

QUALITY POLICY

The mission of the Organization for the Quality is carried out through the continuous implementation of the following objectives:

- ensuring, with reference to the market and competitors, the continuous development and improvement of its products, in compliance with essential requirements of MDD 93/42/EEC (as amended by Directive 2007/47/EC), 21 CFR Part 820, Directive 2001/83/EC, 21 CFR Part 211, CD-MDR, Resolution - RDC no.16 of March 28, 2013 "Technical regulation of good manufacturing practices of medical devices and in vitro diagnostic devices" - ANVISA and applicable horizontal and vertical norms,
- responding promptly to new requirements of healthcare professionals and Regulatory Authorities,
- in a proactive way, develop and maintain a high level of attention to customer requirements in the implementation of its operational processes and decision in order to achieve an ethical and sustainable development,
- ensuring continuous personnel training,
- plan the processes to allow a proper planning of manufacturing activities, guarantee the timeline of the delivery to the customers applying cost in line both with the market and customers' expectations.

Quality objectives

To fulfill its mission and achieve the objectives, the management of FIDIA Farmaceutici S.p.A.

- provides and maintains an integrated Quality Management System in order to meet requirements of GMP, ISO 9001 and ISO 13485 for all types of products (medicinal products, APIs and Medical Devices),
- establishes and consolidates relationships of continuous and mutually advantageous cooperation with suppliers of materials, services, customers,
- ensures commitment, involvement and conscious participation of all members to organization's decision.

Monitoring, verification and reviewing of Quality Policy

At planned intervals are performed:

- review of the organization Quality Management System to ensure the suitability/adequacy, effectiveness of the system over time,
- management review in order to verify whether the Quality Management System has met the general objectives, otherwise to set new targets and to review Quality Policy, considering possible changes in the economic and social field in which the organization operates.

Top Management with all Managers and personnel is committed to promote the diffusion and awareness of the Quality Policy by using all means of corporate communication.

Abano Terme, May 31st 2018

Chief Executive Officer

Dr. Carlo Pizzocaro

