

QUALITY POLICY



QUALITY POLICY OF GALENA PHARMA

Galena Pharma 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 Pharma responds professionally to the needs, expectations and wishes of its customers. We are a trusted business partner committed to being fair and honest. We commit to what we agree upon and offer high quality expertise — in the best interest of our customers.

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

Our operations are based on compliance with regulations, legislation and ethical principles. The manufacturing process, quality assurance and management system are guided by EU GMP guidelines and standards ISO 9001 and ISO 13485. We meet the requirements of Medical Device Regulation (MDR). Additionally, our operations take into account the EU GVP guidelines governing the pharmacovigilance system.

To ensure high quality, efficient and safe 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 monitor the operations and product quality continuously.
- We conduct risk assessments professionally and regularly.
- We react quickly to deviations and disturbances.
- We evaluate our own and our material suppliers' operations regularly.
- We expect responsible and high-quality actions from all of our partners.