SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc. continuously manage the safety and efficacy of its products, which are directly linked to enhancing health and improving quality of life of customers, in accordance with the stringent regulatory requirements of individual national governments.

In particular, product safety and quality are managed in compliance with the relevant regulations and guidelines of the Korean Ministry of Food and Drug Safety (MFDS), the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The product safety and quality management is implemented under the Quality Management System (QMS) of SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc. As part of a continual quality improvement strategy, it is planned to integrate and apply into the system the product quality and safety related policies of the countries where the products are released and to be released and expanded in the future.

These activities will enable to upgrade the existing Product/Service Safety Accident Prevention and QMS, and the relevant policy improvement will allow a more and more progressive implementation and operation of the System.

1. Product/Service Safety Accident Prevention Policy and Quality Management Policy

Every products of SK Biopharmaceuticals Co., Ltd. (all products under the management responsibility of SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc.) is managed under the strict Quality Management System (QMS), which also provides oversight of raw materials management, production, quality control in analytical laboratory, storage, transportation, clinical studies and management of adverse event. For purposes of QMS, Quality Policy is established pursuant to the individual national government regulations and guidance. Then, the Standard Operating Procedures (SOP) is established and developed to indicate the necessary and appropriate activities for each policy item. More detailed Work Instructions are created to perform the established SOPs.

1.1. Establishment of the Harmonized Global Quality Policy

Quality Assurance Teams both SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc. are built a plan and execute to continuously develop and improve the product quality management as well as the Quality Management System (QMS) implemented to this end.

Both companies integrated their respective Quality Policies into the Harmonized Global Quality Policies that are comprehensively reflected the regulations of the Korean Ministry of Food and Drug Safety (MFDS), the U.S. Food and Drug Administration

(FDA) and the European Medicines Agency (EMA) and other agencies throughout the globe since 2021. Those Harmonized Global Quality Policies were completely established on 2021 and have executed and used as of 2022. The newly established Harmonized Global Quality Policies will be distinctly upgraded and more extended in advanced the existing Product/Service Safety Accident Prevention and Quality Management System.

1.2. Pursuit of a Continual Quality Improvement and Enhancement

SK Biopharmaceuticals Co., Ltd. has not only currently established and used the Harmonized Global Quality Policy, but also is establishing mid- & long-term plan for advanced digitalization of Quality Management System (QMS) to meet Global Quality 4.0 trend. Both companies of SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc. will always strive to make every effort to effectively manage the product quality to ensure quality improvement and enhancement, yielding not an inch when it comes to the product quality.

In order to offer a happy life, good health and safety to customers, SK Biopharmaceuticals Co., Ltd. will always endeavor to more improve its Quality Management System (QMS) to a global level, to retain responsibility and trust as a global pharmaceutical company, and to sustain an unflagging and thorough quality management.