93/42/EEC;
- Enhance the professionalism of Employees and Collaborators;
- Motivate, empower and sensitize staff to QMS management and continuous improvement;
- Optimize the management of business management processes in order to increase the company's competitiveness and market opportunities;
- Maintain process efficiency at set standards and improve it if possible;
- Monitor customer satisfaction through appropriate methods established by management;
- Maintain proven reliability of suppliers;
- Disclose the Company Policy to enable its knowledge to those who wish to enter into a relationship with the company.

The Quality Policy will be revised when there are substantial organizational and/or operational changes in the company; in any case, it will be checked periodically, during the Management Review, to verify its congruence and correspondence with the company's QMS intentions and to ascertain its continued suitability.

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