In 2022, Quality Assurance Departments at SK Biopharmaceuticals Co., Ltd. (the Company) and its subsidiary SK Life Science, Inc. has established integrated global quality policies in accordance with the internal plan to continuously improve product quality management and Quality Management Systems (QMS). In addition to the operation of the QMS, Company's goal is to ensure that product quality is managed internally through the Company's contracted manufacturing organizations (CMO) which are periodically assessed and monitored through internally established and standardized quality metrics to prevent quality/service safety accidents and to reinforce quality management. The CMO assessment results including the overall QMS status and quality metrics are reported to the C-Level management.

- ❑ Implementation of the Company's Quality Management Policy

  : Quarterly reporting to the C-Level management at the Quality Management Review Meeting

  - Participants: C-Level management and relevant team leaders
  - Meetings in 2022: April 22, August 23, November 8
  - Meetings in 2023: February 22, May 30, August 24
  - Overall operating status regarding the quality management system and the quality metrics of CMOs are collected and assessed on a quarterly basis, results of which are reported and reviewed at the meeting at the end of each quarter. The identified actions for improvement are actively implemented for further enhancement of quality management system.

❑ Status of quality management monitoring

The Company and SK Life Science, Inc. are periodically monitoring quality and safety related events, results of which are shown in the table below. In addition, continuous monitoring and advancement of relevant systems are pursued to achieve zero quality related safety events.

[Current Status] – 2022

	Jan. 2022	Feb. 2022	Mar. 2022	Apr. 2022	May 2022	Jun. 2022
Recalls or violation of product safety	0	0	0	0	0	0

	Jul. 2022	Aug. 2022	Sep. 2022	Oct. 2022	Nov. 2022	Dec. 2022
Recalls or violation of product safety	0	0	0	0	0	0

[Current Status] – 2023

	Jan. 2023	Feb. 2023	Mar. 2023	Apr. 2023	May 2023	Jun. 2023
Recalls or violation of product safety	0	0	0	0	0	0

	Jul. 2023	Aug. 2023
Recalls or violation of product safety	0	0

❑ Mid-to Long-term Roadmap for the digital advancement of Quality Management System (QMS)

The Company has established a mid-to long-term roadmap to advance digitalization of IT-based QMS aligned with the Global Quality Trend to continuously achieve zero product quality and safety related incidents.

In accordance with the mid-to long-term roadmap up to 2030, the Company will progressively establish an advanced digital platform and enhance the capabilities of the Company's QMS in alignment with the latest international regulations and industry trends.

- **2022~2023**: Completion of introduction of EDMS (Electronic Documentation Management System) & LMS (Learning Management System)
- **2023~2024**: Completion of introduction of E-QMS – Deviation, CAPA (Corrective Action and Preventive Action), Change Control
- **2024~2025**: Stabilization of EDMS/LMS/E-QMS and overall enhancement of related Quality Systems
- **2025~2027**: Completion of introduction of QMS module expansion (Complaint, Recall, Audit)
- **2027~2030**: Additional module expansions (if necessary) and completion of the digital advancement of IT-based QMS