

Category	Product/Quality and Safety Management Principles	Product/Service Safety Accident Prevention and Quality Management System	Revision Date	2022.12
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Last year Quality Assurance Teams of SK Biopharmaceuticals Co., Ltd. (SKBP) and its subsidiary SK Life Science, Inc. established the consolidated global quality policy in accordance with the internal plan aimed at the continuous improvement and advancement of product quality management and the associated Quality Management System (QMS). To upgrade and optimize practicality of SKBP's existing QMS management, to prevent quality/service safety events and to reinforce quality management, quality of SKBP's contracted manufacturing organizations (CMO) were periodically assessed through standardization and monitoring based on the newly established quality metrics. Assessment results including the overall QMS operation status were reported to the management.

Execution of SKBP's Quality Management Policy

; Reporting to the management at the quarterly Quality Management Review Meeting

- Participants: management and team leaders of the relevant divisions
- Meetings held in 2022: April 22, August 23, November 8
- Overall data regarding the operation status of 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 concerned quarter. The identified actions for improvement are actively implemented for further enhancement of quality management.

Status of SKBP's quality management monitoring

; SKBP and its subsidiary SK Life Science, Inc. are periodically monitoring quality related safety 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]

	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
Recalls or violation of product safety	0	0	0	0	0