



POLICY ON QUALITY

Rome, 25th February 2025

The General Management defines the Policy on Quality. It establishes goals and commitments, depending on business strategies towards the customers, the Market, the Owners and Employees of the Company, to implement, maintain and improve the performances of the Company Quality Management System, maintaining adherence to regulatory requirements and applicable regulatory requirements, including also voluntary and obligatory regulations related to medical devices (MDR 2017/745 – Medical Device Regulations) and to other marketed products as indicated in the Annex 3 to the Integrated Management System Manual, “*Normative References*”, periodically updated.

The Company Quality Management System, as described and defined by this document, should enable the compliance with commitments assumed by the General Management and it should enable the management of risks/opportunities assessed as significant by the management itself and for which the management system identified appropriate mitigation /improvement measures.

To this purpose, the General Management believes that the involvement of the whole staff Omikron Italia is essential for implementing Quality Management System, in order to achieve full customer satisfaction and to consolidate Company image on the Market.

The Mission of Omikron Italia is to answer in an exhaustive way to the therapeutic needs of patients affected by main vascular and eye diseases, especially those affected by glaucoma or diabetic retinopathy. Omikron Italia is a Pharmaceutical Company intending to be a partner for Specialists and General Practitioners able to ensure the highest satisfaction of Medical Class and Patients by providing innovative therapeutic tools (medicinal products, medical devices, nutraceuticals).

Innovative therapeutic tools, production technologies and specialization of Sales Representatives serving the Medical Class represent the philosophy of the Mission of Omikron Italia.

Sales Representatives introduce Omikron Italia products and scientific Literature to General Practitioners, Ophthalmologists and Vascular Specialists in accordance with the Corporate Ethical Code, AIFA and Ministry of Health laws.

Technical and scientific training of the Sales Representatives is a key instrument of Omikron Italia.

Omikron Italia, through its business activities, also assumes a serious responsibility, even ethically, towards patients. For this purpose, the Company is committed to making every effort

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Omikron Italia s.r.l.

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in the field of Research, to develop therapeutic and scientific solutions to ensure the highest satisfaction of Medical Class and Patients.

To find and maintain a leading position in the National Market, and continue to obtain further international market shares and to and to achieve satisfaction of Medical Class and Patients, Omikron Italia is continuously engaged in the following activities:

- to plan, develop and market new products, more and more innovative, designed and manufactured specifically to meet therapeutic needs of patients and physicians, anticipating their expectations and providing useful and effective solutions.
- to increase the number of the Sales Representatives to ensure an increasing uniform coverage of the whole national territory.
- to train and update Sales Representatives on findings of scientific Research, on new active ingredients and Company products.
- to speed up products distribution through most innovative and reliable technical tools, thus increasing the organization.
- to constantly assess all information relating to the safety of medicines/drugs of which Omikron Italia is the MAH and to ensure, for all its medicines on the market, a favorable risk/benefit ratio for the population.
- to continuously evaluate all information relating to the safety and performance of medical devices through the acquisition of feedback (positive and negative) from the market and the application of a post-marketing surveillance plan.
- to develop partnerships with foreign distributors to increase their market shares.

To fulfill its own mission, Omikron Italia aims to:

- develop and maintain effectiveness of the Quality Management System as a tool to achieve goals, fulfill commitments, promote continuous improvement of business processes, ensure compliance with regulatory requirements for products and related services, ensure continuous improvement of the organizational skills for Omikron staff.
- comply with legal requirements concerning Medical Scientific Information ordered by the Legislative Decree n° 219/2006 by integrating its business management system with Farindustria Guidelines and Ethical Code;
- comply with the ethical principles, norms and general standards of conduct drafting of the Company Code of Conduct, an element on which the Organization, Management and Control Model, which the Company adopted in accordance with Legislative Decree 231/2001 and its subsequent amendments and additions;
- adopt a Risk-Based Thinking approach for business management and for strategic changes of the organization;
- adopt an integrated risk management system for product safety, in order to ensure minimal residual risk about all manufactured products by providing a policy of risk management appropriate to the different hazard of products;

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- implement an appropriate pharmacovigilance system, designed according to requirements of the applicable regulations and maintained by qualified professionals, in order to manage issues related to safety management of medicines of which Omikron Italia is MAH;
- promote the safe and effective use of its products, especially by providing timely information about safety of its medicines to patients, health professionals and public;
- contribute to the protection of patients and public health;
- focus all the attention and available skills to understand indications, suggestions and wishes of the Medical Class to meet physicians and patients therapeutic needs through Sales Representatives activity;
- focus all activities on patient therapeutic needs to provide increasingly innovative and effective therapeutic solutions in order to affirm a position of leadership in the Market;
- internationalize the Company to ensure distribution of its products in new Markets;
- consolidate the relationship with its partners in order to ensure to the Medical Class and patients effective, safe, reliable, products with competitive retail prices;
- undertake partnerships with new partners to ensure a constant growth of its products;
- provide products compliant with all requirements imposed by the applicable laws to ensure users safety and health;
- transmit correct knowledge and methodologies to the organization, so that everyone working in the Company is constantly able to provide the best expected service to the patient;
- ensure a high level of satisfaction to all Employees through the research of the highest loyalty and sense of responsibility;
- support staff and management in realizing its own individual attitudes, interests and predilections and in developing technical and organizational skills.

Carrying out its mission Omikron Italia is committed to:

- providing physicians and patients products and services that meet mandatory and high-quality requirements, demonstrating transparency and reliability, ensuring quality of products with competitive retail prices, through cost analysis and containment;
- achieving with suppliers successful partnership, in order to be an active part in defining performance and characteristics of the product, and providing necessary support to understand and define needs of the patient and regulatory requirements of the product;
- encouraging the spirit of initiative and professional growth of Employees, ensuring productive and good professional relationships and safe working environment in which everyone can be satisfied;

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- encouraging the growth of the Company, ensuring adequate profitability and financial stability, which are essential for the success of the Policy on Quality.

General Management

Dr. Cristiano Virno

Omikron Italia s.r.l.

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