

## Reliability Assurance System (KM Biologics Co., Ltd.)

### General Rules for Quality Management (Quality Manual) and Quality Initiatives

We strive to ensure the reliability of not only the product itself, but also the data collected during the product development and the information we provide on proper use after marketing. The pillar underpinning these efforts is the General Rules for Quality Management, otherwise known as the Quality Manual.

As a pharmaceutical company, we have established the Quality Policy, a basic policy created in order to contribute to society through ensuring the reliability of products, information, and documents we provide. Under the Quality Policy, we have also established the General Rules for Quality Management/the Quality Manual and are working to ensure reliability in all our activities, from the development and manufacturing to marketing of our products, including the provision of information on their proper use and post-marketing safety management.

There are national standards with which all pharmaceutical companies must comply. Based on these standards, we have established documented in-house standards and standard operational procedures. We strive to improve the reliability of our products, data, and information throughout activities such as product development, manufacturing, marketing, information provision, and post-marketing safety management adhering to the documented in-house standards.

### Quality Management Structure



The Reliability & Quality Assurance Division inspects and guides other divisions in terms of compliance with the standards and policies established under the General Rules, thereby wielding the reliability assurance system. The Reliability & Quality Assurance Division is an independent division from the Research & Development Division, Production Division, and Pharmaceutical Sales Division, which enables us to create a system that ensures reliability from an objective standpoint. Furthermore, in order to not only ensure but also improve reliability, we have established the Operational Rules of Quality Management Review as a system for continuous improvement through the activities with PDCA cycles.

The Operational Rules of Quality Management Review stipulate that, in order to improve reliability, the management drives periodic reviews of achievement status of the quality goals set by each division and promotes continuous improvement of quality by the use of PDCA cycles.

