karo®
pharma

Smart choices for everyday healthcare

Quality Policy

Karo Pharma (Karo) wants to fulfil its purpose of delivering smart choices for everyday healthcare in the most responsible way – towards society, people and the environment.

Our Quality Policy describes how Karo works with its Quality Principles and how the company strives for improvement and high-quality products to our consumers and patients.

Karo shall be a reliable supplier of quality products and services, meeting regulatory requirements and the needs of end-users, our customers and professional partners.

Quality is ensured throughout our value chain by quality management systems, continuous improvement and a highly qualified staff.

Quality Principles

The quality policy outlines the quality in Karo and the development and continuous improvements of quality in the organization. The policy is established on the organizational setup of Karo as a company with outsourced production and warehousing.

Realization of the Quality Policy is managed on a yearly basis by setting the quality objectives. The quality objectives in the organization is in accordance with the business objectives established by the management team. This is to ensure quality in-line with the development of the company, as well as keeping the Quality Management System (QMS) effective.

The Quality Policy is established by the management team and communicated throughout the organization. The Quality Policy and its objectives are reviewed by the management team; this is included in the yearly review of the QMS.

The business and quality objectives have continuous focus on the quality and business control of our suppliers.

The management team of Karo is dedicated to allocating resources for this control and the resource management is also reviewed in the Management review.

Management Responsibility

Quality is an integral part of our business objectives and this quality is ensured by the Quality Management System (QMS), which is supporting the established processes within the company.

The requirements as stated in the scope of the QMS are the framework for our daily business:

- We uphold the highest ethical standards in conducting our business. For the design, development and production of our products we keep safety and reliability as its most important priority and work according to the applicable regulatory requirements. All Karo's products are developed and formulated with the objective of providing our customers with quality, high performance and safe products while striving to minimize any negative impact on the environment. All raw materials used in Karo's products marketed globally are fully compliant with the latest cGMP-, medical device-, cosmetic-, and functional food regulations in the European Union, USA and other major/relevant international markets.

- We aim for the delivery of products and services that satisfy the needs and demands of our clients and that are following the regulatory requirements.
- All pharmaceutical products marketed by Karo are produced in accordance with GMP, a standard, which controls the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale. These suppliers are subject to regular inspections and audits by regulatory agencies as well as by Karo.
- Karo is ISO 13485 certified for Medical Devices, an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. The certification requires Karo to comply with regular third-party audits.
- We strive to create a company environment in which the state of our operations, systems, work conditions and capabilities are continually improved. We guarantee that enough resources are available for the implementation of our Quality Management System, regulatory and customer requirements and maintenance of effectiveness of the Quality Management System. We therefore organize management review meetings and internal and supplier audits to verify correct development and implementation of the QMS and its effectiveness via the status of our quality objectives.
- We establish and maintain employee quality awareness (incl. Quality Policy) via training and day to day communication. Every employee shall, supported by the organization of the company, also guarantee the quality of his/her own work, because he/she knows our products are used for medical purposes. Due to their commitment to quality it is possible to supply products and services that fulfill the requirements and wishes of our customers.
- We maintain quality via effective partnerships with our critical suppliers and subcontractors, who are a key element in our ability to deliver safe products to the medical community. We select and qualify our suppliers/subcontractors based on proven medical technology capabilities and commitment to our Karo Pharma Supplier Code of Conduct and our Quality/ Health & Safety/ Environment & Sustainability Policies as well as current Regulations. We establish and maintain quality awareness at our critical supplier by i.e. additional training, follow up meetings and reviews.
- We continuously seek improvement of the QMS and performance related to the quality, environment, health and safety area and encourage participation of relevant employees in this improvement effort.

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