



QUALITY AND ENVIRONMENTAL POLICY



MISSION	Solutions for better health
VISION	To provide the best partnership value and experience in health business
CORE VALUES	Innovativeness, solutions-focused, optimism
OUR BUSINESS	Medical devices, veterinary medicines and other health care products

We provide professional and value adding customer partnership based on developing, registration, manufacturing services and life-cycle management in order to produce safe, high quality and effective health products. The purpose of the Management System is to satisfy our stakeholders, thanks to the compliance of all the requirements specified by the legislation, regulations, ethical and sustainable principles, and customer needs. The Management System strongly supports sustainable development by continuously improving, reducing and preventing any ecological damage caused by our processes.

All activities, procedures and documentation of Galena Pharma's Management System comply to the following legislation and standards:

- EU Medical Device Regulation (MDR 2017/745)
- EU GMP guidelines
- ISO 9001:2015
- ISO 13485:2016
- ISO 22716:2015
- EU Food Legislation
- ISO 14001:2015

The Management of Galena Pharma undertakes to meet the general objectives:

- Commitment to comply with the legal requirements that are applicable, in addition to complying with the stakeholders' requirements.
- Commitment to set strategic targets and monitor them in the Management Reviews.
- Commitment to maintain the effectiveness and continuously improve the Management System implemented, based on e.g., audits, inspections, stakeholder feedback and management reviews.
- Commitment to effectively manage all our activities, with special emphasis on the quality and safety of our products, their maintenance and continuous evolution.
- Commitment to promote an understanding and implement the Management System within our organization, through continuous training and communication with our employees.
- Commitment to expect responsible and high-quality actions from all of our partners.
- Commitment to prevent pollution e.g., by minimizing our CO₂ emissions and amount of waste generated, increasing the efficiency of waste recycling and using responsibly produced energy in our operations.

All employees are obligated

- To follow Galena Pharma's procedures and instructions.
- To suggest improvements.
- To evaluate and inform about the risks and deviations observed in the work.