



QUALITY POLICY



QUALITY POLICY OF GALENA PHARMA

Galena Pharma (henceforth Galena) develops, manufactures and delivers pharmaceuticals, medical devices and other health products that are high quality, efficient and safe throughout the entire lifecycle of the product. Galena responds professionally to its customers' needs, expectations, and wishes. We are a trusted business partner committed to being fair and honest. We fulfil what we agree upon and offer top-notch expertise - in the best interest of our customers.

Customers and other stakeholders, such as supervisory authorities, perceive us as a reliable, responsible and approachable partner. We receive feedback with pleasure and employ it to improve our operations. Galena is committed to following the principle of continuous improvement that aims at constantly reviewing, evaluating, improving and developing the company's goals, products, services and processes.

Our operations are compliant with regulations, legislation and ethical principles. All our processes follow EU GMP guidelines and standards ISO 9001:2015, ISO 13485:2016, ISO 14001:2015 and ISO 22716:2007. We meet the requirements of the Medical Device Regulation (MDR Regulation (EU) 2017/745).

To ensure the high quality, efficacy and safety of our products:

- Our employees are knowledgeable and qualified.
- Our staff is committed to following the quality system.
- The quality management system includes a comprehensive standard operating procedure and working instruction system.
- We continuously monitor our operations and product quality.
- We conduct risk assessments professionally and regularly.
- We react quickly to deviations and disturbances.
- We regularly evaluate our own and our material suppliers' operations.
- We expect responsible and high-quality actions from all of our partners.



MISSION

To deliver value driven development and manufacturing services through responsible and sustainable practices.



VISION

To become a global manufacturer with a trusted brand and pioneer reputation.



VALUES

Innovation, Solutions focused and Optimism