QUALITY AND SAFETY POLICY

The Quality and Safety Policy sets out the general guidelines and directions relating to Quality and Safety expressed in a formal manner by the Top Management, in line with the overall policy of the company. Abiogen Pharma is committed to high standards and aims to continuously improve its products and services and its performance in terms of Health and Safety in accordance with its mission:

"Enhance its own know-how by specialising and partnering with other companies in the sector, in order to develop, manufacture and market targeted medical solutions in Primary Care and rare diseases, both in Italy and in the world, relying on a high level of competence and quality production to achieve excellence".

The company, as a testimony to its mission, relates to the expression:

EXCELLENCE, FOR EVERYONE.

Abiogen Pharma is committed to meeting all requirements applicable to the organisation, to satisfying customer needs by providing products (medicinal products, medical devices, supplements and foods for special medical purposes) of high quality and to the continuous improvement of its Quality and Health and Safety System. It also undertakes to:

- **Focus on the needs and expectations** of the relevant stakeholders in order to increase their satisfaction
- **Promote awareness of regulatory requirements** throughout the organisation and comply with all applicable regulations and requirements
- **Apply an approach based on processes, risk assessment** and **opportunities**, by constantly monitoring critical issues and opportunities for improvement
- **Ensure the suitability, adequacy and effectiveness** of the Quality, Health and Safety System by defining, revising and continuously monitoring the Quality, Safety and Health objectives
- **Ensure respect for the principles of social responsibility** by counteracting all forms of discrimination and gender differences in the workplace.

Abiogen Pharma has opted to comply with the following standards:

- ✓ **ISO 9001:2015** with regard to the "Development of medicines and conduct of clinical trials, manufacture, including contract manufacture, and sale and distribution of pharmaceutical products. Hospital tender management"
- ✓ **ISO 13485:2016** with regard to the "Design, development, manufacture, import and distribution of medical devices for intra-articular injection"
- ✓ **ISO 45001:2018** with regard to the "Development, manufacture and medical science information of pharmaceutical products and activities required for manufacture"
- ✓ **Medical Devices Regulation (EU) No 2017/745 (MDR)**
- ✓ **DTR Farmindustria certification** for Scientific Information on Medicines

OUR COMMITMENTS

Improve our performance in terms of both health and safety aspects and satisfying customer needs by providing products (medicinal products, medical devices, supplements and FSMP) of high quality

Recognise that having an Integrated Quality, Safety and Health System, based on continuous improvement, is essential to achieving leadership in the pharmaceutical industry

Engage all personnel, also through their Safety Officers, in order to achieve the objectives and appoint competent and qualified personnel to carry out the activities relevant to product quality

Promote stakeholder engagement and systematically evaluate the dynamic setting as an opportunity for ongoing performance improvement

Implement measures to ensure that contractors working at the site on behalf of Abiogen Pharma operate in accordance with the principles of Safety, Health and Environmental Protection

Ensure a safe workplace and appropriate health surveillance for workers

Protect the Health and Safety of all parties by continuously improving performance and providing safe and wholesome working conditions in order to prevent occupational injuries and illnesses

Remove hazards and reduce risks to Workers' Health and Safety

Assess in advance the impact on Workers' Safety and Health of all new activities, products, processes and productivity

Promote information, education and continuous training of personnel both to maintain high levels of product quality and to protect Health and Safety as a moral duty towards themselves, their colleagues and the community

OUR BELIEFS

Responsibility in the management of Quality and Health and Safety in the workplace concerns the entire company organisation, from the Statutory Employer down to each Worker, each according to his or her duties and skill sets, in order to consolidate the culture of individual and collective behaviour required to fulfil their responsibilities.

ACTING TOGETHER TO WORK WELL

All employees are actively responsible for integrating Quality and Health and Safety principles into all their tasks. The Management and Executives are committed to ensuring that the resources required to promote, support and implement Quality and Health and Safety Management activities are duly allocated. The Top Management is responsible for setting targets, rating performance and evaluating results with a view to continuously improving Quality and Safety and Health performance.

Mr Massimo di Martino
Managing Director

Ospedaletto - Pisa, 1 February 2024