

## Company

One of the oldest pharmaceutical companies in the Baltic states specializing in generics mostly for the hospital segment. Over the years we have developed our main therapeutic medicine groups – anesthetics and analgesics, musculoskeletal system, central nervous system and cardiovascular system medicinal products. We are proud that we can help the society by providing them needed medicine which help alleviate and treat diseases.

AS Kalceks activities include finished dosage form development, registration, manufacturing and distribution in accordance with legal requirements, guidelines and market demand for certain pharmaceutical products.

We aim to make available high quality specialized pharmaceutical products and to be competitive in all markets by continuously developing and improving our product portfolio.

Growth and sustainability are integral parts of our strategy, guided by our core values of purposefulness, reliability, flexibility and responsive communication. By embedding sustainability in everything we do – from the lab to the patient – we are helping to strengthen good health and well-being.

## Products oversight

We are proud that our products satisfy the highest quality standards and contribute to a better life. This means that neither their development and manufacture nor their disposal should cause damage to people and the environment. For this reason, we strictly conform to regulations and laws all over the world.

### • Research and development

Drug development is a complex and time-consuming process and is subject to stringent rules. The safety and efficacy of our products is the top priority. AS Kalceks annually develops 10-12 new products, which ensure stable company growth. Currently the hospital segment line are being expanded with antibiotic and anti-infection medicinal products, as well oncological products. As the result of our in-depth market evaluation the most suitable medicines were outlined for our product portfolio.



### • Registration

To market products all over the world they have to be approved by competent authority. The strict international and local regulations and guidelines should be complied for application of marketing authorization. The prescribed efficacy and safety of each product must always be demonstrated as proven as a condition of their marketing authorization approval. Any changes relating to the product requires an additional authorization or variation approval.

We have gained experience through different product registrations in most part of the Europe, Canada, Australia and even in more exotic countries like New Zealand, Malaysia and Singapore.



## • Manufacturing

AS Kalceks product production are ensured by contract manufacturing organizations (CMO) mainly in Europe. Manufacture of pharmaceutical products are subject to very strict quality requirements. The quality management system is based on internationally recognized standards and applicable legal and regulatory requirements. All CMO complies with the standards of Good Manufacturing Practices (GMP), ISO certifications and the guidelines of the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use). From complex requirements to tight production schedules, we along with our CMO faces stubborn obstacles in ensuring that it improves the wellbeing and health of humans while not harming the planet.



Internal experts and external assessors regularly conduct risk-based audits to verify compliance with the statutory requirements and relevant standards in production. In addition to the internal quality assurance mechanisms, all our sites are regularly inspected by the health authorities of the respective countries to verify compliance with the various national and international requirements and certified according to the respective product category (e.g. through GMP certificates or in the form of an official producer permit).

## • Supply chains

Kalceks works with many suppliers around the world for the materials and services we need to produce and distribute our products. Every supplier has been assessed to evaluate compliance with the guides and requirements and approved before implementing in the product life-cycle. Managing these supplier relationships and the flow of goods and services through our value chain is critical to the sustainability, quality and safety of our medicines — and the well-being of our patients — by ensuring continuity of supply. To ensure the continuity of the products the alternative manufacturers of active pharmaceutical ingredients, as well as alternative manufacturing sites are approved for the products. We expect our suppliers to also observe the sustainability-related principles and we support them in doing so. Through this approach we help to improve the sustainability of our supply chain.



For transportation and storage we have procedures in place that ensure that materials are handled, transported and stored according to the relevant regulations and that suitable logistics and warehouse suppliers are selected.

Product distributions are focusing on B2B activities, pharmaceutical wholesalers in most cases are Kalceks direct cooperation partners. We strive to provide medical information in an accurate, fair and balanced way through appropriate channels, and the promotional materials are prepared in accordance with the guidelines.

## • Protection against Product Counterfeiting

Product counterfeiting is an enormous problem worldwide. The Falsified Medicines Directive of the European Union specifies requirements and measures for the verification of the medicines. This includes mandatory security features on external packaging, which Kalceks has used for its prescription products since 2019. These data matrix codes are stored in country-specific databases across the EU. Wholesalers and pharmacies can verify the products' authenticity by simply scanning the code.



## • Product safety monitoring

Our medicines need to be effective in treating the respective disease, while posing as little risk as possible to patients. Therefore, we consistently monitor risks and adverse effects that may arise and take the necessary actions to minimize them. AS Kalceks complies with all required legislation of pharmacovigilance and ensures its effectiveness and continuously maintained. Based on the conditions of regulatory approval, we develop and update educational materials for patients and healthcare providers to communicate any known and potential risks and ways to minimize them for newly approved products.



## Ethics

Our core values – purposefulness, reliability, flexibility and responsive communication - guide us in our daily work defining how we interact with our customers and business partners. We do our business activities to adhere to relevant regulations and ethical standards around the world. We are aware that our company operates in a complex legal environment and incurs various tax obligations with its domestic and foreign business activities. It is our responsibility to ensure compliance with tax legislation in all countries in which we operate and to be transparent.



We are committed to providing a healthy and safe working environment and are embedding a safety, health, and environment culture across the whole organisation

Training and education is an important part of our company's ethics. New employees receive all relevant trainings to an employee's position.

All our results give the whole Kalceks team a strong stimulus, confidence and belief in the company strategy, which has clear and correct action implementation plan. Each member of the Kalceks team individually and whole team together are keen to achieve more than yesterday and we look forward to what might be next potential development "step".

The happiness and engagement of our people is fundamental to our success. To maintain healthy culture in all of Kalceks' employees every year participated in the survey where that share how happy they are to be working at Kalceks.

## Environment

The climate emergency is an environmental and public health crisis. We have an opportunity to 'reset' and create a more sustainable world for people and the planet together.

AS Kalceks as pharmaceutical company without own manufacturing sites, incorporates the green values for everyday office life, as example, waste recycling. Our logistics team also accurately plans product deliveries in order not to organize useless transportation activities. We also ensure that disposal of unused medicines strictly complies to legislation.

We aim to deliver our products in packaging that is safe and easy for customers to handled. We are working on for employing more eco-friendly materials for secondary packging.

Our contract manufacturing organizations are covered by ISO 14001 certificate to comply with environment standards and to establish processes on improving efficiency in manufacturing of products to protect our climate and environment.

