Quality Assurance and Regulatory Affairs
Quality management is an essential part of your company’s management system. Effective and functional quality management system improves the productivity of your company and is a way to keep your operations transparent to your customers and partners.

Quality Management System enhances the performance of operations and improves customer service and satisfaction. It enables the maintenance of high quality of products and services and in the best case, increases sales. In several industries, the requirements for Quality Management Systems are statutory.

Quality Assurance and Regulatory Affairs

BY BUILDING AN EFFECTIVE QUALITY MANAGEMENT SYSTEM WE HELP YOU TO ACHIEVE YOUR FINANCIAL AND OPERATIONAL OBJECTIVES.

The cornerstones of Kasve’s success

- Throughout understanding of effective quality management
- Experience in quality management of different kinds of organizations
- Knowledge of the requirements of the legislation in the healthcare field
- Understanding the registration process in both pharma and medical device sectors

PROMISE - KASVE WILL ALWAYS RESPOND TO ALL QUESTIONS AND REQUESTS WITHIN 24 HOURS

Our clients, our heroes
Kasve Quality Assurance and Regulatory Affairs services include:

QUALITY MANAGEMENT SYSTEM AUDITS AND EVALUATIONS
Our experts execute pre-evaluations of the quality management system and compile action plans to develop or to improve your quality to your target level (for example, certification or accreditation). We are experienced in fulfilling the requirements of the following standards:

- General Quality Management: ISO 9001
- Medical Devices: ISO 13485, ISO 14971, IEC 62304
- Laboratories: ISO 17025, ISO 15189, CLIA (US), CAP (US)

We also provide medical device audits (QMS, technical documentation).

ESTABLISHMENT OF QUALITY MANAGEMENT SYSTEM
Kasve builds the quality management system together with your personnel. QMS is designed to be compliant with the required legislation or standards while keeping the lean principles in mind.

REGULATORY AFFAIRS
Kasve is your partner in medical device regulatory affairs, starting from the regulation strategy all the way to the actual registration activities and placing the CE-mark to the product.

OUTSOURCED QUALITY MANAGER
KASVE QUALITY MANAGER tasks are agreed based on customers’ needs and may include, for example:

- Quality management system implementation and training
- Maintenance and continuous development of the quality management system
- Handling of deviations, coordination and follow-up of corrective and preventive actions (CAPA)
- Coordination of internal audits, participation to external audits
- Coordination of certification or accreditation of the quality management system

Benefits of an outsourced Quality Assurance

- Experienced quality assurance
- Streamlined and efficient internal and external functions of your company
- Improved competition position
- Your personnel can focus on their main tasks
Kasve is healthcare expert with substantial expertise in research and development, supply chain management, quality assurance and business development.