

QUALITY POLICY

HEMOFARM AD

By establishing, implementing, documenting and maintaining the quality management system, we in Hemofarm undertake, as an obligation, to meet the requirements of our users, through development and production which complies with the highest, globally recognised standards which pertain to pharmaceutical industry.

Our quality management system for manufacturing and trade of medicines, medical devices, dietary supplements and manufacturing of plastic pharmaceutical packaging materials is based on all applicable legal requirements, guidelines and standards and specifically on:

- Guidelines for Good manufacturing (GMP) and Good distribution practice (GDP) for medicines,
- Requirements for ISO 13485:2016, MDD Directive 93/42 / EEC for which is underway period of transition to the regulation MDR 2017/754 and all national and international regulations requirements and guidelines applicable of medical devices produced by Hemofarm,
- ISO 9001:2015 standard principles.

We observe and implement all requirements of national and international regulations and guidelines which regulate the areas of development, registration, production, quality control, and trade of medicines, medical devices and dietary supplements, as well as the requirements and provisions of all agreements with local and international partners.

We meet legal requirements and requirements of users, owners, employees, contractual partners and society in general by maintaining and constantly improving the quality management system.

Through creating and maintaining a high level of product quality, accuracy of delivery, through competitive approach to the market, and through securing timely and competent support, we lay foundations of our customers' trust.

We manage processes systematically, while applying risk analysis principles and we introduce all changes in a controlled manner.

We implement prevention, identification, research and reporting on non-compliances and undertake actions to eliminate all causes that can compromise safety, security and quality of products. We recognise and prevent any possible dissatisfaction of our customers and we respond to any complaint or misunderstanding in a timely manner.

We achieve desired results through optimal use of new technical, technological, human, and other resources.

Appropriate qualification level, broadening professional knowledge, improvement of practical experience and work on personal development of all employees are important factors of our success.

We review, check and constantly upgrade our quality system with the aim of improving the efficiency of the quality management system.

The principal task of each employee is to create such an ambiance in the company which would ensure maximum of motivation and dedication, which contributes to creation of good partnership relations with customers and suppliers.

Vršac, March 2022

CEO of Hemofarm A.D. Vršac