

JSC OLAINFARM QUALITY POLICY

JSC Olainfarm manufactures and delivers chemical products, active pharmaceutical ingredients, medicines (incl., investigational and veterinary drugs), medical devices and food supplements to more than 40 various countries.

We wish to build honest and constructive co-operation with our clients — patients, physicians, pharmacists, and co-operation partners.

We have committed to carry out our activities in a way that guarantees the highest quality of our manufactured products and provided services, thus fostering and improving our patients' health.

In order to achieve this commitment, our Quality Policy as the top priority is aimed at safety, effectiveness, and reliability of our products. The reputation and business aims of JSC Olainfarm are based on the following core principles and/or quality of provided services:

Management and support

Our shareholders and the senior management supports and promotes innovations, quality-focused culture with the relevant systems, processes and decision, measures to improve quality, continuous optimisation of the company's processes (automation), modernisation of facilities and infrastructure.

Our Quality Policy is an indispensable element in the positioning of JSC Olainfarm brand on the global market.

Quality system

Our Quality Assurance System is integrated in all activities and areas that can affect the product development, manufacturing, quality control and distribution.

On a daily basis, the management and staff of JSC Olainfarm respect the implemented international standards, incl., Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice, Good Pharmacovigilance Practice, etc., laws of the Republic of Latvia and the EU, and regulatory documents of JSC Olainfarm.

The efficiency of the Quality Assurance System is evaluated in external audits (by clients and competent authorities) and internal audits (self-inspection), client references and CAPA performance assessments; the results are summed up in a Quality Management Report pursuant to ICH Q10 Pharmaceutical Quality System requirements.

The system is based on continuous enhancement, process improvement and introduction of Best Practice Principles.

The procedure of how the Quality Policy of JSC Olainfarm is implemented is prescribed in the Rules of Procedure "Quality Assurance System".



Client focus

The management and the staff of JSC Olainfarm ensure that any feedback about the quality of products and/or provided services is investigated and every effort is invested to find out our clients' wishes and to meet their demands, in order to ensure compliance of product, manufacturing, and support processes to the requirements of our clients and competent authorities.

· Research and development

Our leading research specialists continuously and in co-operation with other scientific research institutions carry out focused work in enhancing the existing products, developing, registering, and introducing new innovative products in the market based on quality risk management principles.

Staff

With more than 40 years' experience in the manufacturing of chemical and pharmaceutical products, our team includes highly qualified, competent leading specialists with extensive professional experience. Our staff is motivated to achieve outstanding targets at work and to improve professionally.

Every JSC Olainfarm employee is responsible for the quality of our products and/or services provided, as well as for client satisfaction and patient safety.

Chairman of the Board

Board Member / Qualified Person

Director of Quality Management Department

V. Maligins

J. Borcova

V. Kiseļovs

08.06.2016