



## **Declaration of Management Quality Policy**

Main objective of GALENTIS S.r.l is to develop its activity as producer of fine chemicals and intermediates for the pharmaceutical industry in compliance with current regulations regarding the products quality, in compliance with the UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016 standard.

The Quality Manual describes the structure, organizational relationships, management methods and responsibilities related to the preparation and implementation of the Quality Management System of Galentis S.r.l., for all activities related to its production.

The Top Management makes known the quality objectives through this document and through the Managers, specified in the company organization chart.

The Top Management aim is to ensure that the Quality Policy is suitable for the company's purposes and for the continuous service improvement offered to the Customers. The Top Management has established objectives and processes necessary to provide results in accordance with the Customer requirements, with the organization policies and in compliance with the laws. In addition to carrying out these processes, it is necessary monitoring over the time and measure processes and products against the policy, same objectives and requirements related to the products, reporting the results. For this reason, each Manager is required to use graphs, statistics and/or anything else necessary to review and verify the improvement degree over a period between a Management Review and the next (one year). An intrinsic commitment of the Quality Policy and of the whole company's organization is to adopt actions to continually improve the processes performance.

The implementation of the Quality System is a commitment fully shared and approved by the Top Management and by the Management apparatus of Galentis S.r.l.

For this aim, the Top Management has made available the resources necessary for the application and compliance with the Quality Policy. In particular, the Top Management ensures the continuous training of personnel according to the Training Plan and constantly stimulates the personnel awareness in their duties and in compliance with the procedures.

Each Manager identified in the Quality Manual has the direct responsibility for carrying out the provisions of the Manual, related to the area or service in which it operates. Quality Assurance has full responsibility and authority to ensure compliance with the provisions of the Manual. Quality Assurance has the full responsibility and authority to ensure compliance with the provisions of the Manual; he will directly refer to the Top Management for any problem concerning the quality that he cannot independently solve throughout the organizational structures described in the Manual. Quality Assurance is responsible of contents, update and distribution of Quality Manual.

The Top Management has adopted an Ethics Code and the personnel have been trained and are aware of their responsibilities. This code is an integral part of the Organization, Management and Control Model, which describes all the controls and rules adopted by the company to reduce the risk of incurring in the "presupposition offenses" envisaged by Legislative Decree 231/2001.

This Quality Policy is posted on the bulletin board so that the staff can see it and it is updated annually in the context of the Management Review.

Marcon November 11, 2020

Managing Director