The Aseptic Product GMP Committee

January 2026

CHAIRPERSON	Yasuhito Ikematsu, The University of Osaka
VICE-CHAIRPERSON	Mitsuo Mori, Kyowa Kirin Company Limited
VICE-CHAIRPERSON	Chikako Yabuki, Merck Ltd.

OVERVIEW

The Committee's primary mission is to provide information and educational programs on technologies and regulatory science related to the development, manufacturing, and quality control of healthcare products, with a focus on sterile pharmaceuticals and ATMPs (including regenerative medicine products). We also actively engage in research collaborations that contribute to regulatory harmonization and development of guidelines in Japan and abroad.

THE CHAIR'S MESSAGE

Sterile medicinal product quality and ATMPs are directly linked to patient safety and public health. As technological innovation accelerates and regulatory expectations continue to evolve, the need for scientifically sound, practical knowledge and internationally aligned perspectives has never been greater.

Since its establishment in 2004, the Committee has been committed to advancing the science, regulation, and education related to sterile product manufacturing and quality management. Our members represent diverse areas of expertise and work together to analyze emerging regulatory trends, conduct practice-oriented research, deliver high-quality education programs, and engage in constructive dialogue with domestic and international regulatory authorities. Through these efforts we strive to contribute to the enhancement of quality culture across the industry.

We place strong emphasis on scientific rigor, transparency, and practical applicability. By addressing challenges at the *"Genba*"* and exploring sustainable approaches to implementation and control, we aim to support the continuous improvement of manufacturing and quality systems. We are also dedicated to fostering the next generation of professionals and ensuring the effective transfer of knowledge and experience.

Moving forward, we will continue to strengthen collaboration among industry, academia, and regulatory bodies and promote scientific and globally harmonized approaches to ensure that safe, high-quality products reach patients.

We sincerely appreciate your continued support and engagement as we pursue these initiatives.

* Genba: Japanese for "operational site"

OBJECTIVES

To ensure the quality of sterile medicinal products and ATMPs and to enhance patient safety, we aim to contribute to the scientific, effective, and rational development, manufacturing, and quality management of these products through the following activities:

- Providing scientific and technical input to the development and revision of relevant regulations and guidelines

・Analyzing the latest regulations and guidelines and delivering clear, practical interpretations for industry applications

・Researching manufacturing and quality control of sterile medicinal products and ATMPs in accordance with relevant regulations and guidelines, utilizing the latest technologies, and disseminating insights and recommendations for effective implementation and control

・Applying the outcomes of research and surveys to education and cultivation of human resources through training courses and workshops

ACTIVITIES

Our research and survey activities are organized into six research groups and an associated subcommittee (including two research groups), addressing a wide range of issues related to the manufacturing and quality control of sterile products.

The outcomes of these research groups are shared broadly with industry professionals, regulatory authorities, and related organizations through our training courses, workshops, and symposiums on aseptic manufacturing and regulatory science.

Additionally, we actively provide information and support to domestic and international regulatory authorities and related institutions on regulations and guideline-related matters.

★ RESEARCH GROUPS (RGs)

● RG-1：Container Closure Integrity Testing

For sterile medicinal products, qualification of the barrier function against microorganisms must be demonstrated throughout the lifecycle of the product, and effective container closure integrity management is a key control element.

In recent years, descriptions of gas barrier functionality have been added to both USP<1207> and the general information section of Japanese Pharmacopoeia 18 (JP 18). Additionally, PIC/S GMP Annex 1 has expanded its guidance on Container Closure Integrity (CCI) testing. As a result, regulatory requirements for controlling CCI of parenteral products are becoming increasingly stringent. However, a single test method cannot be applied to all products. Therefore, it is essential to select an appropriate testing method based on a product's characteristics, considering both feasibility and reliability.

This research group identifies factors that can compromise CCI and assesses their impact on contamination risk and examines effective strategies to maintain closure integrity.

● RG-2：Visual Inspection of Injectable Products

This group conducts research on insoluble particulate matter in injectable products, intending to standardize assurance methods that meet Japanese market requirements, with the aim of future international adoption. Although inspection methods have been harmonized between the Japanese, European, and United States pharmacopoeias, the criteria for acceptance remain ambiguous, being only defined as "injectable products must be free from readily detectable foreign insoluble matter."

In Japan, where quality requirements tend to be stricter, products manufactured overseas often require additional visual inspection upon import. In response this research group developed a standard ampoule kit and, based on the results of trial studies conducted in collaboration with

multiple companies, quantified visual inspectors' detection capability. As a means of standardizing evaluation methods, the Japan PDA Pharmaceutical Society launched the *Visual Inspection of Insoluble Particulate Matter in Injectable Products: Training System for Certified Supervisors and Inspectors* in October 2025.

Through the dissemination of this program, the group will continue its efforts to standardize evaluation methodologies. Establishing standardized procedures and uniform inspector qualification levels will enable objective demonstration of compliance with Japanese Pharmacopoeia requirements and facilitate international alignment with Japanese quality standards.

- **RG-3：Rapid Microbiological Methods (RMM)**

Microbiological quality control and environmental monitoring are essential to pharmaceutical manufacturing, human cell therapy, and gene therapy products to reduce contamination risk and ensure product quality. Rapid Microbiological Methods (RMM) has gained attention, with increased recognition and reference in the JP General Information and PIC/S GMP Annex 1. As a result, there is a growing demand for new, effective, and rational microbial control using RMM.

This group aims to create value for regulatory authorities, pharmaceutical companies (users), and equipment manufacturers (suppliers) by continuously exploring RMM concepts and applications, publishing the findings on an ongoing basis. The RG-3 group conducts flexible research, leveraging insights from both users and suppliers, focusing on the practical implementation and qualification of RMM for use in manufacturing environments.

- **RG-4：PIC/S GMP Annex 1 – Contamination Control Strategy (CCS)**

Since 2021 the revised GMP Ministerial Ordinance has been in effect in Japan, incorporating principles from the PIC/S GMP Guide. Among the various Annexes, PIC/S GMP Annex 1 (Manufacture of Sterile Medicinal Products) is particularly significant. It was revised on September 9, 2022, and came into force on August 25, 2023. Accordingly, regulatory GMP inspections based on the new requirements are now underway.

Many companies and manufacturing sites are experiencing confusion, particularly around the development, design, and implementation of the Contamination Control Strategy (CCS), an essential requirement of Annex 1. To promote the practical and appropriate adoption of CCS, this group is accelerating their research efforts. This group aims to conduct a cross-sectional analysis of Annex 1, extracting key concepts and proposing practical approaches for CCS implementation. Findings will be shared with industry and regulatory bodies to support effective and appropriate CCS adoption.

- **RG-5：PIC/S GMP Annex 1 – Sterilization Technologies**

Sterilization is recognized as one of the critical control points in the manufacturing of sterile products. As of August 2024, in the revised PIC/S GMP Annex 1, the requirements for sterilization technologies outlined in Chapter 8 are more clearly defined than in the 2008 revision.

The RG-5 research group focuses on Chapter 8 and related clauses of Annex 1, carrying out a gap analysis to compare existing facility design and operational practices with the updated sterilization requirements. Based on these findings, the group is identifying measures to ensure compliance and analyzing case studies to support effective implementation.

- **RG-6：PIC/S GMP Annex1 – Environmental and Process Monitoring**

With the implementation of PIC/S GMP Annex 1 starting from August 2023, it has become clear that manufacturing facilities for sterile products (including regenerative medical products)

will need to transition to comply with Annex 1. In particular, the development and implementation of a Contamination Control Strategy (CCS) is crucial.

This group will focus on "environmental and process monitoring" in the context of CCS development and operation, conducting research on the establishment of practical environmental monitoring programs based on risk assessment as well as Aseptic Process Simulation (APS).

■ **Subcommittee on Advanced Therapy Medicinal Products (ATMP)/Regenerative Medicine**

ATMPS, including regenerative medical products, are aseptically manufactured products whose production and quality control must comply with Good Manufacturing Practices. Compared to the manufacture of pharmaceutical products, ATMPs are manufactured in smaller lots but require significantly more human intervention; they introduce additional technical challenges that limit automation and mechanization, increasing reliance on manual labor and the skills of workers. In addition, there is a wide variability of raw materials (such as human cells) and final products, which often require a case-by-case operation. Because of this, the industrialization of ATMPs is still immature, and many issues differ from those of aseptic drug products, especially in manufacturing and quality control. Our committee believes that there is an urgent need for the development of technical know-how and regulatory science to discuss these issues and lead them to a global standard.

The subcommittee will address the specific challenges associated with ATMPs and will establish research groups to facilitate in-depth discussions on common issues. To promote activities in both eastern and western regions of Japan, research groups will be set up to study the challenges faced in the manufacturing and quality control of ATMPs and explore solutions. Our subcommittee aims to revitalize the industry and accelerate its industrialization by presenting the research findings both domestically and internationally.

- **RG-East：Eastern Japan Research Group**

Consisting of members from the eastern Japan region, the group primarily holds monthly in-person meetings.

- **RG-West：Western Japan Research Group**

Likewise, this group is comprised of members from the western Japan region and meets monthly.

★ MEMBERSHIP AND ACTIVITY OVERVIEW

・**Activity Frequency**: Meetings held on Saturdays once every two months (six times per year) at venues in Tokyo and Osaka

・**Membership**: 72 (as of January 2026)

The Committee frequently collaborates with domestic and international regulatory authorities on research, striving to create an environment where members can focus on their research without hesitation or concerns. A dedicated *Members' Guidebook* has been established, and new members are briefed on its contents and expected to adhere to its guidelines.

Applications submitted solely for the purpose of information gathering are not accepted.