

GMP / GCTP Annual Report

FY 2025

PMDA



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Introduction

GMP/GCTP Annual Report FY 2025 The Director's Statement

<Message from PMDA>



This year marks the fourth edition of the GMP/GCTP Annual Report. This Annual Report serves as an important platform for sharing PMDA's initiatives with stakeholders, including efforts to enhance transparency in quality management, promote risk communication, and strengthen international collaboration. These initiatives have been undertaken to restore and continuously improve confidence in pharmaceutical quality, drawing lessons from recent GMP violations, API mix-up incidents, quality-related issues, and the societal challenge of pharmaceutical supply shortages.

The environment surrounding pharmaceuticals is undergoing significant change. Globalization has made supply chains increasingly complex, while quality risks have become more diverse. At the same time, the mission of ensuring a stable supply of medicines needed by patients remains unchanged, both domestically and internationally. Addressing this challenge requires sustained cooperation among all stakeholders, including regulatory authorities, marketing authorization holders, manufacturers, local governments, and international partners, each fulfilling their respective responsibilities.

PMDA places great importance on supporting quality improvement through science-and risk-based inspections and regulatory oversight, while encouraging proactive improvements at manufacturing sites through transparent communication and constructive dialogue. In FY2025, in addition to continuing its existing activities, PMDA advanced the development of key foundations to support a new era of pharmaceutical quality assurance, including the launch of Warning Letter system and the operation of the GMP/GCTP Manufacturing Quality Data System. We believe that these initiatives represent important steps toward preventing quality issues before they occur and building a more resilient pharmaceutical supply system.

Quality cannot be assured by any single organization alone. We believe that it can only be achieved through transparent information sharing, science-and risk-based regulation, and ongoing efforts by stakeholders across manufacturing sites, industry, government, and the international community working together beyond national borders.

Guided by its mission to ensure the timely and stable delivery of high-quality pharmaceuticals to patients, PMDA will continue to steadily advance initiatives aimed at enhancing quality and contributing to the maintenance and strengthening of confidence in the quality of pharmaceuticals in Japan, both domestically and internationally.

July 31, 2026

Associate Executive Director(in charge of Quality Control Division), PMDA

Hideo Eno

GMP/GCTP Annual Report

The Office of Manufacturing Quality for Drugs (OMQD) at PMDA publishes the GMP/GCTP Annual Report, which compiles information such as achievements in GMP inspection, inspection frameworks, international initiatives, current challenges, and future vision. OMQD aims to enhance regulatory the transparency of GMP inspection operations and strengthen mutual trust between PMDA and pharmaceutical companies by actively disseminating information related to pharmaceutical quality management. OMQD aims to provide information to overseas pharmaceutical companies, manufacturing sites and regulatory authorities, gather feedback and advice from abroad, and further improve its operations.

< Past issues >

GMP/GCTP Annual Report 2022 ([Japanese Version](#), [English Version](#))

GMP/GCTP Annual Report 2023 ([Japanese Version](#), [English Version](#))

GMP/GCTP Annual Report 2024 ([Japanese Version](#), [English Version](#))

In conjunction with the release of the FY 2024 edition, OMQD conducted an anonymous survey and received responses from 368 individuals regarding the types of information they would like to see included in the Annual Report. Based on the survey results, the FY 2025 edition incorporates some of the feedback as outlined below.

OMQD intends to continue conducting surveys on a regular basis in order to further improve the content of its information dissemination. We would therefore greatly appreciate receiving your comments and feedback on the FY 2025 edition as well. Please feel free to submit your feedback via the QR code provided at the end of this report.

Summary of feedback and OMQD response in this Annual Report is as follows:

Summary of feedback	Reflections in this Annual Report
- The FY 2024 edition contains significantly more pages than previous editions, making it difficult to read in its entirety. - We would like OMQD to consider initiatives that encourage readership of the current edition, for example, by introducing Special Topics.	An Executive Summary has been introduced for the first time in this edition, providing a one-page overview of the activities and achievements of the Office of Manufacturing Quality for Drugs. In addition, as Special Topics for FY 2025, this edition focuses on the following key themes: “Amendment of the Pharmaceuticals and Medical Devices Act,” “Advanced Technologies,” and “Promotion of Reliance.”
In the List of Identified Deficiencies, the “License/Certification Categories” included in the FY 2023 edition were removed in the FY 2024 edition, making it more difficult to understand the type of each manufacturing site.	The “License/Certification Categories” included in the FY 2023 edition were removed in the FY 2024 edition, as more detailed information on the identified deficiencies was provided after confirmation with the relevant parties. However, recognizing the importance of providing such contextual information, the FY 2025 edition includes the “Inspection Category” in the List of Identified Deficiencies. For further details, please see Section 3-3, List of identified deficiencies.
The analysis of Other Deficiencies introduced in the FY 2024 edition was useful. We would like to see a more detailed analysis of identified deficiencies by various categories, such as manufacturing site location (domestic or overseas), product type (sterile or non-sterile), and manufacturing stage (API or drug product), in order to better understand trends.	In the FY 2024 edition, we analyzed frequently identified categories of Other Deficiencies, focusing on those with a high number of observations and related to ministerial ordinance requirements. In the FY 2025 edition, we analyzed Other Deficiencies after classifying them by categories such as domestic and overseas manufacturing sites. The results are presented in Section 2-3, Trend of identified deficiencies.

Also, the following feedback could not be reflected in this Annual Report, as a result of consideration. Here is the OMQD's policy.

Summary of feedback	OMQD's policy
We would like OMQD to disclose the names of manufacturing sites that received identified deficiencies.	As a general principle, the Annual Report does not include information that could identify specific manufacturing sites, such as manufacturing site names. However, PMDA began making GMP inspection results public on its website in March 2025 and, from September 2025, began publishing information on manufacturing sites found to be non-compliant, including site names. For information on GMP compliance and non-compliance, please refer to the PMDA website.
We would also like to know about identified deficiencies related to medical devices, in vitro diagnostics, and cosmetics, as well as observations provided to marketing authorization holders (MAHs).	OMQD does not conduct inspections of medical devices, in vitro diagnostics, or cosmetics, nor does it conduct inspections targeting marketing authorization holders (MAHs). Therefore, these areas are not covered in the Annual Report.
We would like to know the basis on which OMQD determines that identified deficiencies should be issued, as well as the risk assessment methodologies used in making such determinations.	The issuance of the notice of deficiencies is determined in accordance with the Criteria for Concluding GMP Conformity set out in Appendix 3 of the GMP Investigation Guide (and similarly for GCTP). Whether a deficiency is classified as a Critical Deficiency or a Major Deficiency depends on whether it constitutes non-compliance with the provisions specified in the relevant ministerial ordinances. On the other hand, when determining the issuance of a notice of Other Deficiencies, a key consideration is whether the deficiency could pose a risk to patients. However, as the level of risk varies depending on factors such as product characteristics and manufacturing processes, OMQD considers it difficult to provide a generally applicable risk assessment methodology.
We would like the GMP/GCTP Annual Report to serve as a practical guide for GMP audits.	The GMP/GCTP Annual Report is intended to serve as an annual report of the OMQD, providing an overview of its activities related to GMP and GCTP compliance inspections, inspection framework, international activities, current challenges, and future outlook. It is not intended to serve as a guidebook for GMP audits. As a reference resource for GMP audits, OMQD publishes the ORANGE Letters.
Would it be possible to omit "1 PMDA OMQD Overview" if its content remains largely unchanged from year to year?	We acknowledge this concern and recognize the need to reconsider whether content that remains unchanged should continue to be included. In the FY 2023 edition, sections unchanged from the previous edition were identified. In the FY 2024 edition, we expanded the content based on survey feedback indicating that the OMQD overview was a useful reference, and therefore did not indicate revisions. In the FY 2025 edition, sections updated due to the amendment of the Pharmaceuticals and Medical Devices Act and other changes are clearly identified. For future editions, we will consider whether the OMQD overview should be separated from the GMP/GCTP Annual Report and provided as a brochure or similar publication.

Additionally, after careful consideration, we decided not to reflect certain other opinions in this Annual Report. The OMQD's policies regarding those points are explained within this report.

We also received many other valuable suggestions, which we greatly appreciate.

Furthermore, aside from this Annual Report, PMDA regularly publishes [annual GMP-related inspection statistics](#) on the number of GMP on-site inspections and other data as part of its annual GMP-related performance reports.

Executive Summary

To ensure the timely and stable delivery of quality-assured pharmaceuticals to patients through the maintenance of appropriate manufacturing and quality control at pharmaceutical manufacturing sites.

Achievements in FY 2025

130 cases
On-site GMP inspection

2,013 cases
Desk-top GMP inspection

568 cases
Facility inspection

40 cases
Ad-hoc on-site inspection

2 cases
GMP inspection of investigational drugs

26 cases
Consultation services

Key Activities in FY 2025

Special Topics 1: PMD Act Revisions

- Shortening the interval for periodic GMP/GCTP compliance inspections
- Streamlining periodic inspections for low-risk manufacturing sites
- Partially revising the inspection authority for generic drug products
- Establishing a new category-specific compliance inspection framework for designated pharmaceuticals and other specified products

Special Topics 3: Strengthening Collaboration with Singapore HSA

- Concluded a MoC with Singapore's Health Sciences Authority(HSA)
- Conducted Joint GMP Inspector Training
- Strengthened Regulatory Cooperation with Asian Regulatory Authorities
- Seconded an Expert Staff Member to the PIC/S Secretariat

Risk communication activities

- Conducted three GMP Roundtable Meetings
- Issued six ORANGE Letters
- Published the GMP/GCTP Annual Report (FY2025)

Special Topics 2: Initiatives on Advanced Technologies (AT)

- Actively Engaged in International Discussions on AI in Manufacturing
- Launched the AT Review Team (Dec, 2024)
- Participated in the PIC/S-EMA Joint Working Group on Annex 22 and Annex 11
- Presented on Annex 22 at the PIC/S Seminar in Hong Kong

Trend of identified deficiencies

- No Critical deficiencies identified
- Details of all 45 Major deficiencies were published
- Analysis of 928 Other deficiencies
 - 1 Cleaning, validation for cleaning
 - 2 Written testing directions/records (including DI)

International activities

- Continued Participation in the PIC/S Executive Bureau and Subcommittees
- Participated in API Programme (US FDA/EMA /WHO etc)
- Participated in the EMA GMDP Inspectors Working Group (GMDP-IWG) as an Observer
- Conducted the PMDA-ATC GMP Seminar

Future vision

✓ Enhanced Collaboration Through a New Information System

In collaboration with MHLW, PMDA has centralized the management of inspection information from PMDA and prefectural governments through of the GMP/GCTP Manufacturing Quality Data System, thereby strengthening information sharing and coordination while enhancing risk-based inspection planning.

✓ Initiatives on Advanced Technologies

Proactive Engagement in the Development of International Guidelines (e.g., Annex 22) and Support for Their Early Implementation by the Advanced Technologies (AT) Task Force.

✓ Further Strengthening International Collaboration

Promoting Reliance with Regulatory Authorities in Asia, Continuing Joint Inspections with the U.S. FDA, and Actively Contributing to the Harmonization of PIC/S Standards.

PMD Act Revisions

In response to challenges such as pharmaceutical supply shortages arising from compliance-related incidents and changes in the drug development environment, and with the objective of continuing to ensure the timely and appropriate delivery of quality-assured pharmaceuticals and other medical products to the public, the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and Other Related Acts (Law No. 37 of 2025) was promulgated on May 21, 2025. The Amendment Act is scheduled to be implemented in phases to further strengthen measures for ensuring the quality and safety of pharmaceuticals and other medical products.

The key elements of the revision to the GMP/GCTP compliance inspection framework, which is scheduled to come into effect on a date to be specified by Cabinet Order within two years of the promulgation of the Amendment Act, are outlined below. For further details, please refer to the relevant materials published by MHLW.*^{1,2}

- ① The interval for periodic GMP/GCTP compliance inspections will be shortened from five years to three years.
- ② For periodic GMP/GCTP compliance inspections (excluding regenerative medicine products), inspections will not be conducted for manufacturing sites assessed as low risk based on the results of the pre-inspection risk assessment.
- ③ PMDA will be designated as the authority responsible for conducting pre-approval GMP compliance inspections of the manufacturing processes for new applications of generic drug products containing active ingredients that are approved as generic drugs for the first time.
- ④ For Product category-based inspection for which prefectural governments are responsible, PMDA may, where necessary, conduct additional inspections in coordination with the relevant prefectural government.
- ⑤ Periodic GMP/GCTP compliance inspections for pharmaceuticals intended exclusively for export will be brought within the scope of the Compliance Confirmation Certificate system.

In response to the Amendment Act, PMDA will continue to optimize its inspection framework and further enhance the efficiency of its operations based on the principles of a risk-based approach. Through these efforts, PMDA will strive to prevent the occurrence and spread of harm arising from deficiencies in manufacturing control and quality control.

The quality of pharmaceuticals is not ensured by regulatory compliance alone. It is reinforced through the ongoing commitment of each manufacturing site to continuous improvement. PMDA will continue to enhance the quality of its inspection activities and promote initiatives that support quality improvement across manufacturing sites, including through effective risk communication.

- ※1 The Act for Partial Revision of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 37 of 2025)
https://www.mhlw.go.jp/stf/newpage_58083.html
- ※2 The Summary on the revision of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices and related systems, issued by the Health and Science Council on January 10, 2025. https://www.mhlw.go.jp/stf/shingi2/0000189913_00003.html

Initiatives on Advanced Technologies

PMDA Contributes to the Development of PIC/S GMP Guide Annex 22 (AI in Manufacturing)

PMDA is actively contributing to the development of PIC/S GMP Guide Annex 22 (AI in Manufacturing), participating in international discussions on the appropriate application of advanced manufacturing technologies, including artificial intelligence (AI) and robotics.

To maintain and enhance the global competitiveness of Japan's pharmaceutical industry, it is important to strengthen manufacturing capabilities that can ensure a stable supply of high-quality medicinal products. Advanced manufacturing technologies can support this objective by improving productivity through automation, enhancing data utilization, enabling early detection of potential issues, helping prevent deviations, and improving the consistency of decision-making. These technologies also have the potential to make quality management systems more preventive and proactive. Against this background, PIC/S is developing Annex 22 (AI in Manufacturing). PMDA has participated in the drafting process and has also launched a project under the FY2026 Health and Labour Sciences Research Grant Program to develop use cases supporting implementation of Annex 22.

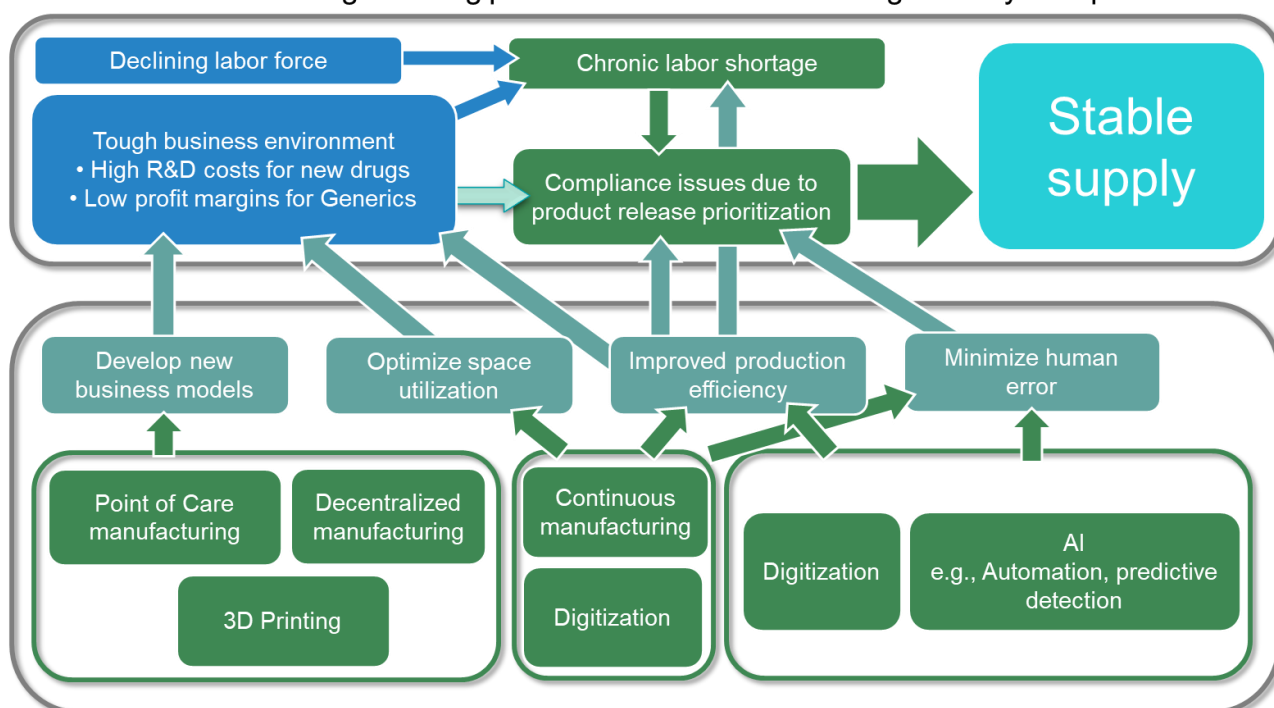
The successful adoption of advanced manufacturing technologies requires not only clear guidelines but also a shared understanding between industry and regulators of the concepts and principles behind them. PMDA therefore maintains ongoing dialogue with Japanese pharmaceutical companies to better understand practical challenges and needs. PMDA also plays a bridging role by bringing industry perspectives into international discussions within PIC/S and sharing developments from those discussions with domestic stakeholders.

Through its involvement in the drafting of Annex 22, PMDA has contributed to discussions on use cases and risk-based approaches from an early stage, helping ensure that practical needs and experiences from Japan are appropriately reflected in the guideline.

PMDA will continue to contribute to the development of science-based regulation and to the competitiveness of Japan's pharmaceutical industry through active participation in international regulatory initiatives.

Advanced Technologies Have the Potential to Address Challenges

Current challenges facing pharmaceutical manufacturing industry in Japan



Leveraging advanced technologies to address key challenges

Strengthening Collaboration with Singapore HSA

Promoting Mutual Reliance in the GMP Field

On April 20, 2026, Ministry of Health, Labour and Welfare (MHLW) and Health Sciences Authority (HSA) of Singapore concluded a Memorandum of Cooperation on Regulatory Collaboration (hereinafter referred to as the "Memorandum").※³

Since joining PIC/S in July 2014, PMDA has actively participated in international activities in the GMP field and has contributed to the international harmonization of GMP standards and the enhancement of GMP inspectors' competencies. In the Asia-Pacific region, PMDA has also utilized frameworks such as the PMDA Asia Training Center (ATC) to continue technical discussions with Asian GMP authorities, including HSA, aimed at strengthening regulatory cooperation. Through these efforts, PMDA has enhanced its GMP inspection capabilities and, in particular, has further developed mutual understanding and trust with HSA in the field of pharmaceutical regulation. Based on this progress, the Memorandum was concluded with the aim of further promoting mutual reliance on GMP inspection outcomes, thereby contributing to the more efficient use of regulatory resources.

In accordance with the PMDA's Fifth Mid-term Plan, PMDA is promoting the enhancement of GMP inspection capabilities and the strategic allocation of resources to priority areas through strengthened mutual trust with overseas regulatory authorities. The areas of cooperation under the Memorandum are fully consistent with this policy. Specifically, PMDA and HSA will cooperate in the following areas:

- Exchange of information contributing to the mutual use of GMP inspection plans and inspection results
- Joint training activities aimed at improving the expertise and technical capabilities of GMP inspectors

The exchange of information to facilitate the mutual use of GMP compliance inspection results is expected to provide benefits to pharmaceutical companies, including a reduced burden associated with on-site inspections and enhanced predictability of GMP compliance inspection procedures. In addition, knowledge and experience gained through joint training and other collaborative activities will be utilized by the PMDA to support the continuous improvement of GMP inspection methodologies. PMDA will continue to work closely with overseas GMP authorities to promote the efficient and effective implementation of GMP regulation and to contribute to creating an environment that supports the stable supply of high-quality pharmaceutical products to patients worldwide.

※³ Press Release issued by the Office of International Pharmaceutical Regulatory Affairs, Pharmaceutical Bureau, MHLW, April 21, 2026 https://www.mhlw.go.jp/stf/newpage_72720.html



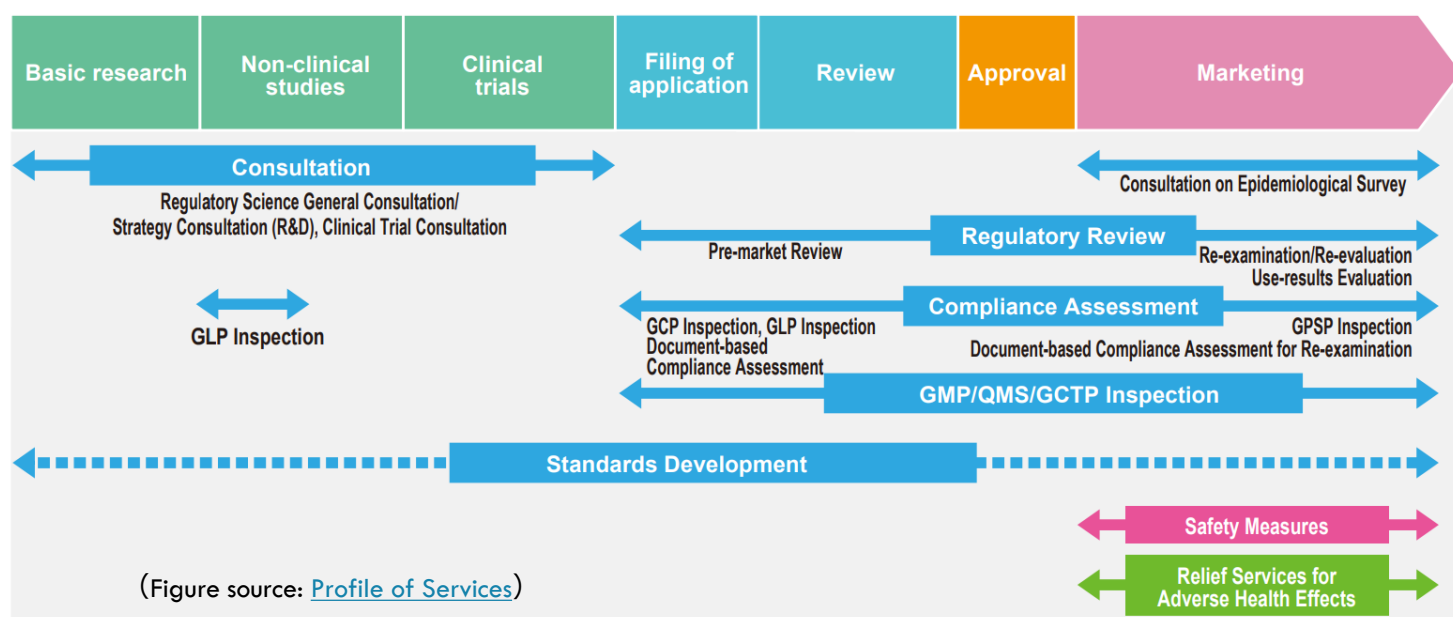
Front row (from left): Yasuhiro Fujiwara, Chief Executive, PMDA; Raymond Chua, Chief Executive Officer, HSA, Singapore; Naoki Miyamoto, Director-General, Pharmaceutical Bureau, MHLW; and Daisaku Sato, Counsellor for Pharmaceutical Affairs, Minister's Secretariat, MHLW
Back row: Officials and representatives from the participating organizations

1 PMDA OMQD overview

1-1 About us

1-1-1 About PMDA

One of the key objectives of PMDA is to contribute to the improvement of public health by providing prompt relief services to patients suffering from adverse drug reactions and infections acquired through biological products (Relief for Adverse Health Effects), providing guidance and reviews on the quality, efficacy, and safety of drugs, medical devices, and gene, cellular and tissue-based products through a consistent system from pre-clinical research to approval (Approval Review), and collecting, analyzing, and disseminating post-marketing safety information (Safety Measures). PMDA performs various functions throughout the lifecycle of medical products, from early development to post-marketing. The main categories are shown in the diagram below.



1-1-2 Mission of OMQD

The mission of OMQD is to conduct its operations with timely decision-making under a high level of transparency with the goal of ensuring the distribution of high-quality pharmaceuticals, quasi-drugs and gene, cellular and tissue-based products based on its absolute mission to protect citizens' lives and health. To achieve this mission, OMQD has established a Quality Management System to ensure appropriate and effective GMP/GCTP inspections, including the formulation of quality policies. In addition, the Head of inspectorate (Chief Executive of PMDA) conducts management reviews to appropriately maintain the Quality Management System, address arising issues, and to assess the validity of the quality policy.

Quality policy of Office of Manufacturing Quality for Drugs

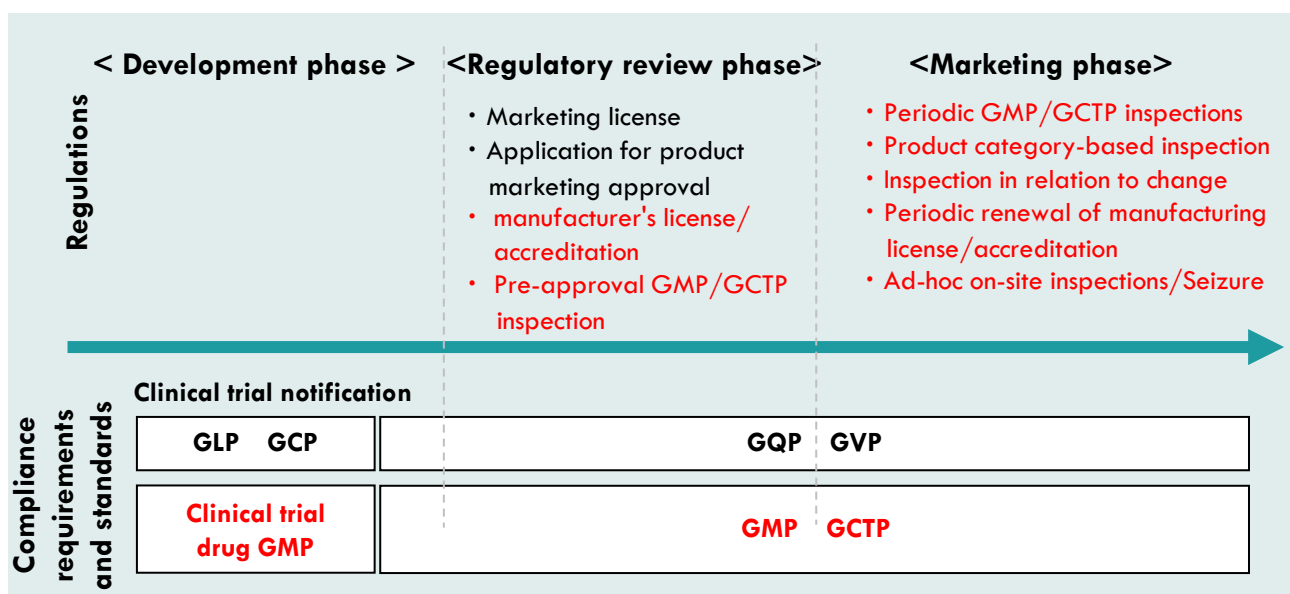
Head of inspectorate (Chief Executive of PMDA) shall ensure the following matters within its quality policy;

- Quality policy of the PMDA Office of Manufacturing Quality for Drugs, based on its absolute mission to protect citizens' lives and health, aiming for distribution of high-quality pharmaceuticals, quasi-drugs and gene, cellular and tissue-based products shall make its operations be conducted with timely decision making and highly transparency.
- Such quality policy should be communicated to and understood by all the GMP inspectors in the PMDA Office of Manufacturing Quality for Drugs.
- Sustained effectiveness of such quality policy should be reviewed regularly.

1-1-3 Scope of responsibilities of OMQD

As part of PMDA's review-related services, OMQD conducts GMP inspections for drugs and GCTP inspections for gene, cellular and tissue-based products. These inspections are intended to assess whether manufacturing sites for such products are operating under appropriate quality management systems and may be conducted either as on-site inspections or as desk-top inspections.

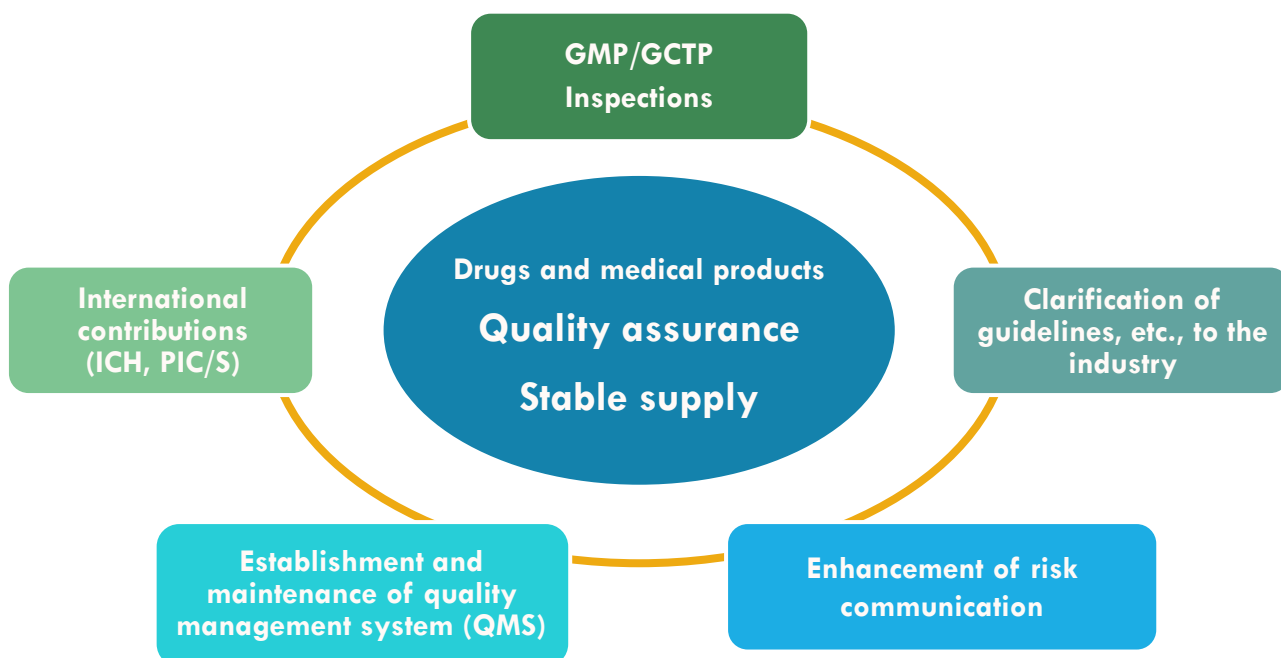
The matters related to OMQD's activities are indicated in **red** in the diagram illustrating the drug lifecycle below. Details of each matter are shown in [1-2 Type of inspection](#).



In addition to the above, OMQD is also working on activities for the purpose of global harmonization of pharmaceutical regulations through the provision of information for the pharmaceutical industry, preparation of guidelines, establishment and maintenance of the quality management system in cooperation with prefectural governments, and participation in ICH*4 and PIC/S*5, etc. Details are shown in [Chapter3 : Risk communication activities](#) and [Chapter 4: International Activities](#).

*4 International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
<https://www.ich.org/>

*5 Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
<https://picscheme.org/>



1-1-4 GMP inspectorate in Japan and scope of inspection

Drugs

Overseas manufacturing site: PMDA

Japanese manufacturing site: PMDA (limited to the following) and prefectural governments

- A) GMP inspection of a manufacturing site where a new drug is manufactured pre-approval*
- B) GMP inspection of manufacturing sites where the following drugs are manufactured pre-approval
 - ✓ Drugs using genetical recombination technology including antibody products
 - ✓ Drugs designated by the Minister of Health, Labour and Welfare as requiring special attention among drugs manufactured using human or other living organisms as raw materials such as blood transfusion preparations
 - ✓ Radiopharmaceuticals including contrast media
- C) Periodic GMP inspections performed every 5 years specified by a cabinet order, which is not less than 3 years after approval of a drug, have elapsed (hereinafter referred to as "periodic inspection").*
 - ✓ The periodic inspection of drugs shown in B) is performed by the PMDA.
 - ✓ For regular inspections of drugs other than those shown in B), the first inspection is conducted by the PMDA, and the second and subsequent inspections are conducted by the prefectural government (the prefecture where the manufacturing site is located).

Gene, cellular and tissue-based products

All manufacturing sites: PMDA

Scope for GMP inspections		Japanese manufacturing site	Overseas manufacturing site
Drugs	Mainly new drugs	PMDA	PMDA
	Mainly generic drugs	Prefectural governments*	PMDA
gene, cellular and tissue-based products		PMDA	PMDA

* Certain aspects of the regulatory framework are expected to be reviewed following [the revision of the PMD Act](#).

1-1-5 Organization structure of OMQD (Partially updated)

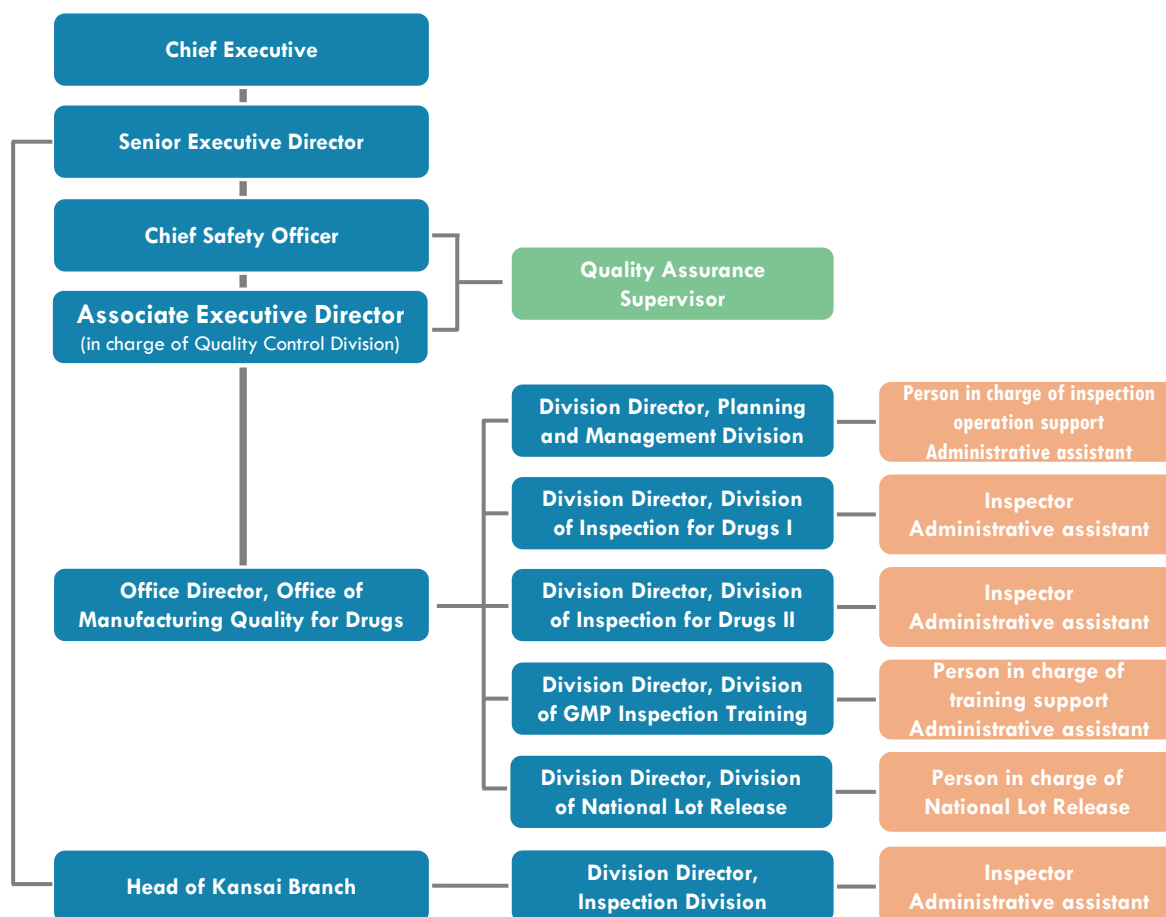
OMQD consists of the following 5 divisions (as of April 2, 2026).

- Planning and Management Division : Support for inspection operations, etc.
- Division of Inspection for Drugs I : Mainly in charge of inspection of biopharmaceuticals and gene, cellular and tissue-based products
- Division of Inspection for Drugs II : Mainly in charge of inspection of chemical products and products other than handled by Division I
- Division of GMP Inspection training : Support for inspections conducted by prefectural governments and overseas GMP authorities
- Division of National Lot Release : National Lot Release operations (Summary Lot Protocol (SLP) review, etc.)

In addition to the above, a Division of Inspection has been established at the Kansai Branch, which is responsible for GMP inspections in Japan and overseas in cooperation with OMQD.

Additionally, to report to the Chief Safety Officer/Associate Executive Director (in charge of the Quality Control Division) who is in charge of safety measures of drugs and quality control of drugs and medical devices, the quality assurance supervisor (independent of the Inspection Division, responsible for monitoring the progress of inspection operations and ensuring compliance) is allocated under such personnel to perform operations.

The organizational structure prior to March 31, 2026 is available in the GMP/GCTP Annual Report 2024.



1-1-6 Conflict of interests

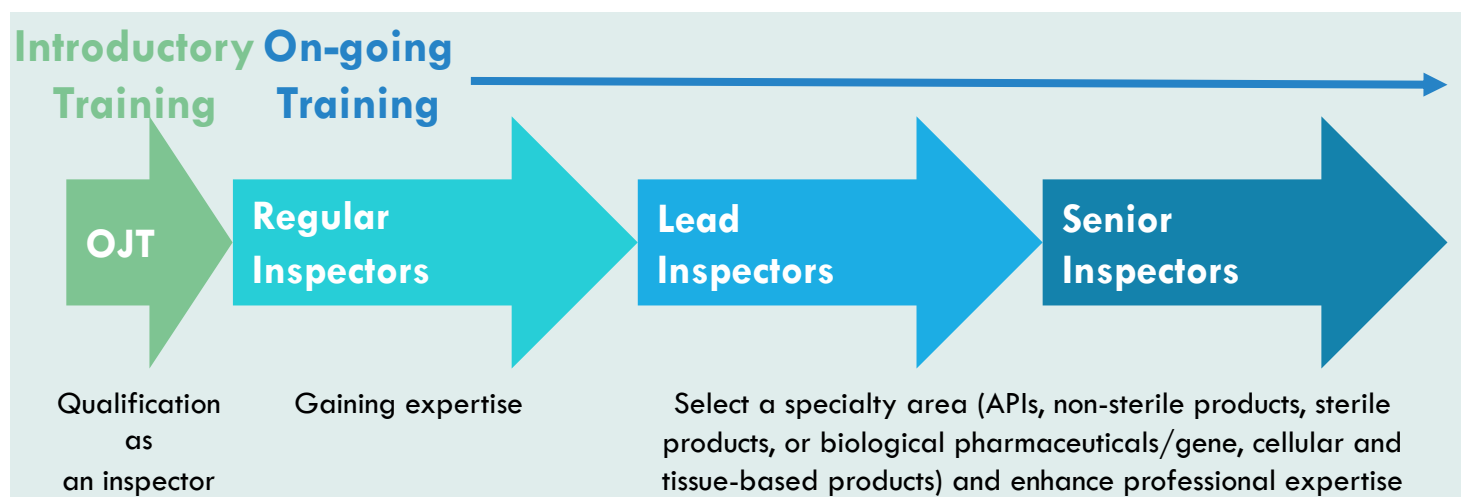
Staff from the private sector are subject to the rules for Conflict of Interests stipulated in the Rules of Employment for Staffs of the Pharmaceuticals and Medical Devices Agency (Regulations No. 2, 2004) and the Detailed Rules on Restriction of Duties for Staffs of the Pharmaceuticals and Medical Devices Agency (Detailed Rules No. 1, 2005).

The rules for Conflict of Interests stipulate that, regardless of whether or not the duties at the PMDA are closely related to their former private-sector duties, they must not be engaged in the duties related to drugs, etc., of their former private sector for 5 years after being employed by PMDA. In OMQD, they shall not be engaged in the inspections of the manufacturing site with interests including their former private sector.

The operating status of the rules for Conflict of Interests in OMQD is checked by the Quality Assurance Supervisor periodically and also by an internal audit (implemented twice a year (half-yearly)) conducted by the PMDA Audit Office.

1-1-7 Training for inspectors

An overview of the training provided to OMQD inspectors is presented below.



Introductory Training

- Gain experience in at least, generally, 5 GMP inspections as part of on-the-job training (OJT)
- Theoretical training on the overview of inspection operations, pharmaceutical-related laws and regulations, and necessary procedures to conduct inspections. (Examples include: The PMD Act, Marketing authorization documents and the Japanese Pharmacopoeia, Global trends related to GMP inspections and PIC/S guidelines, Key points and precautions during on-site inspections, Change of clothes procedures, Overall structure, facilities, and support systems, Communication skills required for inspectors, Fundamental attitudes expected of inspectors, The role of GMP in pharmaceuticals, Detailed topics: Quality systems, Quality control, Validation, APIs, Tablets, Sterile pharmaceuticals, biological pharmaceuticals, Cleaning validation, GCTP inspections, fermentation-based APIs, Clinical trial GMP inspections, radiopharmaceuticals, crude drugs, etc.)

On-going Training

- Routine Training : On-going training on inspection operations to acquire or share appropriate interpretations of regulations, the latest scientific knowledge, international regulatory trends, key case studies, and regulatory guidance. The aim is to maintain and enhance inspection methodologies and capabilities. (Held 4 times a month, with sessions lasting 30 to 90 minutes.)
- Specialized Training : Periodic intensive training to gain technical expertise and GMP inspection skills, including case studies, group work, and/or role playing. Additionally, participation is open to prefectural officials and staff from other ministries. (Held 3 times a year, each lasting 3 consecutive days)

Other Training

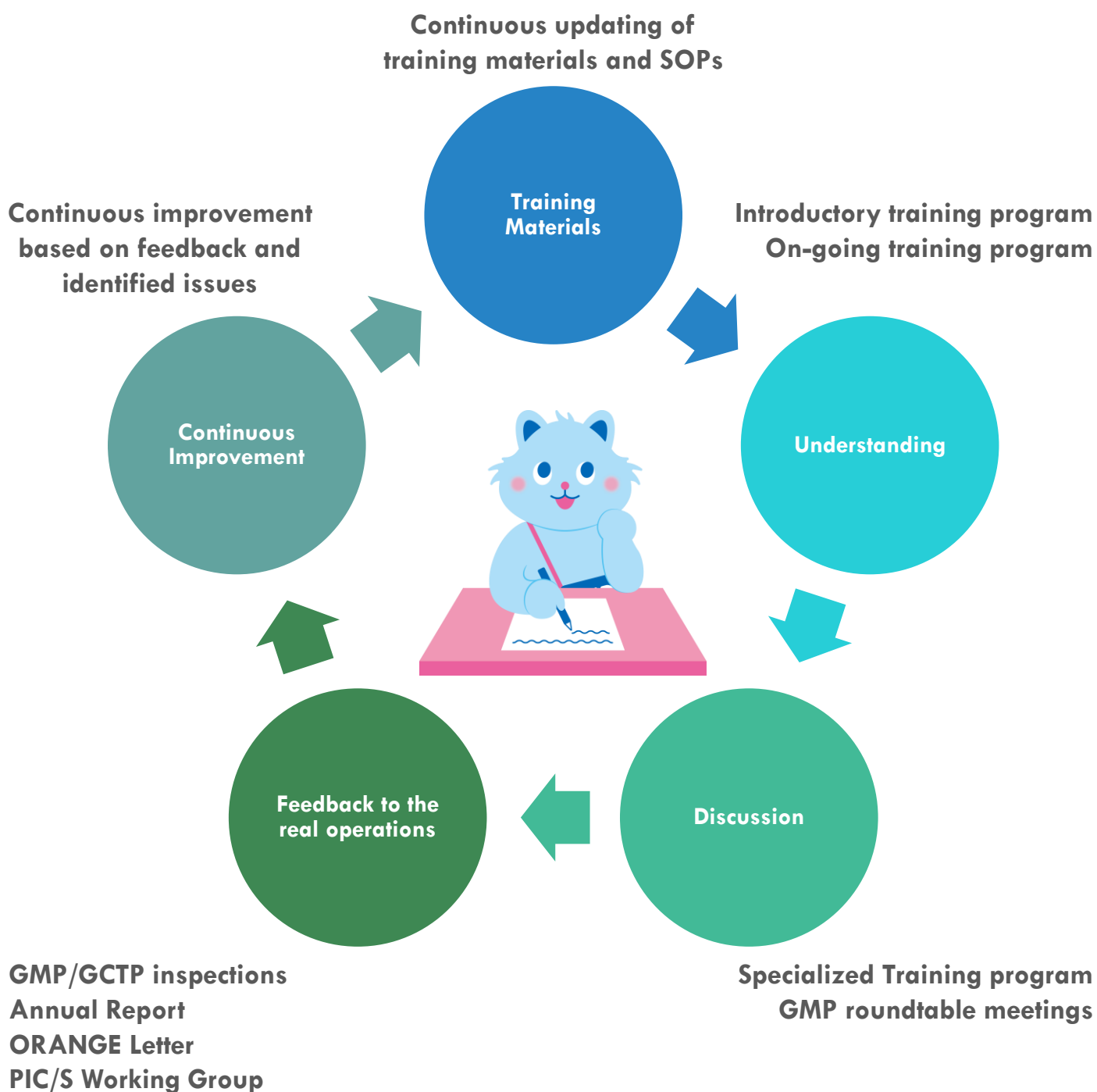
- Temporary training conducted by invited external instructors
- On-site training at manufacturing sites and training facilities, etc.

1-1-7 Training for inspectors (Continued)

The training materials used for introductory and on-going training are developed internally by OMQD and are used to train OMQD inspectors, with the aim of enhancing their understanding of GMP/GCTP. Based on this understanding, inspectors actively participate in discussions with external stakeholders during specialized training sessions and GMP roundtable meetings, in preparation for GMP/GCTP inspections. In addition to this Annual Report, we are also working to publish other materials useful for training purposes, such as the ORANGE Letters and documents from the PIC/S Working Group.

During GMP/GCTP inspections, we sometimes receive feedback from industry stakeholders, including requests and complaints. Additionally, issues are identified through risk communication activities and the annual management review conducted by PMDA.

Based on such feedback and identified issues, we continuously update the training materials and work to improve our training system. Furthermore, OMQD's standard operating procedures (SOPs) are also regularly reviewed (at least once every five years).



1-2 Type of inspection

1-2-1 GMP / GCTP inspections

The GMP/GCTP inspection is classified into application-based inspections and Inspections not based on applications (Ad-hoc on-site inspections), etc.

GMP / GCTP inspections (Updated following the revision of the PMD Act)

Application-based inspections are conducted to confirm whether the actual status of manufacturing and quality control at the facility comply with the Ministerial Order on GMP / GCTP^{*6} or not, based on the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (hereinafter referred to as the “PMD Act”)^{*7}, which are classified further into (1) pre-marketing approval inspection, (2) post-marketing approval inspection, (3) product category-based inspection, (4) inspection in relation to change management protocol, and (5) inspection on manufacturing of a product for export.

^{*6} The Ministerial Order on GCTP (Order of the Ministry of Health, Labour and Welfare (MHLW) No. 93 of August 6, 2014)

https://www.mhlw.go.jp/web/t_doc?dataId=81ab4197&dataType=0&pageNo=1

^{*7} The PMD Act (Law No. 145 of 1960) <https://laws.e-gov.go.jp/law/335AC0000000145>

(1) Pre-marketing approval inspection;

- (a) Inspection that is conducted upon the application for product marketing approval (as provided in Article 14, paragraph (6) of the PMD Act for GMP, Article 23-25, paragraph (6) for GCTP)
- (b) Inspection that is conducted upon the application for approval for partial changes of any matter prescribed in the existing marketing approval (as provided in Article 14, paragraph (6) as applied mutatis mutandis in Article 14, paragraph (13) of the PMD Act for GMP, Article 23-25, paragraph (6) as applied mutatis mutandis in Article 23-25, paragraph (13) for GCTP)
- (c) Inspection that is conducted upon the application for exceptional marketing approval for a product manufactured in a foreign country (as provided in Article 14, paragraph (6) as applied mutatis mutandis in Article 19-2, paragraph (5) of the PMD Act for GMP, Article 23-25 paragraph (6) as applied mutatis mutandis in Article 23-37, paragraph (5) for GCTP)
- (d) Inspection that is conducted upon the application for approval for partial changes of any matter prescribed in the existing exceptional marketing approval for a product manufactured in a foreign country (as provided in Article 14, paragraph (6) as applied mutatis mutandis in Article 14, paragraph (15) as applied mutatis mutandis in Article 19-2, paragraph (5) of the PMD Act for GMP, Article 23-25, paragraph (6) as applied mutatis mutandis in Article 23-25, paragraph (13) as applied mutatis mutandis in Article 23-37, paragraph (5) for GCTP)

(2) Post-marketing approval inspection;

- (a) Periodic inspection concerning an existing marketing approval (as provided in Article 14, paragraph (6) of the PMD Act for GMP, Article 23-25, paragraph (6) for GCTP)
- (b) Ad-hoc inspection in cases when deemed necessary, concerning an existing marketing approval (as provided in Article 14, paragraph (8) of the PMD Act for GMP, Article 23-25, paragraph (8) for GCTP)
- (c) Periodic inspection concerning an existing exceptional marketing approval for a product manufactured in a foreign country (as provided in Article 14, paragraph (6) as applied mutatis mutandis in Article 19-2, paragraph (5) of the PMD Act for GMP, Article 23-25, paragraph (6) as applied mutatis mutandis in Article 23-37, paragraph (5) for GCTP)
- (d) Ad-hoc inspection in cases when deemed necessary, concerning an existing exceptional marketing approval for a product manufactured in a foreign country (as provided in Article 14, paragraph (8) as applied mutatis mutandis in Article 19-2, paragraph (5) of the PMD Act for GMP, Article 23-25, paragraph (8) as applied mutatis mutandis in Article 23-37, paragraph (5) for GCTP)

1-2-1 GMP / GCTP inspections (continued)

- (3) Product category-based inspection (as provided in Article 14-2, paragraph (2) of the PMD Act for GMP, Article 14-2, paragraph (2) as applied mutatis mutandis in Article 23-25-2, paragraph (1) for GCTP)
- (4) Inspection in relation to change management protocol (as provided in Article 14-7-2, paragraph (3) of the PMD Act for GMP, Article 23-32-2, paragraph (3) for GCTP)
- (5) Inspection on manufacturing of products for export (as provided in Article 80, paragraph (1) of the PMD Act for GMP, Article 80, paragraph (3) for GCTP)
- (6) Inspection for emergency approval (as provided in Article 14-2-2, paragraph (2) of the PMD Act for GMP, Article 23-26-2, paragraph (2) for GCTP)
- (7) Inspection for special approval (as provided in Article 14-2-2, paragraph (2) as applied mutatis mutandis in Article 14-3, paragraph (2) of the PMD Act for GMP, Article 23-26-2, paragraph (2) as applied mutatis mutandis in Article 23-28, paragraph (2) for GCTP)

On-site inspections not based on applications (Ad-hoc on-site inspections)

On-site inspections not based on applications (Ad-hoc on-site inspections), etc., are classified into (1) surveillance inspections based on the risk analysis, and (2) for case inspections depending on the purpose.

- (1) Surveillance inspections which are based on the risk analysis Periodic inspection to confirm compliance with the Ministerial Order on GMP
- (2) For case inspections such as those addressing a violation of the Ministerial Order on GMP, etc., mainly for the following purposes
 - (a) Confirmation of the details of corrective/preventive actions (other than those to be performed as an inspection)
 - (b) Examinations into compliance status with the Ministerial Order on GMP, at the manufacturing sites concerned with those manufactured products which have been recalled, rejected at National Lot Release or complained, etc., and
 - (c) Others

Product category-based inspection

Product category-based inspection is conducted based on an application by the manufacturing sites. The manufacturing process is classified into 17 types, such as the manufacturing process of specified biological products, manufacturing process of radiopharmaceuticals, and manufacturing process of sterile drug substances.

If the inspection authorities judge that the site is compliant with GMP based on the results of the product category-based inspection, a certificate will be issued to the manufacturing site. The validity period for the certificate is 3 years, and it is possible to omit the second and subsequent periodic inspections for products in the manufacturing category shown in the certificate within the period.

Inspection in relation to change management protocol

In accordance with the principles shown in the ICH Guideline, "[ICH Q12 Pharmaceutical Product Lifecycle Management](#)", a system for changing approved items is operated using a protocol for partial change of approved items (change management protocol).

If the marketing authorization holder and PMDA agree in advance about the contents of changes in manufacturing methods, etc., evaluation methods and acceptance criteria for the contents of changes, proposed changes in approved items related to quality, necessity of compliance evaluations of drugs, etc. (confirmation of compliance with the standards specified in the Ministerial Order on GMP), and the expected results are obtained according to the agreed evaluation methods, it is possible to promptly change approved items related to quality by notification.

1-2-2 Manufacturer license / accreditation inspections

When engaging in the commercial manufacture of drugs, quasi-drugs, or gene, cellular and tissue-based products, domestic manufacturing sites are required to obtain a manufacturing license, while overseas manufacturing sites must obtain manufacturing accreditation.

In both cases, an inspection is conducted to determine whether the facility is equipped with the necessary buildings and facilities to obtain the license or accreditation, in accordance with Regulations of Buildings and Facilities of Pharmacies, etc.*8

*8 Regulations of Buildings and Facilities of Pharmacies, etc. (Ministerial Ordinance No. 2 of 1961)
<https://www.pmda.go.jp/files/000153560.pdf>

1-3 Deficiencies in GMP/GCTP inspection

1-3-1 Process for issuance of the notice of deficiencies

In order to deepen the understanding of the manufacturing sites, subject to inspection in the GMP/GCTP inspections (on-site inspection), OMQD provides comments such as inspection results and summarizes the entire inspection. In addition to this, a violation of the GMP/GCTP Ministerial Ordinance and other deficiencies are communicated during the inspection, and opinions on these matters are exchanged between the inspector and the responsible person of the inspected manufacturing sites.

After completion of the inspection, OMQD's inspectors review the contents of the deficiency again, classify into 3 level (Critical, Major, and Other) in accordance with the criteria for concluding GMP/GCTP conformity, prepare the notice of deficiencies, and the deficiency confirmed (hereinafter referred to as "deficiency") will be issued to the responsible person of the manufacturer, etc., subject to inspection.

1-3-2 Classification of deficiency identified

Deficiencies are classified into 1) critical, 2) major, and 3) other depending on their contents, and the criteria for each classification are specified as follows in [the GMP Inspection Guide](#) or in the GCTP Inspection Guide*9.

● Critical

Cases where an identified deficiency that does not comply with any provisions in the GMP/GCTP Ministerial Ordinance fall into any of the following:

- ✓ Any drugs hazardous to patients have been manufactured, or any significant risks which may cause such products has been confirmed, or
- ✓ With regard to products or records, any falsification or false statement or dishonest alteration by the manufacturer has been confirmed.

● Major

Cases where an identified deficiency that does not comply with any provisions in the GMP/GCTP Ministerial Ordinance does not fall into "critical deficiencies" above.

● Other

Cases where an identified deficiency that is not significant to be non-compliance with provisions in the GMP/GCTP Ministerial Ordinance, however, that any rectification is needed for suitable manufacturing control or quality control.

*9 Notification on the Enactment of the GCTP Inspection Guide (PSEHB/CND Notification No. 0730-3 dated July 30, 2021, issued by the Director of Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, the MHLW)
https://www.mhlw.go.jp/web/t_doc?dataId=00tc6091&dataType=1&pageNo=1

1-3-3 Confirmation of the status of improvement

If any deficiency is issued to the manufacturing sites, subject to inspection by the notice for deficiencies identified during a GMP/GCTP inspection, it is necessary to submit a detailed report on corrective/preventive action outcome or a concrete report on corrective/preventive action to OMQD to report the status of improvement within 15 business days after the issuance date of "Critical deficiencies" identified during a GMP/GCTP inspection or within 30 business days after the issuance date of "Major deficiencies".

(1) When only "other deficiencies" are identified

After confirming the content of the report on corrective/preventive action outcome or a report on corrective/preventive action submitted, if any deficiency is properly improved or if it is presumed to be improved promptly, OMQD will notify the manufacturing sites of the conformity status as "compliance."

If the report on corrective/preventive action has been submitted, the report on corrective/preventive action outcome is required to be submitted to confirm that the required corrective actions have been completed, even if the "compliance" inspection results have been notified. In this case, their status of improvement should be examined in the next regular inspection.

(2) When "major deficiencies" are identified

When the contents of the report on corrective/preventive action outcome or a report on corrective/preventive action are determined to be appropriate, OMQD will notify the inspected manufacturing sites of the conformity status as "compliance."

If the report on corrective/preventive action has been submitted, the report on corrective/preventive action outcome is required to be submitted to confirm that the required corrective actions have been completed, even if the "compliance" inspection results have been notified. In this case, their status of improvement should be examined in the next regular inspection.

If the inspectorate agency cannot judge the corrective/preventive actions to be appropriate, the conformity status is concluded as "non-compliance" in principle, and the results will be notified to the manufacturing sites subject to inspection.

(3) When "critical deficiencies" are identified

When the appropriate corrective/preventive actions are determined to be completed within 15 business days, OMQD will notify the inspected manufacturer of the conformity status as "compliance."

When corrective/preventive actions to be justified by the inspectorate agency cannot be completed within 15 business days, the conformity status is concluded as "non-compliance" in principle, and the results will be notified to the manufacturing sites subject to inspection.

In addition, the contents of the "critical deficiencies" will be shared with the MHLW, and the presence or absence of an impact on the quality of the product distributed to the market and the necessity of the contents of guidance to the manufacturing sites, will be promptly examined.

| 1-4 Qualifications for inspectors

1-4-1 GMP/GCTP inspection

OMQD specifies the qualification requirements for inspectors based on the GMP Inspection Guide and GCTP Inspection Guide. As shown in [<1-1-7 Training for Inspectors>](#), there are three levels of inspector qualification: Regular inspectors, lead inspectors, and senior inspectors. The qualification requirements for each inspector are specified in 4 fields of drug substances, a) drug substances, b) non-sterile products, c) sterile products, and d) biological drugs/gene, cellular and tissue-based products.

Regular inspectors are certified by the qualified persons of OMQD based on the level of understanding of the education and training after receiving lectures on related laws and regulations, basic inspection skills, and OJT education (accompanying on-site inspections).

Lead inspectors are certified by the qualified personnel of OMQDs based on their expertise and experience in each field among personnel qualified as regular inspectors.

Senior inspectors are certified by the qualified personnel of OMQD after their ability as an educator to inspectors is assessed among personnel qualified as lead inspectors.

In principle, an inspection team is organized by two or more inspectors from the viewpoint of mutually supplementing the expertise and experience among the inspectors and securing the safety of the inspectors. A responsible inspector for the GMP inspection is designated, who organizes the overall GMP inspection, and comments on the observations, conveys the deficiency report, and documents the inspection report. In addition, the inspection team consists of at least one person who meets the qualification requirements for a lead inspector or a senior inspector for each inspection.

1-4-2 Inspection not based on application (Ad-hoc on-site inspection)

Those who conduct inspections based on Article 69 of the PMD Act (on-site inspections, etc., not based on an application for inspections) must have the qualifications specified by Cabinet Order, and the Enforcement Ordinance^{*10} of Article 69-2 paragraph (4) the PMD Act requires that they fall under any of the following:

- Pharmacist, physician, dentist or veterinarian
- A person who has completed a specialized course in pharmaceutical science, medical science, medical dentistry, veterinary medicine, science, or engineering at a university or high vocational school and has sufficient knowledge and experience in pharmaceutical inspection
- A person who has been engaged in administration related to pharmaceutical affairs for more than 1 year and has sufficient knowledge and experience in pharmaceutical inspection

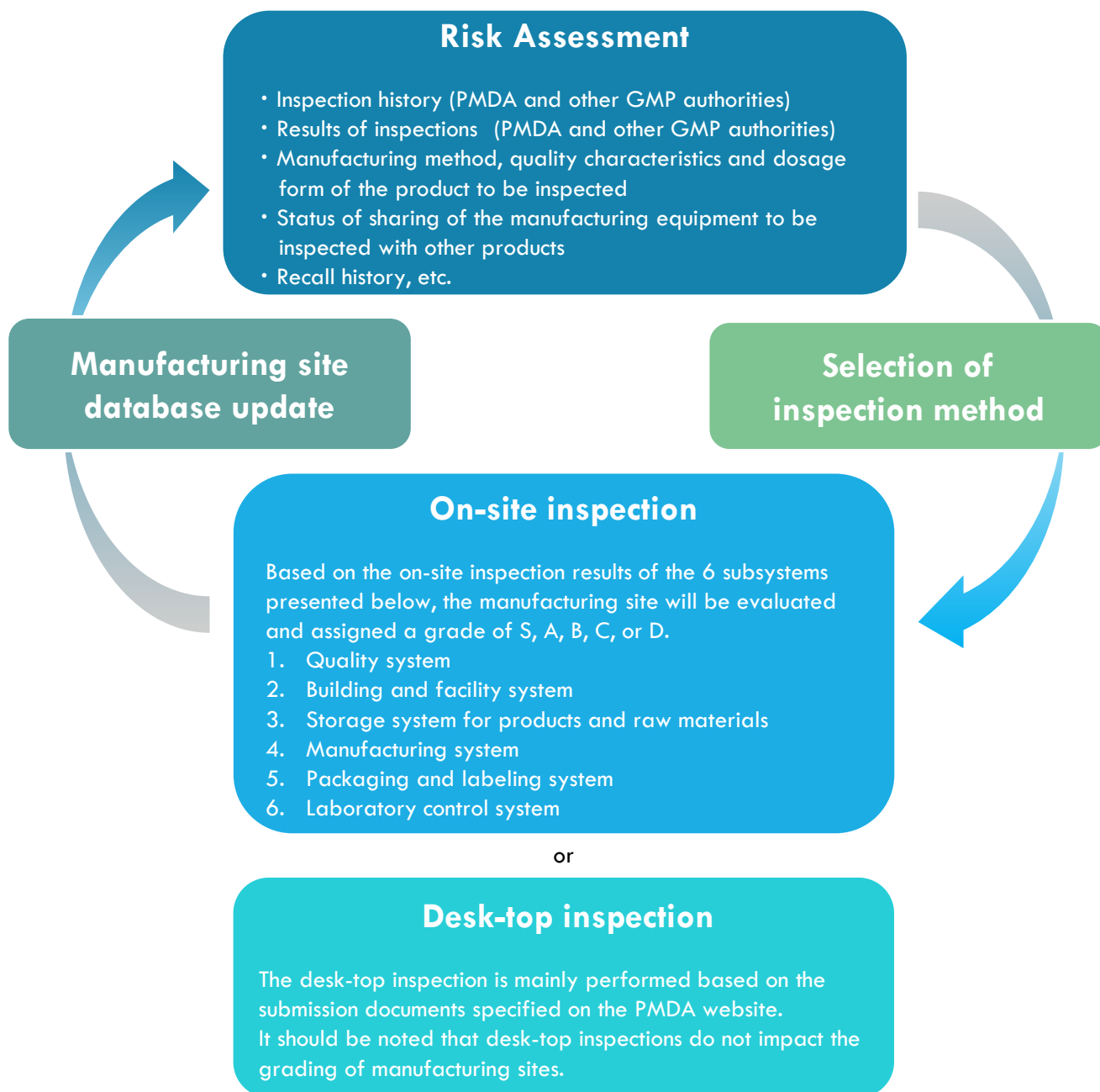
^{*10} Enforcement Ordinance of the PMD Act (Cabinet Order No. 11 of 1961)

<https://laws.e-gov.go.jp/law/336CO0000000011>

1-5 Risk-based selection of inspection method

OMQD conducts a risk evaluation of the applied manufacturing site to be inspected and selects the inspection method (on-site inspection or desk-top inspection) based on the results.

Inspection methods are selected using a risk-based approach in accordance with the flow outlined below.



1-6 GMP training support (Partially updated)

OMQD established the Division of GMP Inspection Training in FY 2022 and operate training support programs for prefectural officials to enhance the training support for prefectural officials who perform GMP inspections. PMDA is making proactive efforts to improve the quality of prefectural GMP inspectors and enhance the inspections.

Our current training programs are as follows:

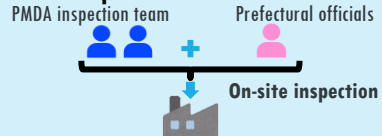
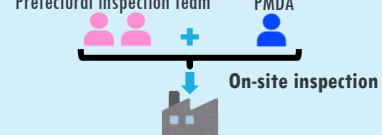
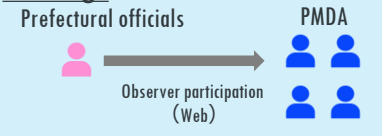
- ✓ Accept observers from prefectural governments in PMDA's GMP inspection
- ✓ Conduct PMDA-prefectural governments joint GMP inspections without prior notice to generic drug manufacturers under the jurisdiction of the prefectural governments
- ✓ Dispatch PMDA inspectors to GMP inspections conducted by prefectural governments
- ✓ Provide GMP training materials with prefectural governments
- ✓ Dispatch PMDA instructors to mock inspections sponsored by prefectural governments

In FY 2025, we started the following new initiative:

- **GMP Technical Training**

An initiative to provide training focused on technical issues considered beneficial to prefectural government officials.

GMP TRAINING SUPPORT FOR PREFECTURAL INSPECTORS (INITIATIVES UNDERLINED BEGAN IN FY 2025)

1 Support for on-site inspection	2 Provision of PMDA training materials, etc.	4 Dispatch of speakers / Consultations
Accept observers in PMDA's GMP inspection 	Introductory GMP training PMDA provides GMP introductory training which are considered useful for prefectural GMP inspectors.	Dispatch of GMP experts to training sessions and mock inspections sponsored by prefectural governments PMDA GMP experts give basic and advanced lectures, etc.
Conduct PMDA-prefectural governments joint GMP inspection 	GMP Technical Training PMDA provides training focused on technical issues considered beneficial to prefectural government officials.	Consultation on questions regarding GMP inspection To resolve questions recognized regarding prefectural GMP inspections
Dispatch of PMDA inspector to prefectural government GMP inspection 	Lectures on specialized fields of GMP To make Lectures on specialized fields of GMP by PMDA widely available to prefectural inspectors.	Sharing PMDA GMP inspection reports To strengthen collaboration system including information sharing between domestic inspection authorities
Observer participation in planning and decision-making meetings 	GMP training materials To provide training slides and videos to prefectural inspectors.	5 Information collection, accumulation, analysis, and sharing using inspection reports To maintain and improve the inspection capabilities of inspectors, at the request of the Ministry of Health, Labour and Welfare (MHLW), PMDA conducts analysis of the Prefectural and PMDA inspection reports.
	3 Seminars, etc. GMP Round Table Meeting Refer to 3-1 GMP roundtable meeting	

1-7 Consultation services

OMQD is in charge of the following consultation services.

(1) Simple consultation

The simple consultation is conducted to confirm matters related to GMP/GCTP inspections, where PMDA is the investigative authority. For more details, please refer to [<2-5-1 Simple consultation>](#).

(2) Consultation on SAKIGAKE(Japan's fast-track designation system for innovative drugs and medical devices) overall evaluation

Consultation on SAKIGAKE overall evaluation is conducted for SAKIGAKE-designated products to promote the development of innovative drugs/medical devices/gene, cellular and tissue-based products.

(3) Consultation on innovative manufacturing technology for drugs

Consultation on innovative manufacturing technology for drugs is conducted to formulate development strategies in anticipation of future commercial production, establishing product control strategies and validation methods when new innovative manufacturing technologies and manufacturing equipment are introduced for future commercial production of drugs.

This consultation is conducted on a trial basis from FY 2020 to date (July 2026), and two consultations concerning “continuous production” were received per year (1 consultation in the first half of the year, 1 consultation in the second half of the year). Consultation on both new drugs and generic drugs can be provided, with OMQD in charge of the consultation.

In this consultation, PMDA's GMP inspectors and reviewers visit the manufacturing sites, and discuss while checking the actual facilities. If the GMP inspectorate agency of the manufacturing site is a prefectural government, inspectors of the prefectural government in charge may accompany the inspection.

(4) Consultation on conformity assessments of reliability criteria

Consultation on conformity assessments of reliability criteria is conducted to provide guidance and advice on the compliance with the reliability criteria for data scheduled to be attached to approval applications for drugs or gene, cellular and tissue-based products.

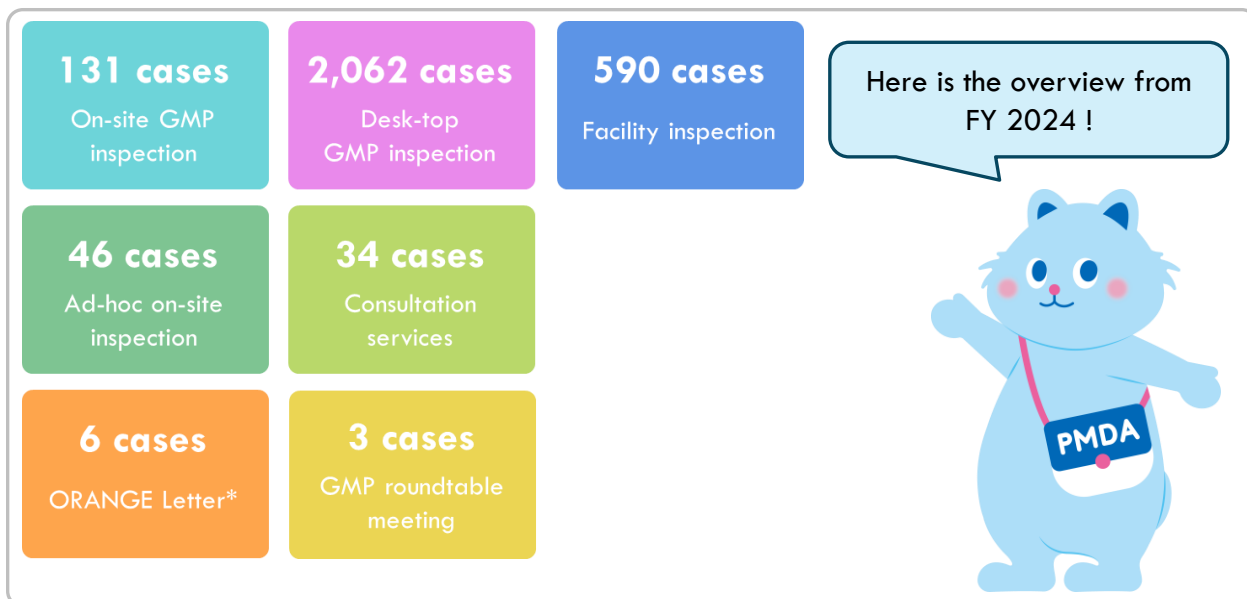
2 Achievements in FY 2025

2-1 Overview

Main achievements of Office of Manufacturing Quality for Drugs in FY 2025 are as follows:

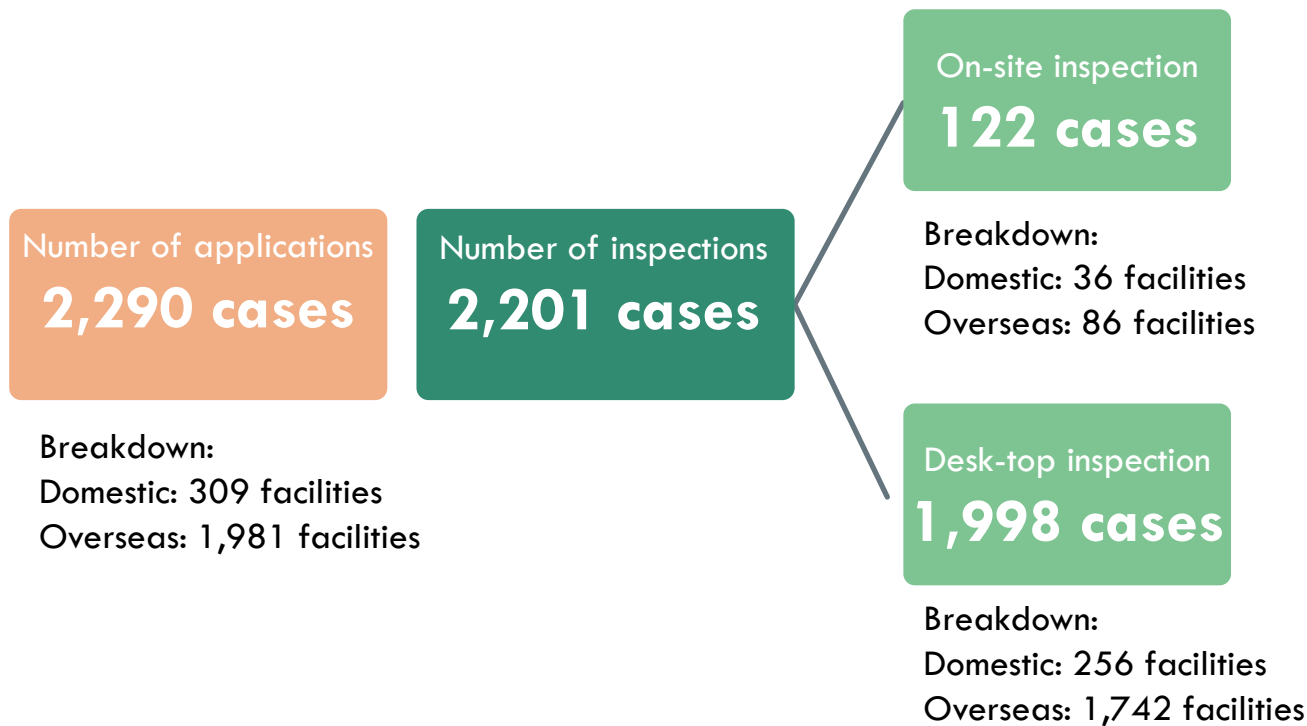


(*An information bulletin issued by OMQD to share important findings and notices regarding GMP inspections)

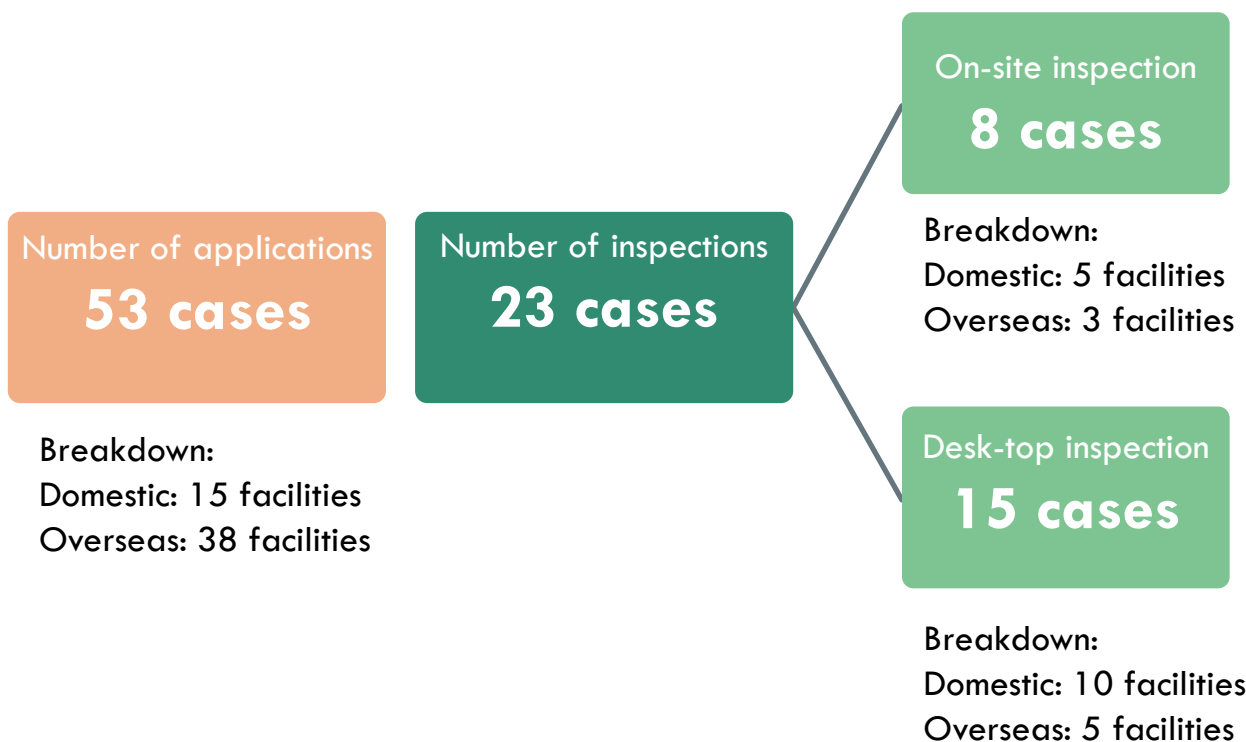


| 2-2 Number of inspections, etc.

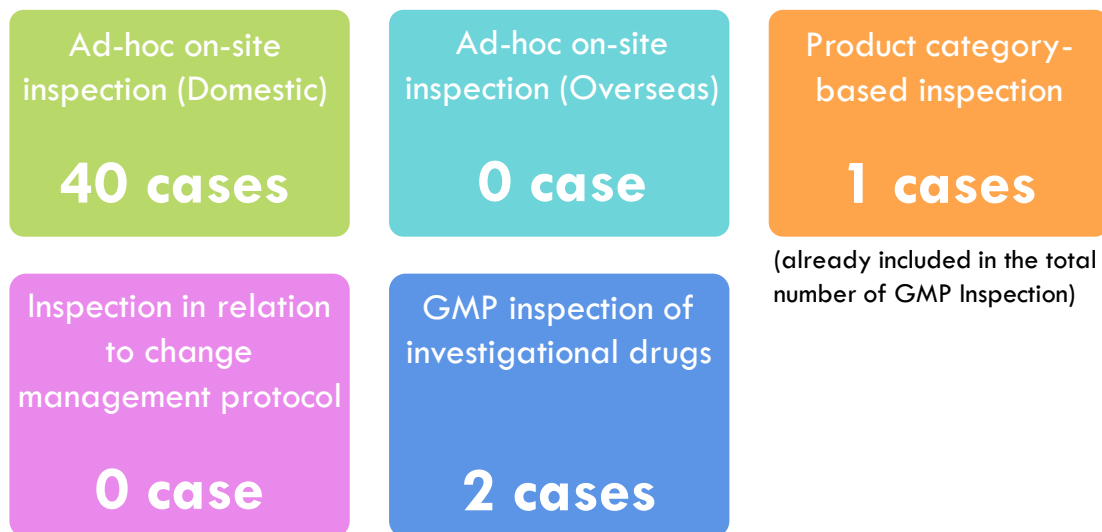
2-2-1 GMP inspection (manufacturing sites for drugs)



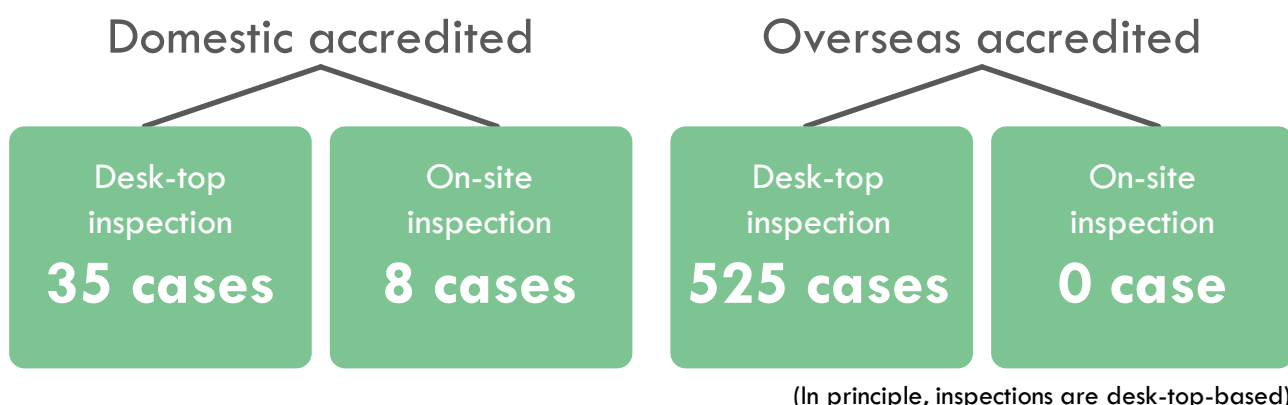
2-2-2 GCTP inspection (manufacturing sites for gene, cellular and tissue-based products)



2-2-3 Number of inspections not based on applications (Ad-hoc on-site inspections) and other inspections conducted (on-site)



2-2-4 Facility inspection



The results of inspection in FY 2025 and the calculation method of each value are as follows.

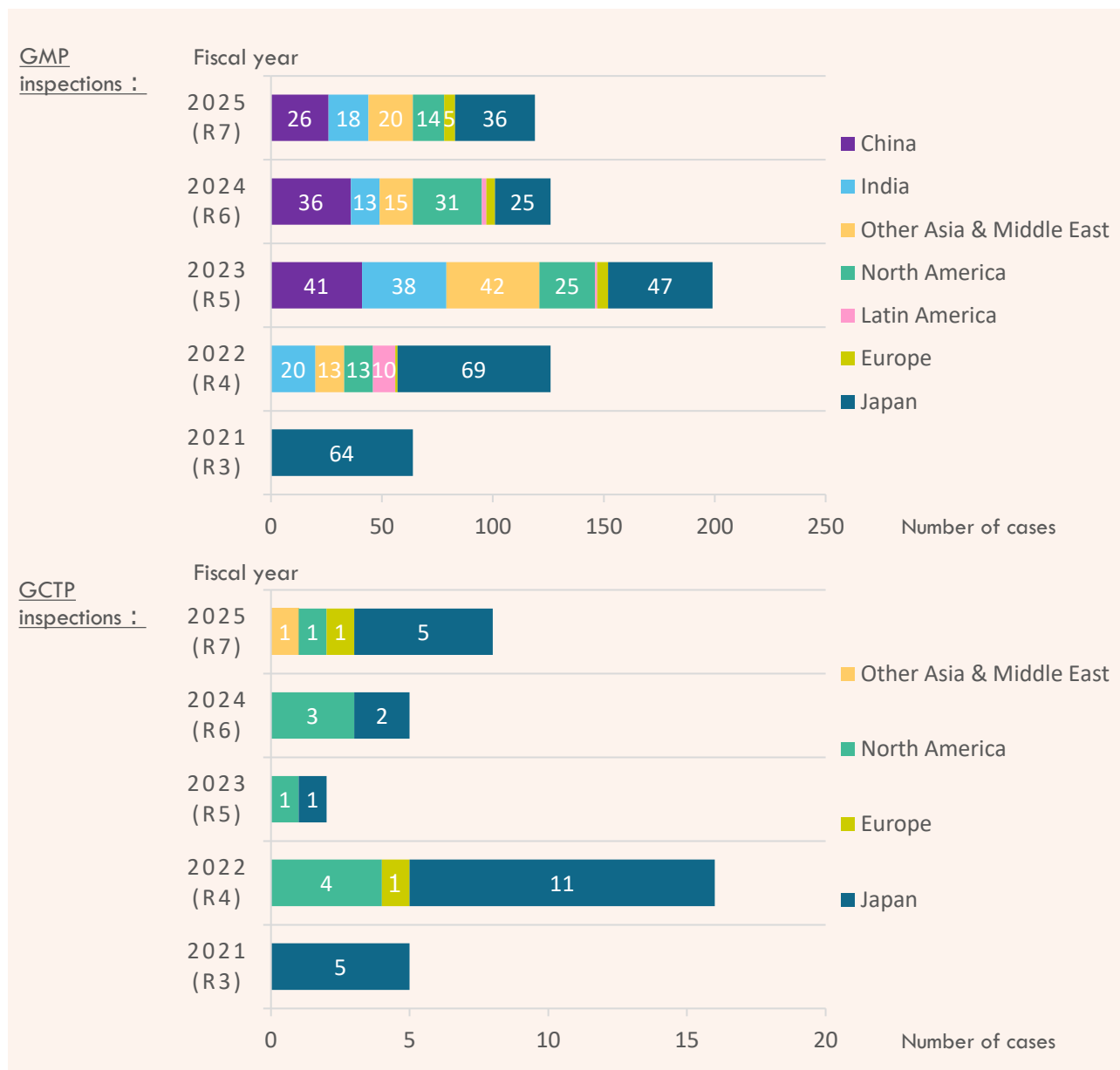
- ▶ Number of applications : Number of applications accepted in FY 2025
- ▶ Number of inspections (on-site inspection) : Number of on-site inspections conducted in FY 2025
- ▶ Number of inspections (desk-top inspection (document-based inspection)) : Number of inspections completed in FY 2025
If a separate inspection was conducted at the same facility, each inspection was counted.

Even if the application was accepted within the fiscal year, it is not possible to complete all inspections within the fiscal year in relation to the period required for inspection. Therefore, the number of applications does not match the number of inspections.

2-2-5 Countries/Regions of On-site Inspection

The number of GMP inspections conducted by OMQD by country/region where the sites are located are as follows. (Past 5 years)

The number of inspections is limited to GMP/GCTP inspections based on applications for inspection and does not include the number of other types of inspection, including Ad-hoc on-site inspections (30 to 40 cases as GMP, a few cases as GCTP per year), etc.



In FY 2023, on-site inspections were resumed in China. The number of GMP inspections in China was 41, which are equivalent to the level in FY 2019 before the COVID-19 pandemic. In addition to China, 38 on-site inspections were conducted in India, 42 in Asia/Middle East excluding China and India, 25 in North America, and 5 in Europe (sites not covered by MRA). The number of on-site inspections in all countries/regions increased from FY 2022.

The number of on-site inspections in FY 2024 decreased compared to FY 2023. This is considered to reflect the fact that many of the overseas inspections that could not be conducted temporarily due to travel restrictions following the COVID-19 pandemic from FY 2020 were carried out in FY 2023, resulting in a peak in that year.

The number of on-site inspections in FY 2025 remained at approximately the same level as in FY 2024.

2-3 Trend of identified deficiencies

2-3-1 Ranking of identified deficiencies

Deficiencies identified by OMQD are categorized based on their profiles and aggregated for each fiscal year. The rankings of frequency of issuance of other deficiencies and major or critical deficiencies are as follows. Note that multiple deficiencies of the same category identified during a single inspection are counted as one.

Major or Critical deficiencies

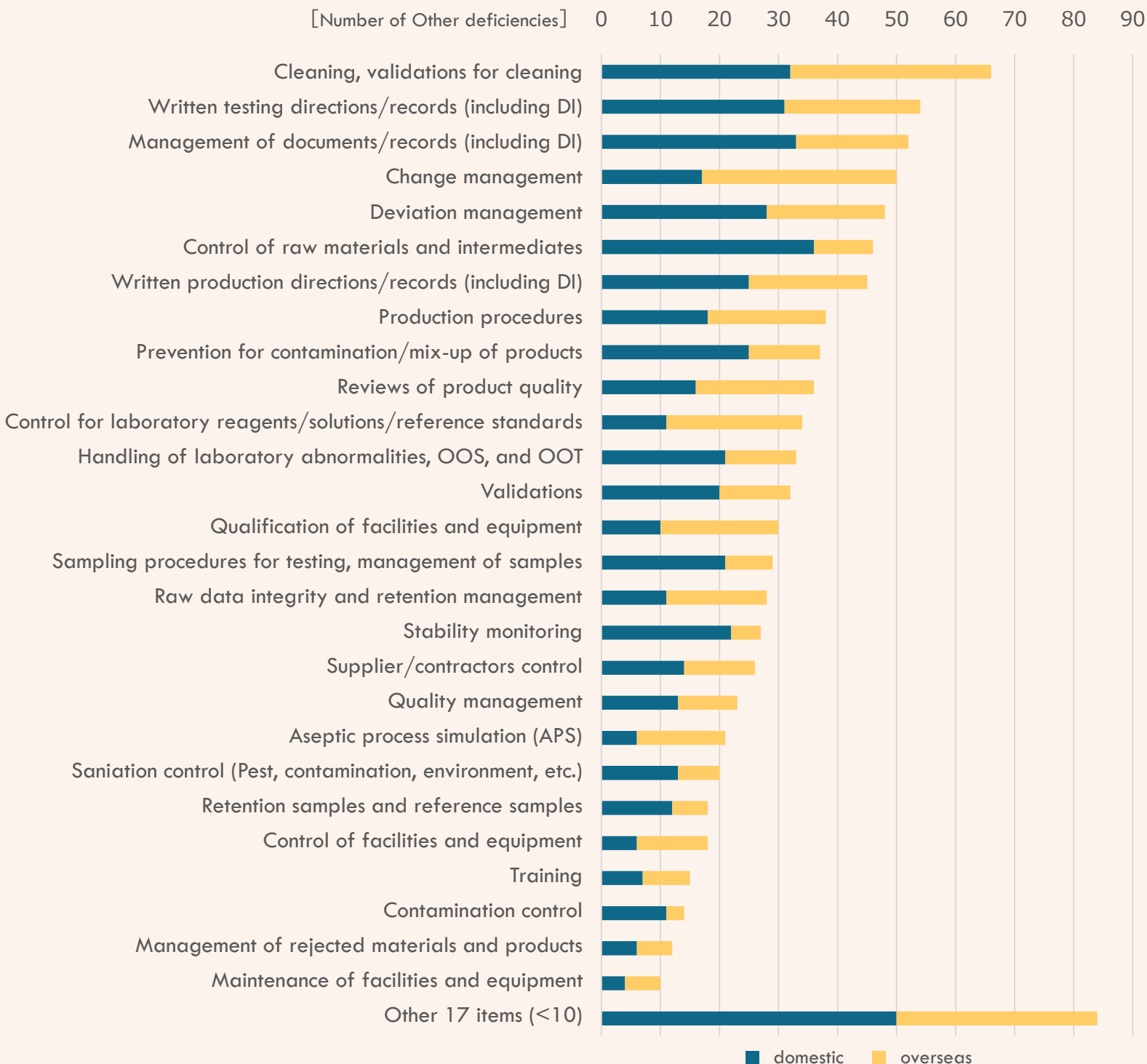
	2021	2022	2023	2024	2025
1	Deviation handling	Organizational management, quality management	Deviation handling	Quality management Management of Documents/Records (including DI) Change management	Management of Documents/Records (including DI) Stability monitoring
2	DI-related	Validations Supplier control	Validations DI-related Document management Handling of laboratory abnormalities, OOS, and OOT	Handling of laboratory abnormalities, OOS(Out of Specification), and OOT	Release Certification Deviation management
3	Test records, test procedures Sterility assurance	Document management DI-related	Other 8 items	Cleaning, validations for cleaning	Organization and Management Responsibilities Validations Prevention for contamination/mix-up of products
4	Other 5 items	Sterility assurance Reviews of product quality		Written production directions/records (including DI)	Quality management Supplier/contractors control
5		Other 5 items		Deviation management Sanitation Control (Pest, contamination, environment, etc.) Training Written testing directions/records (including DI)	Other 11 items

Other deficiencies

	2021	2022	2023	2024	2025
1	Control of raw materials and intermediates	Written production directions/records, procedures	Written production directions/records, procedures	Deviation management	Cleaning, validations for cleaning
2	Written production directions/records, procedures	Control of raw materials and intermediates	Control of raw materials and intermediates	Written testing directions/records (including DI)	Written testing directions/records (including DI)
3	Control of facilities and equipment	Document management	Control of facilities and equipment	Written production directions/records (including DI) Management of Documents/Records (including DI)	Management of Documents/Records (including DI)
4	Document management	Control of facilities and equipment	Document management	Control of raw materials and intermediates Change management	Change management
5	Test records, test procedures	Test records, test procedures	Deviation handling	Control for laboratory reagents/solutions/reference standards Cleaning, validations for cleaning	Deviation management
6	Sanitation/hygiene control, utility Deviation handling	Sampling procedures for testing, management of samples	Sampling procedures for testing, management of samples	Sampling procedures for testing, management of samples	Control of raw materials and intermediates
7	Sampling procedures for testing, management of samples	DI-related	Test records, test procedures	Handling of laboratory abnormalities, OOS, and OOT	Written production directions/records (including DI)
8	Validations DI-related	Control for laboratory reagents/solutions/reference standards Sanitation/hygiene control, utility Deviation handling	Change management Organizational management, quality management	Supplier/contractors control Control of facilities and equipment	Production procedures
9	Cleaning, validations for cleaning Supplier control	Prevention for contamination/mix-up of products	Cleaning, validations for cleaning	Production procedures	Prevention for contamination/mix-up of products
10	Handling of laboratory abnormalities, OOS, and OOT	Supplier control	Sanitation/hygiene control, utility	Prevention for contamination/mix-up of products	Reviews of product quality

2-3-1 Ranking of identified deficiencies (continued)

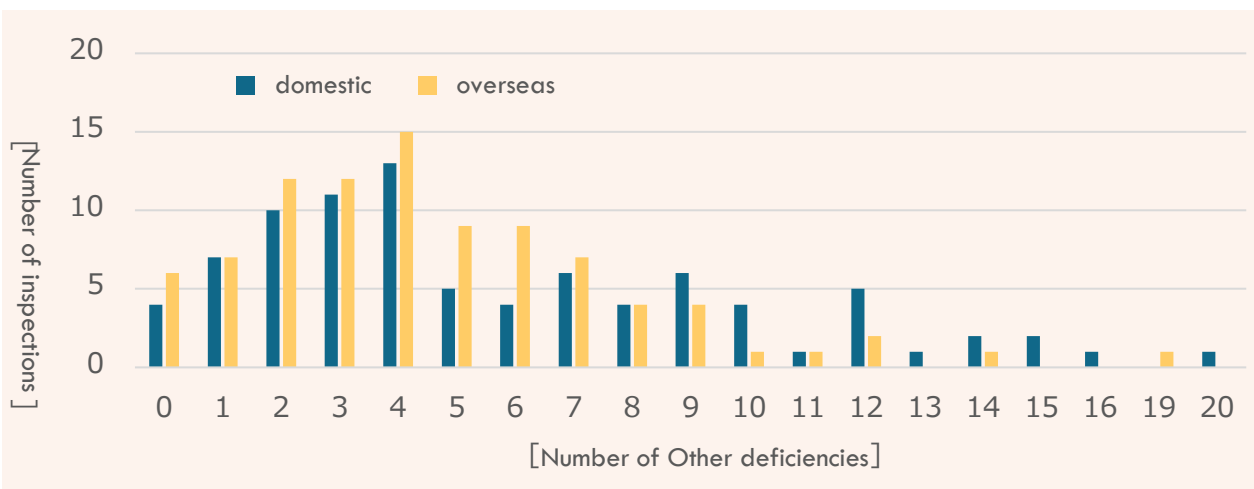
A total of 928 Other deficiencies (507 domestic and 421 overseas) were issued during FY 2025. The numbers of Other deficiencies issued in FY 2025 by category, broken down into domestic and overseas inspections, are shown below.



A total of 178 on-site inspections (87 domestic and 91 overseas) were conducted in FY 2025, including inspections, investigational product GMP inspections, and on-site assessments performed as part of SAKIGAKE Designation System Comprehensive Consultation, for which the inspection start date fell within FY 2025. A total of 928 Other deficiencies were issued, corresponding to an average of 5.2 Other deficiencies per inspection (5.8 for domestic inspections and 4.6 for overseas inspections). For Critical deficiencies and Major deficiencies, please refer to [Section 3-3, List of Deficiencies](#).

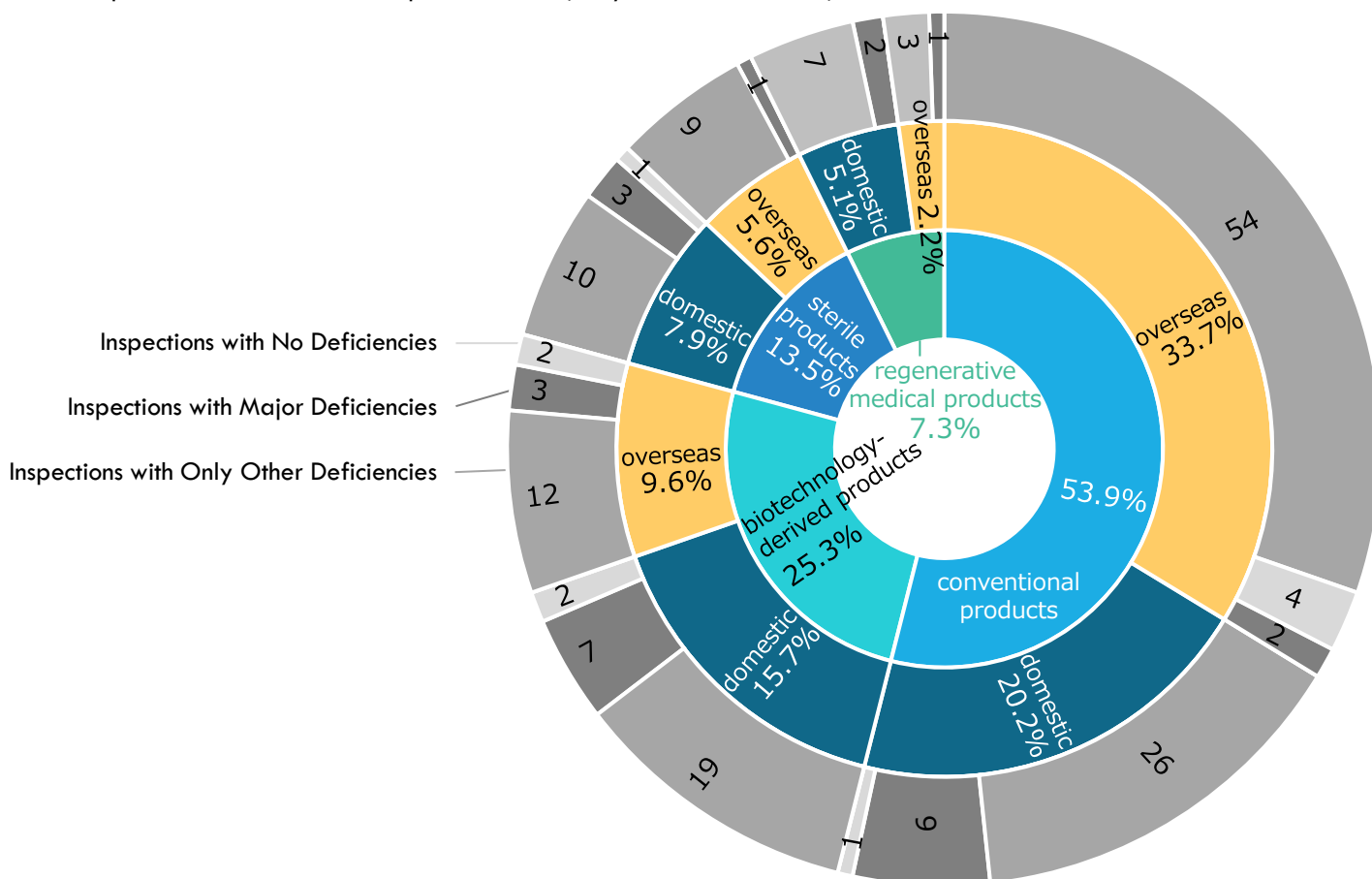
2-3-1 Ranking of identified deficiencies (continued)

In addition, the distribution of inspections according to the number of Other deficiencies issued was as follows.



Approximately 6% of manufacturing sites received no Other deficiencies, 57% received 1 to 5 Other deficiencies, 28% received 6 to 10 Other deficiencies, 8% received 11 to 15 Other deficiencies, and 2% received 16 to 20 Other deficiencies.

The figures below show the distribution of inspections by inspection category (with the packaging category included in the conventional products category and the radiopharmaceutical category included in the sterile products category), together with the proportions of domestic and overseas inspections, and the numbers of inspections that resulted in Major deficiencies, only Other deficiencies, or no deficiencies.



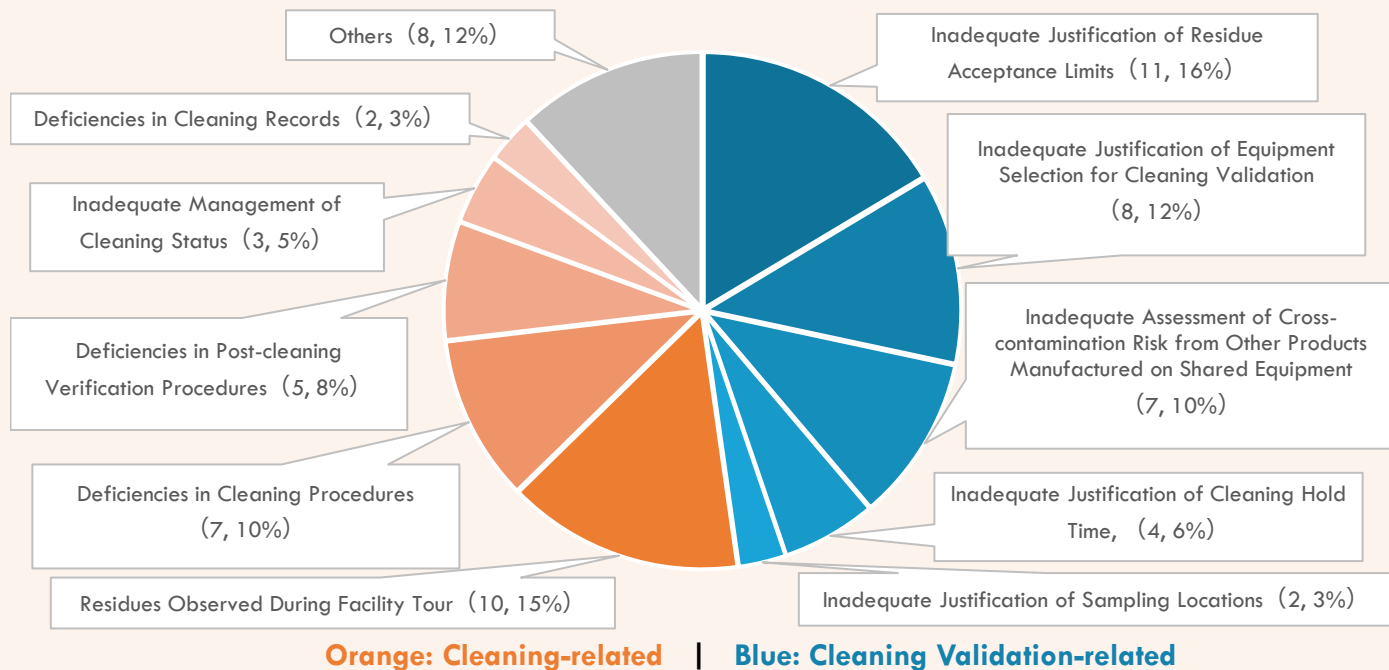
Furthermore, trend analyses were conducted for the top 10 categories of deficiencies issued during FY 2025. The key observations and findings from these analyses are discussed in the following pages.

2-3-2 Analysis of identified deficiencies

Related to Article 8-2 (Prevention of Cross-contamination), Article 9 (Buildings and Facilities), and Article 13 (Validation)

Of the 928 Other deficiencies issued during FY 2025, the most frequently cited category was “Cleaning and Cleaning Validation,” accounting for 66 deficiencies (32 domestic and 34 overseas). When analyzed by inspection category, 54 deficiencies were identified in inspections related to conventional products, 7 in inspections related to biotechnology-derived drug substances, and 6 in inspections related to sterile products (including biotechnology-derived products). Although most deficiencies were identified in the conventional product category, similar deficiencies were also observed in biotechnology and sterile manufacturing operations, suggesting that these are common management challenges across all categories. In addition, among the 45 Major deficiencies disclosed in the Attachment, only one deficiency was related to Cleaning and Cleaning Validation. When this deficiency is combined with the 66 Other deficiencies described above, a total of 67 deficiencies can be further classified as shown in the pie chart below. Broadly, these deficiencies can be divided into two groups: Cleaning Validation-related deficiencies and Cleaning-related deficiencies, with both groups accounting for almost equal proportions of the total.

No. 1 Category: Breakdown of Deficiencies Related to Cleaning and Cleaning Validation (Total: 67 Deficiencies)



Where multiple categories were identified for a single deficiency, only the category considered most significant was assigned for classification purposes.

【Deficiencies Related to Cleaning Validation】

- ✓ **Inadequate Justification of Residue Acceptance Limits (16%):** Deficiencies were identified in cases where the establishment of residue acceptance limits did not take into account the results of pharmacological and toxicological evaluations, such as those based on PDE values, did not reflect equipment surface areas, or did not consider swab recovery rates when assessing residues. In addition, deficiencies were also identified in analytical methods used for residue evaluation, where there was no verification that the methods possessed sufficient specificity and sensitivity to adequately detect residues of the selected marker compounds.
- ✓ **Inadequate Justification of Equipment Selection for Cleaning Validation (12%):** Deficiencies were identified in cases where the rationale for evaluating only representative equipment had not been demonstrated, or where hard-to-clean locations, such as ball valves, had not been included within the scope of cleaning validation studies.
- ✓ **Inadequate Assessment of Cross-contamination Risk (10%):** Deficiencies were identified in cases where the impact on existing acceptance criteria had not been assessed when introducing new products to shared equipment, or where toxicological risk assessments had not been performed for developmental products manufactured using shared equipment.

2-3-2 Analysis of identified deficiencies (continued)

- ✓ Inadequate Justification of Cleaning Hold Time (6%) and Inadequate Justification of Sampling Locations (3%) were also identified.

【Deficiencies Related to Cleaning】

- ✓ Residues Observed During Facility Tours (15%): Deficiencies were identified in cases where powder residues or other materials remained inside equipment even after cleaning. Such observations may indicate that an adequate state of cleanliness had not been achieved.
- ✓ Deficiencies in Cleaning Procedures (10%) Deficiencies: were identified in cases where procedures did not clearly specify conditions critical to effective cleaning of equipment and facilities, such as temperature, flow rate, cleaning duration, and methods for disassembly and cleaning.
- ✓ Deficiencies in Post-cleaning Verification Procedures (8%): Deficiencies were identified in cases where the acceptance criteria for visual inspection were unclear or where hard-to-clean locations had been omitted from verification activities.
- ✓ Inadequate Management of Cleaning Status (5%) and Deficiencies in Cleaning Records (3%) were also identified.

Although these deficiencies were issued individually to different manufacturing sites, the overall findings suggest common challenges in both the design of cleaning validation programs and the execution of cleaning operations. In particular, cases where acceptance limits were not established based on scientific justification, including pharmacological and toxicological evaluations, or where validation strategies did not adequately cover the entire equipment train, represent fundamental weaknesses in cleaning validation programs. Furthermore, despite the fact that effective cleaning is essential to ensuring product quality, numerous cases were identified in which powder residues or other materials were observed inside equipment during facility tours, indicating challenges in the effectiveness of cleaning practices during routine operations.

These deficiencies suggest inadequate compliance with the requirements of Article 8-2 (Prevention of Cross-contamination), Article 9, Paragraph 1 (Buildings and Facilities: Cleaning and Maintenance), and Article 13 (Validation) of the GMP Ordinance. In addition, when assessed against the definition and principles of cleaning validation described in [Section 4, Validation Guidance of the MHLW notification “Partial Revision of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Pharmaceuticals and Quasi-drugs” issued on April 28, 2021](#), these deficiencies indicate shortcomings in both the validation approach and the actual implementation of cleaning activities.

Among the deficiencies identified, Inadequate Justification of Residue Acceptance Limits, which was the most frequently cited category, was observed more frequently at domestic manufacturing sites. The establishment of residue acceptance limits based on toxicological justification is explicitly described in the PIC/S guideline^{※11} on the establishment of Health-Based Exposure Limits (HBELs) (PI 046-1), issued in July 2018. The Japanese GMP Ordinance also identifies this guideline as a useful reference for the prevention of cross-contamination when manufacturing equipment is shared^{※12}. While manufacturing sites in Japan have been working to implement these requirements, cases of insufficient implementation continue to be identified. Further understanding and consistent application of these requirements are therefore expected.



If there is insufficient scientific justification for residue acceptance limits or equipment selection, cleaning cannot be considered adequate regardless of how thoroughly it is performed. Conversely, residues may still be observed inside equipment even when the validation approach is appropriate. Effective cleaning therefore requires both sound justification of cleaning conditions and reliable verification of the results. **“Any risk that is not properly controlled will ultimately be borne by patients.”** Let us reaffirm the importance of this message from the ORANGE Letters.

(Reference: PMDA ORANGE Letters)

No.2 : [Risks associated with handling substances with unknown pharmacological](#)

No.25 : [Risks associated with handling substances with unknown pharmacological \(part 2\)](#)

- ※11 PI 046-1 “Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities” <https://picscheme.org/docview/2467>
- ※12 Notification of the Director, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated April 28, 2021 (Yakuseikanma No. 0428-2), Section 13, Relationship to Article 9 (Buildings and Facilities), (1), ⑤(e).

2-3-2 Analysis of identified deficiencies (continued)

Related to Article 20 (Document and Record Management)

Among the 928 Other deficiencies issued during FY 2025, deficiencies related to Test Procedures and Records (including DI) ranked second with 54 cases, Document and Record Management (including DI) ranked third with 52 cases, and Manufacturing Instructions and Records (including DI) ranked seventh with 45 cases. Together, these three categories accounted for 151 deficiencies and represented a substantial proportion of all Other deficiencies. Among the 42 Major deficiencies, six involved Document and Record Management (including DI), while Test Procedures and Records (including DI) and Manufacturing Instructions and Records (including DI) each accounted for one case. Notably, Document and Record Management (including DI) represented approximately 14% of all Major deficiencies.

Common issues included insufficient documentation of the rationale for test conditions and decisions on retesting or reprocessing, unclear procedural requirements for record revision and reissuance, and document retention periods that were not aligned with the requirements of the Japanese GMP Ordinance. Although manufacturing or testing activities had been performed, the supporting rationale was not always adequately documented.

At domestic manufacturing sites, deficiencies mainly involved operational aspects of document control, such as document management, storage, issuance, and retrieval practices. At overseas manufacturing sites, common issues included document retention periods required under the Japanese GMP Ordinance and consistency between marketing authorization documents or master files and manufacturing or testing records.

Analysis by product category, including drug substances, non-sterile products, sterile products, and regenerative medical products, did not reveal any notable differences. Common themes included the level of detail and traceability of manufacturing and testing instructions and records, consistency with approved documentation, and document retention periods.

Related to Article 10 (Manufacturing Control) and Article 13 (Validation)

Deficiencies related to Manufacturing Procedures, which ranked eighth among the 928 Other deficiencies issued during FY 2025, accounted for 38 cases (18 domestic and 20 overseas). Approximately half of these cases involved activities that were performed in practice but were either not described, or not clearly described, in procedures or manufacturing instructions and records. Another major category, accounting for approximately 40%, involved incomplete records, such as missing calculations, raw material lot numbers, or quantities used.

A further group of cases, representing approximately 10%, was specific to manufacturing procedures. In these cases, process parameters or control criteria had been established based on experience or customary practice, or had not been adequately evaluated through change control. As a result, supporting justification was either insufficient or not documented, even where verification activities had been conducted.

No notable differences were observed between domestic and overseas manufacturing sites. However, analysis by inspection category showed that 23, 8, 5, and 2 cases were identified in inspections related to conventional products, sterile products, biotechnology-derived products, and regenerative medical products, respectively. Considering the overall distribution of inspections, deficiencies related to manufacturing procedures appeared relatively more frequently in the sterile products category. Overall, 9 of the 38 cases involved aseptic operation procedures or contamination control in manufacturing environments. These findings suggest that inspections focusing on sterility assurance contributed substantially to the number of deficiencies identified in manufacturing procedures.

Related to Article 8-2 (Prevention of Cross-contamination) and Article 13 (Validation)

Deficiencies related to Foreign Matter, Contamination, and Mix-up Prevention, which ranked ninth among the Other deficiencies issued during FY 2025, accounted for 37 cases (25 domestic and 12 overseas). Similar to the observations described above, more than half of these cases involved measures intended to prevent cross-contamination that were either not adequately described in procedures or manufacturing instructions and records, or could not be adequately verified from the records. In addition, more than 30% of the cases involved procedures whose adequacy could not be sufficiently justified because necessary verification activities had not been adequately conducted. In this respect, deficiencies related to Cleaning and Cleaning Validation, which ranked first among Other deficiencies, may be considered part of the same underlying issue.

As a characteristic finding in this category, four cases were identified during facility tours in which conditions that could lead to foreign matter contamination, contamination, or mix-ups were observed, such as inadequate cleaning of manufacturing areas or operations performed without appropriate gowning procedures.

2-3-2 Analysis of identified deficiencies (continued)

Related to Article 14 (Change Control)

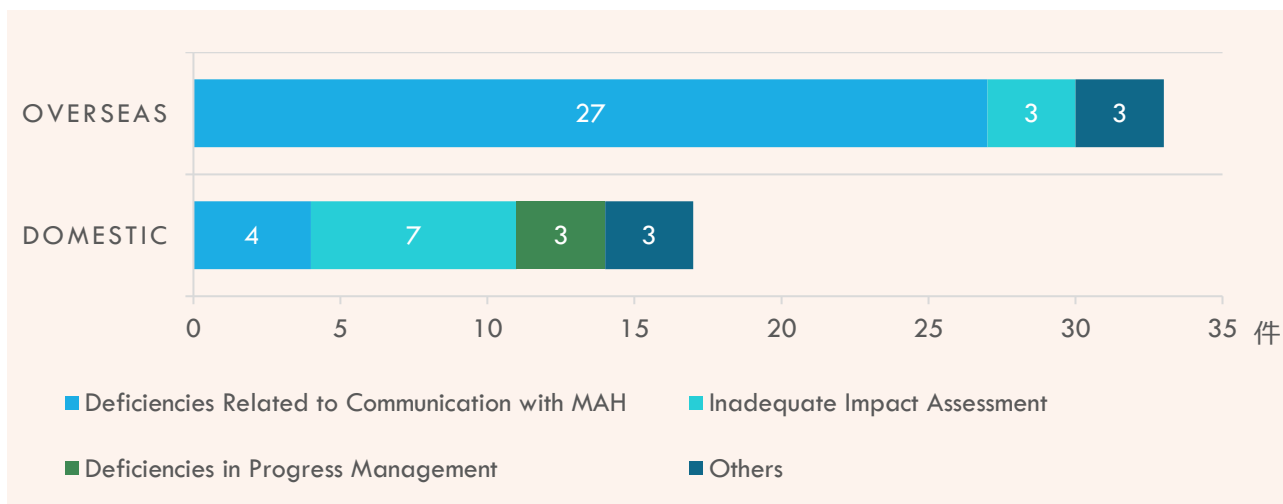
Among the Other deficiencies issued during FY 2025, Change Control remained the fourth most frequently cited category, with a total of 50 deficiencies (17 domestic and 33 overseas). Of these, 31 deficiencies (4 domestic and 27 overseas) were related to communication with Marketing Authorization Holders (MAH), similar to the findings identified in FY 2024, including the following issues:

- ✓ Procedures for notifying MAHs of changes that may affect product quality or approved matters, obtaining prior confirmation, and providing post-implementation notification were not defined in procedures, quality agreements, or other relevant documents.
- ✓ Procedures required assessment of the impact on product quality but did not require assessment of the impact on approved matters. As a result, changes that deviated from, or could potentially affect, approved matters might not be communicated to the MAH.
- ✓ Procedures stated that notification to the marketing authorization holder was unnecessary for changes that did not affect approved matters and did not require regulatory action, even when such changes affected, or could affect, product quality.
- ✓ Procedures did not require preparation and retention of records relating to notifications provided to MAHs concerning changes that affected, or could affect, product quality or approved matters.
- ✓ Although procedures requiring prior and post-implementation communication with MAHs were established, the required notifications were not actually performed.

Among the 45 Major deficiencies disclosed in the Attachment, one deficiency was related to change control and involved the same issue.

Under Article 14 of the GMP Ordinance, manufacturers are required to notify the relevant MAH in advance of any change that may affect product quality or approved matters, obtain confirmation where appropriate, provide notification after implementation, and prepare and retain records of such communications. As this requirement is specifically stipulated in the GMP Ordinance and is routinely reviewed during on-site inspections, the high frequency of these deficiencies suggests that the regulatory requirement has not been sufficiently understood, particularly by overseas manufacturing sites.

Among the remaining Other deficiencies (13 domestic and 6 overseas), insufficient impact assessment was the most common issue (7 domestic and 3 overseas). Domestic observations also included deficiencies in progress management (3 cases), discrepancies between procedures and actual practice, deficiencies in regulatory procedures due to insufficient communication with MAHs, and changes implemented outside the change control system (1 case each). Overseas observations included deficiencies in task management within change control, changes implemented outside the change control system, and implementation of regulatory non-compliant changes (1 case each).



2-3-2 Analysis of identified deficiencies (continued)

Related to Article 15 (Deviation Management)

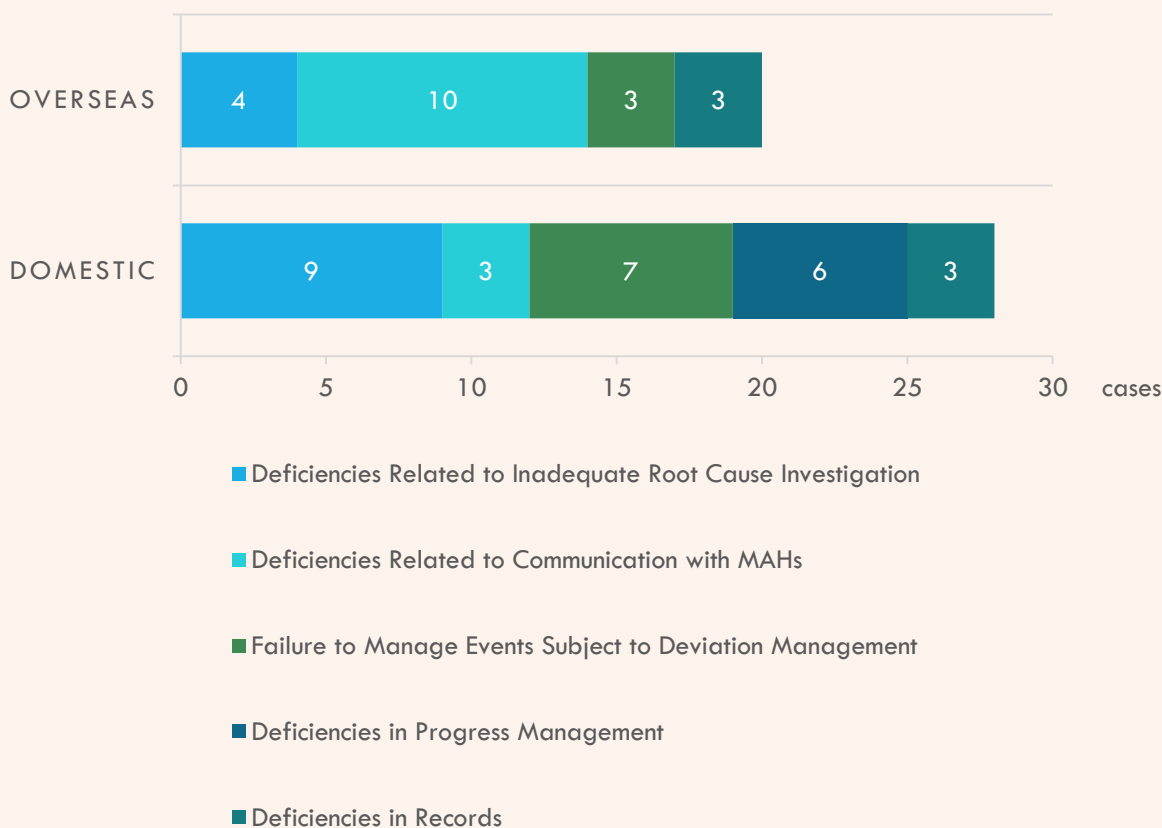
Deviation Management, which ranked first in FY 2024 with 80 Other deficiencies, ranked fifth in FY 2025 with a total of 48 deficiencies (28 domestic and 20 overseas). These included deficiencies related to inadequate root cause investigation for individual deviations (13 cases; 9 domestic and 4 overseas), communication with MAHs (13 cases; 3 domestic and 10 overseas), failure to manage deviation events through the deviation management system (10 cases; 7 domestic and 3 overseas), deficiencies in progress management (6 cases; all domestic), and deficiencies in records (6 cases; 3 domestic and 3 overseas).

Among the 45 Major deficiencies disclosed in the Attachment, four were related to deviation management and included issues frequently observed among Other deficiencies, such as inadequate impact assessment, deficiencies in progress management, and deficiencies in records.

Compared with FY 2024, the number of Other deficiencies related to deviation management decreased to approximately 60% of the previous year's level. In contrast, the number of Major deficiencies increased to four cases, compared with two cases in FY 2024.

Although inadequate root cause investigation and related deficiencies remained the most frequently observed issue, their proportion decreased from approximately half of all deviation management deficiencies in FY 2024 to approximately 30% in FY 2025.

In contrast, deficiencies related to communication with MAHs increased from approximately 20% in FY 2024 to approximately 30% in FY 2025. Article 15 of the GMP Ordinance requires manufacturers to promptly notify the relevant MAHs when a critical deviation occurs, such as a deviation that affects, or may affect, product quality or involves, or may involve, non-compliance with approved matters. The Ordinance also requires records of such communications to be prepared and retained. As these requirements are specifically prescribed in the GMP Ordinance and are routinely reviewed during on-site inspections, the high frequency of such deficiencies suggests that the regulatory expectations have not yet been sufficiently understood, particularly at overseas manufacturing sites.



2-3-2 Analysis of identified deficiencies (continued)

Related to Article 11 (Quality Control): Logistics Management of Raw Materials and Intermediate Products

Deficiencies related to the logistics management of raw materials and intermediate products (receipt, sampling, testing, storage, and inventory control) accounted for 46 deficiencies, ranking sixth among all Other deficiencies. In addition, 36 of these deficiencies were identified at domestic manufacturing sites, representing a higher proportion than those identified at overseas manufacturing sites.

The deficiencies were broadly categorized as deficiencies related to storage conditions and labeling control (12 cases), expiry date management (11 cases), sampling (9 cases), and receipt records and procedures (9 cases). All nine sampling-related deficiencies were identified at domestic manufacturing sites. Most involved unclear justification for the number of samples collected or for the practice of pooling samples prior to testing. Similar deficiencies have been identified repeatedly in past inspections. The number of samples collected from received materials and the acceptability of sample pooling should be established based on an assessment of factors such as unit-to-unit uniformity, taking into account the results of supplier audits and other relevant information.

No notable trends were identified among deficiencies observed at overseas manufacturing sites. However, several deficiencies related to receipt procedures and records were identified, including cases in which QA was not informed when raw materials were returned due to abnormalities identified during receipt inspection. As information related to defects in raw materials and other materials is important for supplier management, it is desirable that QA maintains comprehensive oversight of such information.

As noted in [ORANGE Letter No. 1](#), failure to assure the suitability of received raw materials may ultimately lead to risks to patients. Maintaining appropriate records throughout the process from receipt, testing, and storage to issuance of raw materials is therefore an important element in assuring the quality of the final product.

Related to Article 11-3 (Product Quality Review)

Deficiencies related to Product Quality Review (PQR) accounted for 36 deficiencies, ranking tenth among all Other deficiencies (20 overseas and 16 domestic). The most frequently observed deficiencies were related to insufficient review scope and coverage (11 cases), delays in review completion and timeline management (9 cases), and inadequate evaluation of trend analysis results (7 cases).

When analyzed by region, the most common deficiencies identified at domestic manufacturing sites were related to progress management, including delays in the preparation and approval of PQR reports. One possible reason is that PQR periods are often defined on a fiscal-year basis in Japan, resulting in an increased workload for QA, particularly at manufacturing sites handling multiple products, during the end-of-year reporting period. Resource constraints in personnel and time may also lead to an excessive focus on completing reports by the required deadline, potentially resulting in more significant deficiencies, such as inadequate evaluation of abnormal trends identified through stability monitoring, which was the most frequently observed Major deficiency. In contrast, overseas manufacturing sites more commonly exhibited deficiencies related to review coverage, including insufficient review periods and exclusion of non-routine batches from the review scope.

PQR is not intended to be merely a routine annual reporting exercise. Its primary objective is to contribute to continual improvement of the quality system through analysis of annual manufacturing trends. If PQR is not conducted appropriately, changes over time or deteriorating trends may not be detected in a timely manner, even when no issues are evident in individual batches. As a result, opportunities to prevent potential quality problems may be missed, ultimately increasing the risk of defective medicinal products being released to the market.

| 2-4 GMP training support

The achievement of support operations in FY 2025 is as follows:

1 Support for on-site inspection	2 Provision of PMDA training materials, etc.	3 Seminars, etc.
Accept observers in PMDA's GMP inspection 6 cases (6 Japanese cases, 0 overseas cases)	Introductory GMP training April : 149 participants	GMP Round Table Meeting September : 8 participants (Yamaguchi Prefecture Co-host) October : 15 participants (at Tokyo) March : 5 participants (Ibaraki Prefecture Co-host)
Conduct PMDA-prefectural governments joint GMP inspection 13 cases	GMP Technical Training 401 registrations in total of 5 cases	4 Dispatch of speakers / Consultations
Dispatch of PMDA inspector to prefectural government GMP inspection 0 cases	Lectures on specialized fields of GMP July(1st) : 28 participants October(2nd) : 8 participants March(3rd) : 17 participants	Dispatch of GMP experts to training sessions and mock inspections sponsored by prefectural governments 7 cases
<u>Observer participation in planning and decision-making meetings</u> 598 participants in total	GMP training materials GMP training for beginners' videos/slides (renewals), PMDA's specialized training slides (renewals)	Consultation on inquiry regarding GMP inspections conducted by prefectural governments 3 cases
		Sharing PMDA GMP inspection reports 92 cases

2-5 Consultation services

2-5-1 Simple consultation

OMQD is in charge of consultations related to GMP and GCTP inspections among Simple consultations based on "Implementation Guideline, for Face-to-Face Consultations and Examinations Confirm Certification Conducted by Pharmaceuticals and Medical Devices Agency" (PFSB/ELD/OMDE Notification No. 0302070 dated March 2, 2012; hereinafter referred to as the "Implementation Guideline").

The numbers of receipt¹ and meetings² of simple consultations related to GMP and GCTP inspections in the past 3 years are shown below.

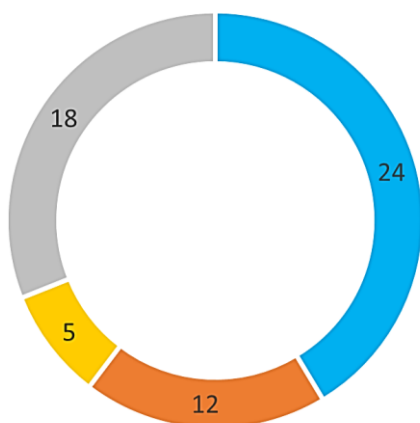
Fiscal year	Number of receipt	Number of meetings
2023	42	15
2024	62	33
2025	53	23

1) Number of Simple consultations received

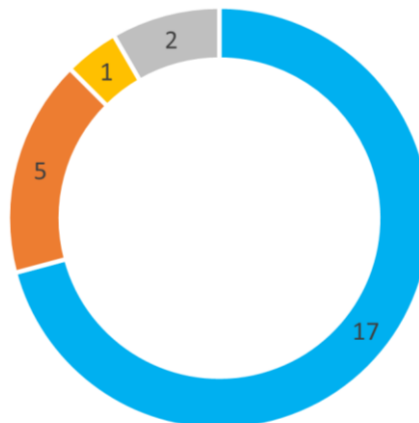
2) Number of Simple consultations (meetings) conducted

The breakdown of the simple consultation applications and reception details for the fiscal year 2025 is as follows. Several items included in one consultation were counted individually.

**Applications
(Including Withdrawal)**



**Receptions
(Excluding Withdrawal)**



- **Concept of validation**
- **Appropriateness of exemption from testing by application of MRA**
- **Confirmation of necessity of inspection**
- **Others**

2-5-1 Simple consultation (continued)

In FY 2025, as in previous years, the most frequent topic of consultation is the “Concept of validation.” Of the 24 consultation requests submitted during the fiscal year, seven were withdrawn. All of these cases involved either requests for the assessment of individual validation activities or consultation requests that lacked sufficient information, such as inadequate consideration of risk assessment perspectives or insufficient information regarding the product concerned.

The principal reasons for the withdrawal of consultation requests submitted in FY 2025 included the following:

- ✓ The request included topics that are not described in the implementation guidelines and are therefore outside the scope of the GMP consultation service.
- ✓ The request included matters that cannot be determined by PMDA, such as the appropriate description in marketing authorization applications or the necessity of submitting an application for a periodic GMP compliance inspection.
- ✓ The request included questions regarding the interpretation of laws, regulations, or administrative notices.

Examples of withdrawn consultation requests are provided on the PMDA website. Applicants are encouraged to review these examples, as appropriate, prior to submitting a consultation request.

In addition, information regarding withdrawn consultation requests is shared, as necessary, with relevant organizations, including PMDA review offices and MHLW, to facilitate access to the information required by consultation applicants.



Simple consultation is intended not only to provide answers to specific questions, but also to promote a common understanding between regulators and industry regarding the rationale, scientific justification, and supporting data underlying manufacturing decisions. PMDA encourages stakeholders to make effective use of this consultation service so that it can continue to provide value for both industry and regulatory authorities.

2-5-2 Other consultations

The outlines and results of various consultations other than “Simple consultations” in FY 2025 are as follows.

Number of consultations in FY 2025

* The number of consultations completed in FY 2025 was tabulated



For Consultation on SAKIGAKE overall evaluation, PMDA conducted one consultation related to GMP (pharmaceutical products) and two consultations related to GCTP (regenerative medicine products).

3 Risk communication activities

3-1 GMP roundtable meeting

Since FY 2022, PMDA has been holding GMP roundtable meetings to address challenges and facilitate opinion exchange pharmaceutical companies, regulatory authorities, and academia to ensure the quality of drugs.

In FY 2025, PMDA convened the 5th GMP Roundtable Meeting. Following the 4th meeting, discussions on the vision and direction for cultivating a robust quality culture were highly active, and securing and developing human resources continues to be an industry-wide challenge. Accordingly, the 5th meeting focused on training and education and self-inspections, which are key activities for cultivating a robust quality culture, and featured extensive discussions. The meeting concluded with a panel discussion involving distinguished experts from industry and regulatory authorities. As a new initiative, part of the lecture segment was made available through [PMDA's official YouTube channel](#) ([▶ Watch the Lecture Videos](#)).

Feedback from participants indicated that over 90% found both the group discussions and the panel discussion to be valuable. The meeting provided an opportunity for meaningful discussions with participants, including strategies for cultivating a robust quality culture and identifying practical solutions to ongoing issues. It also served as a valuable opportunity for PMDA inspectors to consider solutions to the questions and challenges faced by pharmaceutical companies.

Furthermore, following the previous fiscal year, PMDA continued to hold regional GMP Roundtable Meetings, wherein staff members travel to local prefectures to host such events. With the cooperation of prefectural authorities and other stakeholders, these regional meetings were held in Yamaguchi Prefecture in July 2025 and Ibaraki Prefecture in March 2026.

PMDA remains committed to organizing GMP Roundtable Meetings in FY 2026 and beyond by addressing emerging challenges and new topics and providing a valuable forum for dialogue with pharmaceutical companies and other stakeholders.

Past meeting summaries, presentation materials, and discussion outputs are available at the following URL.

<https://www.pmda.go.jp/review-services/gmp-qms-gctp/gmp/0023.html>

[The 5th GMP Roundtable Meeting]

Date: Tuesday, October 28, 2025

Place: Nihonbashi Life Science Hub

Participants: 61 from pharmaceutical companies; 30 from PMDA and prefectural authorities

Theme: Transforming People and Organizations through Enhanced Training and Education and Self-Inspections

[FY 2025 Regional GMP Roundtable Meeting in Yamaguchi]

Date: Wednesday, July 30, 2025

Place: Conference Rooms 702 and 703, Yamaguchi Prefectural South General Government Office Building

Participants: 33 from pharmaceutical companies; 20 from PMDA and prefectural authorities

Theme: Fostering a Quality Culture Together Through Shared Learning

[FY 2025 Regional GMP Roundtable Meeting in Ibaraki]

Date: Wednesday, March 4, 2026

Place: Main Conference Room, 3rd Floor, Ibaraki Pharmaceutical Association Hall

Participants: 38 from pharmaceutical companies; 12 from PMDA and Ibaraki Prefecture; 6 from the Ibaraki Pharmaceutical Manufacturers Association

Theme: Training and Education and Self-Inspections



Photo (left): 5th GMP Roundtable Meeting, Photo (center): Regional Meeting in Yamaguchi, Photo (right): Regional Meeting in Ibaraki

3-2 Rapid announcement of observations (ORANGE Letter)

As part of risk communication activities with pharmaceutical manufacturers, OMQD has been publishing on the PMDA website([Quality Assurance Activities](#)) information on deficiencies found during GMP/GCTP inspections, which is deemed useful for prompt dissemination and raising awareness across the entire industry as “Rapid Announcement of Observations” (ORANGE Letter: Observed Regulatory Attention/Notification of GMP Elements Letter; hereinafter referred to as "ORANGE Letter") since FY 2022.

The primary purpose of ORANGE Letter is to encourage voluntary efforts of pharmaceutical manufacturers to improve quality. Information that may infringe on intellectual property of a specific companies is withheld from publication.

The list of ORANGE Letters issued in FY 2025 is as follows (No. 20 to 25; 6 issues in total).

No.	Date of issuance	Title
20	May 2025	Events suggesting underlying issues behind differences from the product authorization requirements
21	August 2025	Deficiencies in Sterility Assurance Identified Through Sterilization Validation
22	October 2025	Cases frequently observed after the enforcement of the revised GMP ministerial ordinance. ~Handling of Products Deemed Unsuitable for Use or Shipment [No. 13 (Follow-up)] ~
23	December 2025	Addressing Staffing Shortages that Lead to Human Error
24	January 2026	Handling of stability monitoring results (part 3)
25	March 2026	Risks associated with handling substances with unknown pharmacological activities and toxicities (part 2)

In an effort to provide more practical and effective information, we conducted an anonymous survey of ORANGE Letter readers from late February to the end of March 2026. We received responses from 288 individuals. A summary of the survey results has been published in ORANGE Letter Special Issue No. 02.

3-3 List of identified deficiencies

In response to requests from the pharmaceutical industry to disclose additional information related to drug quality, OMQD began disclosing major deficiencies identified during GMP inspections in GMP/GCTP Annual Report 2023. In addition, based on feedback received through the survey indicating that “the publication of identified deficiencies alone does not provide sufficient background information and is therefore difficult to utilize for voluntary improvement activities at manufacturing sites,” the GMP/GCTP Annual Report 2024 began providing brief descriptions of the background that led to the issuance of the notice of deficiencies. Furthermore, in response to feedback that “the ‘License/Certification Categories’ included in the FY 2023 edition were removed from the FY 2024 edition, despite being necessary as background information,” the GMP/GCTP Annual Report 2025 includes the more detailed “Inspection Category” as background information.

The list of major deficiencies identified in OMQD’s GMP inspections in 2024 has been published as shown in the Attachment.

*The Attachment is posted as an Excel file at the following URL.

<https://www.pmda.go.jp/review-services/gmp-qms-gctp/gmp/0011.html>

However, three Major Deficiencies are not included in the list because even if manufacturing site names and other identifying information were withheld, the associated manufacturing sites could potentially be identified through cross-referencing with publicly available information, making it difficult to maintain anonymity.

In addition, there were no Critical Deficiencies issued by OMQD during GMP compliance inspections in FY 2025.

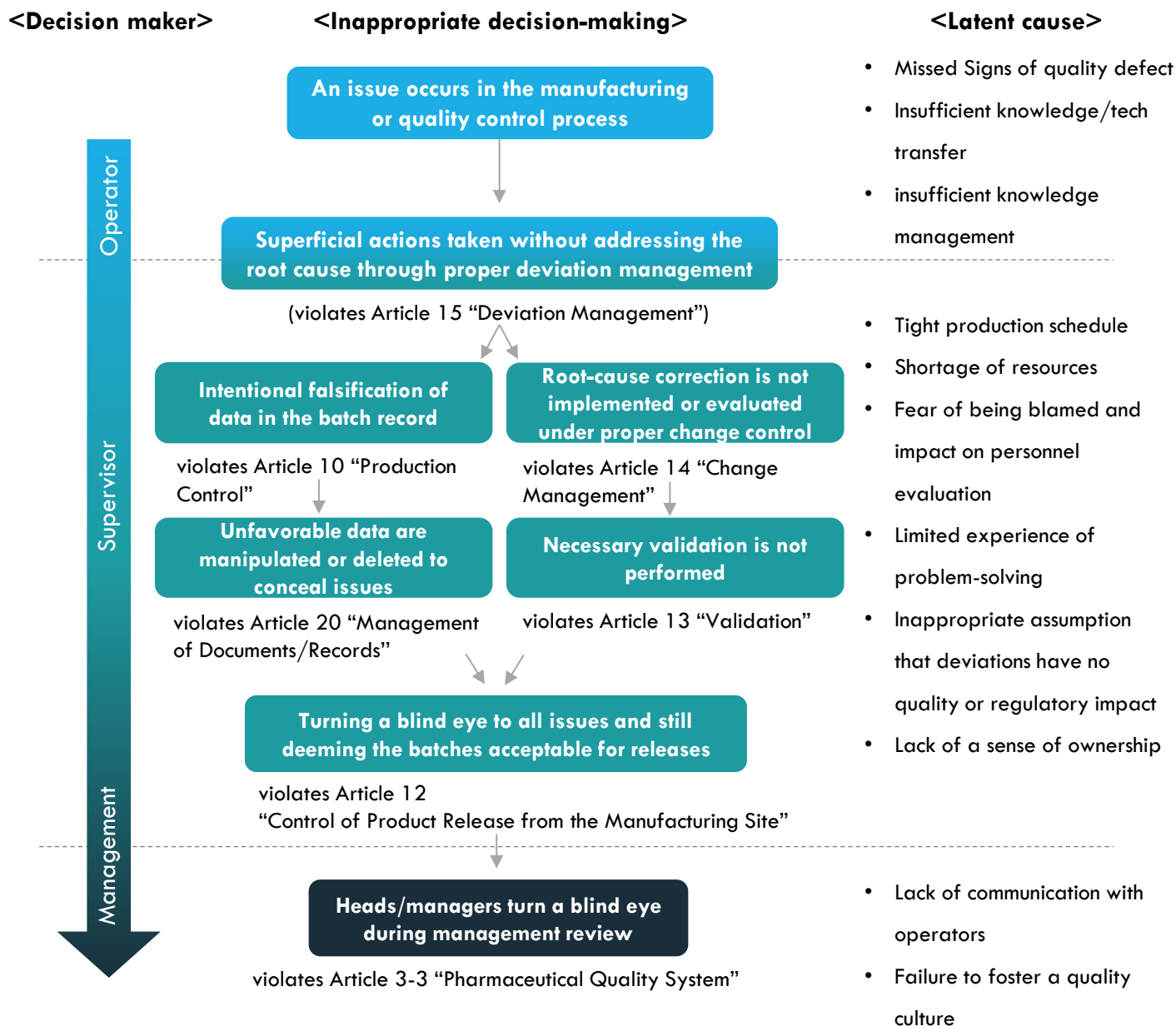
3-4 Characteristics of recent critical deficiencies

Regarding recent quality issues involving generic drugs, the Ministry of Health, Labour and Welfare is currently examining measures to ensure appropriate manufacturing and quality control systems through the “Expert Committee on the Ideal Industrial Structure for Ensuring Stable Supply of Generic Drugs” ※13.

Many cases of misconduct related to quality stem from so-called “upstream issues,” such as inadequate development or insufficient technology transfer to manufacturing departments—ultimately leading to the inability to produce products according to specifications. Contributing factors often include poor corporate governance and a lack of maturity in quality culture.

OMQD’s recent on-site inspections have also identified cases where such upstream problems triggered quality or manufacturing failures, which in turn led to multiple and interconnected violations of the Pharmaceutical and Medical Device Act (PMD Act) and GMP Ministerial Ordinance due to the absence of root-cause resolution. One example is illustrated below:

※13 Expert Committee on the Ideal Industrial Structure for Ensuring Stable Supply of Generic Drugs
https://www.mhlw.go.jp/stf/shingi/other-isei_ryutsu-yakka_00002.html

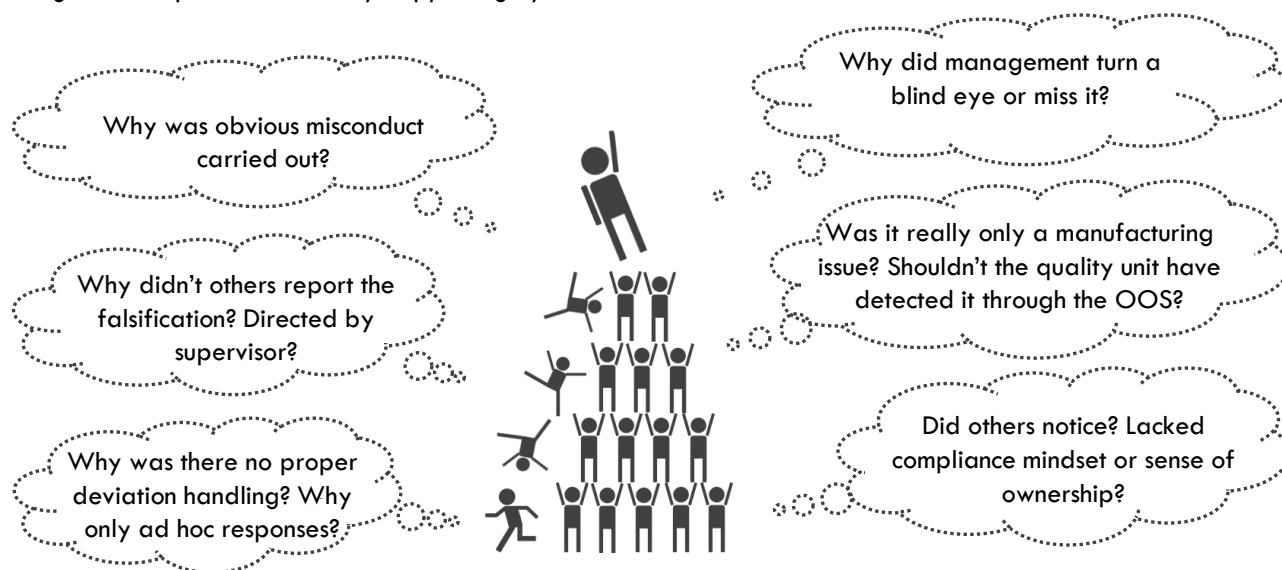


Knowledge management, which was a central theme of the 3rd GMP Roundtable Meeting, plays a crucial role when identifying the root cause of quality defects. Please refer to the presentation slides and discussion output available on "[GMP Roundtable Meetings](#)" under PMDA's website.

As illustrated in the figure "Collapse of the Quality-Supporting Pyramid," it is essential not to view quality issues merely as problems caused by an individual department or person, but to recognize that the root causes may lie within the organization's structure, decision-making processes, and communication pathways.

Companies must proactively address and resolve the specific challenges faced at each manufacturing site.

Figure: Collapse of the Quality-Supporting Pyramid



Technical problems may sometimes be unavoidable. However, many past pharmaceutical quality defects have been exacerbated by a corporate culture of turning a blind eye and an environment where employees felt discouraged from reporting issues. This in turn led to a cascade of regulatory violations and ultimately resulted in serious quality failures. Such misconduct and inappropriate practices may lead to product recalls or supply disruptions and, in some cases, could even undermine the very foundation of a company's business.

- If something is unclear, clarify it.
- If something feels off, report it to your supervisor without hesitation.
- If a serious regulatory violation is identified, promptly report it to the competent authority.

Each individual's awareness and initiative become the foundation that safeguards quality—and ultimately protects patients.

Systems alone cannot ensure quality.

What is crucial is the professional mindset of the operators and responsible individuals who implement the system, as well as the cultivation of shared values within the organization.



4 International activities

4-1 Importance of international activities

In recent years, the pharmaceutical supply chain has become increasingly globalized, and the number of overseas manufacturing sites supplying pharmaceuticals to Japan has continued to grow. In this context, regulatory authorities are required to respond appropriately within an international oversight framework.

On the other hand, regulatory authorities face limitations in human resources, making rapid staffing increases unrealistic. Even under such constraints, it is necessary to maintain a certain level of operational quality while carry out their duties reliably.

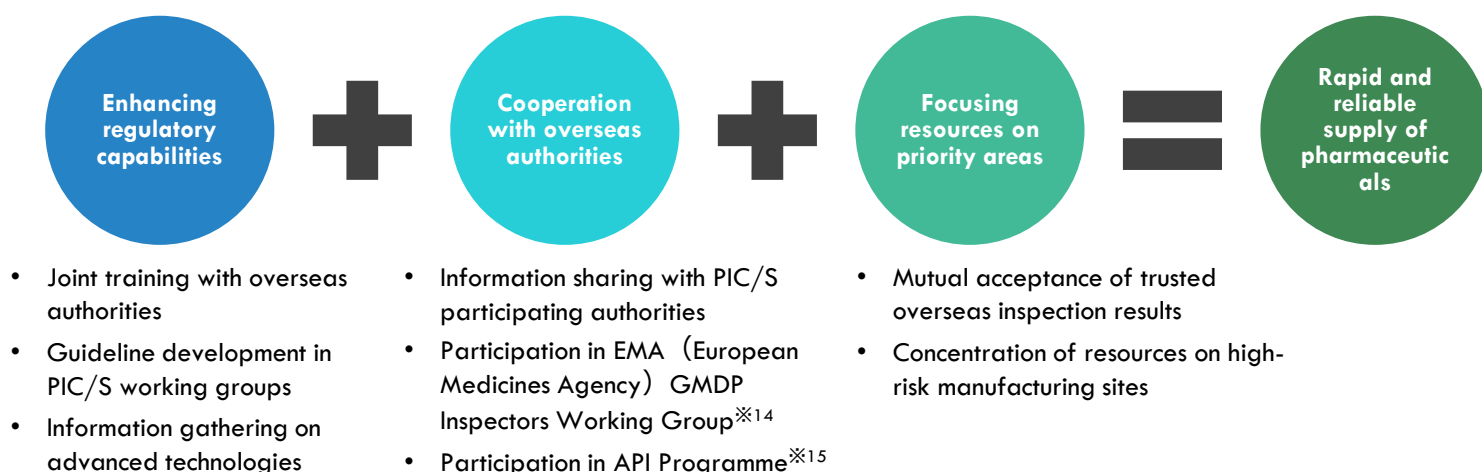
To address these challenges, it is effective to enhance regulatory capabilities, cooperate with overseas authorities, and focus resources on priority areas. In particular, strengthening international cooperation and collaboration with foreign regulatory authorities are essential measures.

Specifically, by actively collecting inspection information conducted by overseas regulatory authorities and conducting risk assessment of manufacturing sites with higher accuracy, on-site inspections are carried out at high-risk manufacturing sites. When utilizing overseas inspections information, it is premised on the alignment of the inspected authority's GMP standards and inspection capabilities with the PIC/S standards.

Therefore, OMQD is actively engaged in activities related to the international harmonization of GMP standards at PIC/S, simultaneously promoting the building of cooperative relationships with overseas authorities and enhancing its own inspection capabilities.

Many benefits gained through international activities serve as an important foundation for continuously and stably conducting GMP inspection operations. Utilizing overseas inspections results, avoiding duplicate inspections, and achieving internationally harmonized and prompt responses contribute not only to operational efficiency but also to ensuring the quality of pharmaceuticals.

As a result, it becomes possible to deliver necessary pharmaceuticals to patients who need them more quickly and reliably.



※14 EMA GMDP Inspectors Working Group

<https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/good-manufacturing-practice-gmp-distribution-practice-practice-gdp-inspectors-working-group>

※15 Programme to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers https://www.ema.europa.eu/en/documents/other/programme-rationalise-international-good-manufacturing-practice-inspections-active-pharmaceutical-ingredient-active-substance-manufacturers-terms-reference-and-procedures-participating-authorities_en.pdf

4-2 Strategy of OMQD in international activities

OMQD formulates its international activity policies in a coherent manner, taking into account the national basic policies, measures of relevant administrative agencies, trends and mid- to long-term directions in international organizations, as well as the strategic objectives of PMDA as a whole ([PMDA the fifth mid-term strategic plan](#)). The specific strategy policies are as follows:

- **Enhancing Regulatory Capabilities**

- ✓ Improve OMQD's inspection capabilities
- ✓ Analyze the gaps between Japanese GMP regulations and global GMP regulations to identify OMQD's technical vulnerabilities
- ✓ Continue all activities centered on PIC/S (see subsequent pages for details)

- **Cooperation with Overseas Authorities**

- ✓ Aim to strengthen the cooperative framework, especially with Asian countries, to further accelerate pharmaceutical regulatory harmonization

- **Focusing Resources on Priority Areas**

- ✓ Establish GMP inspection regulatory reliance (i.e., the act of one regulatory authority considering and giving weight to another authority's inspection outcomes when making its own decisions) framework in Asia
- ✓ Enroll the activities that would be helpful for Japanese Pharmaceutical industry.



4-3 Collaboration with overseas regulatory authorities and international organizations

4-3-1 PIC/S activities

PIC/S is an international organization aimed at the international harmonization of GMP standards and improvement of inspector competencies. Japan's GMP regulatory authorities (PMDA, Ministry of Health, Labour and Welfare, and prefectural governments) joined PIC/S in 2014, and since then have been promoting international initiatives centered on PIC/S activities. The main activities are as follows:

Participating in PIC/S Executive Bureau and PIC/S subcommittee

PIC/S has a committee composed of representatives from each member country. Under the committee, seven subcommittees (SC) have been established, each supported by the PIC/S Executive Bureau (EB) and the PIC/S Secretariat: SC COM (Communication and Information Sharing), SC SD (Strategic Development), SC H (GMDP Harmonisation), SC B (Budget), SC EC (Expert Circle), SC T (Training) and SC COMPL (Compliance)

OMQD served as a member of the PIC/S Executive Bureau through its role as Chair of the SC COM (term of office: January 2022 to December 2025), leading collaboration among participating authorities as well as engagement with external organizations, information sharing, and communication activities. Upon completion of the term, the chairmanship was transferred to ANVISA, the Brazilian regulatory authority. The Office of Manufacturing Quality for Drugs continues to contribute to SC COM activities as a committee member. In addition, staff members of the Office currently serve on SC T. They are actively involved in training-related initiatives, including the review of PIC/S training materials and support for the organization of PIC/S seminars.

Contributing to PIC/S Seminar

PIC/S Seminar is one of the most important educational events of PIC/S, attended by nearly all PIC/S member authorities. Since Japan's PIC/S accession in 2014, PMDA has consistently participated in every seminar, attending training sessions and actively dispatching instructors. In 2019, PMDA hosted a PIC/S seminar in Toyama with the theme of "Sterility Assurance of Medicinal Products," significantly contributing to training member authority personnel.

In FY2025, OMQD delivered a presentation on Annex 22 at the PIC/S Seminar in Hong Kong, contributing to the promotion of international regulatory harmonization and enhancing understanding of the latest regulatory developments.

Secondment a specialist staff to PIC/S secretariat (Secondment period: April 2024 to February 2026)

PMDA seconded a staff member from the OMQD to the PIC/S Secretariat in Geneva, Switzerland (secondment period: April 2024 to February 2026). During the secondment, the staff member engaged in a wide range of activities, including supporting the operation of the PIC/S Committee and its Sub-Committees, assisting in the development of PIC/S guidance documents, supporting the planning and organization of PIC/S Seminars, and contributing to the assessment of applicant authorities seeking PIC/S membership. The staff member also participated in activities supporting the operation of the PIC/S Inspectorates' Academy (PIA), a training platform for PIC/S Participating Authorities, as well as collaborative initiatives with the World Health Organization (WHO), thereby contributing to the promotion of international GMP harmonization, human resource development, and capacity building. Through this secondment, PMDA accumulated practical experience in the operation and organizational management of PIC/S, gained insights into the latest international GMP developments, and further strengthened working relationships and professional networks with PIC/S Participating Authorities, international organizations such as WHO, and other relevant stakeholders. The knowledge and professional networks acquired through these activities have been leveraged in PMDA's GMP inspections, inspector training, and international cooperation activities, thereby contributing to the enhancement of PMDA's GMP inspection capabilities, the strengthening of its international cooperation framework, and the promotion of international GMP harmonization.

4-3-1 PIC/S activities (continued)

Information sharing with PIC/S member authorities

Based on PMDA's 5th Mid-Term Plan, OMQD is actively promoting information exchange on GMP inspections to strengthen cooperation with overseas regulatory authorities. The performance over the past five years is shown in the table below. Information sharing with overseas regulatory authorities continued at a steady level in FY2025. The authorities with which information was shared were primarily major regulatory organizations, including those in the Republic of Korea, Taiwan, Singapore, the United States, and Canada, as well as WHO and the European Medicines Agency (EMA). Collaboration frameworks based on the PIC/S Agreement, Mutual Recognition Agreements (MRAs), and the API Programme were also maintained, enabling the efficient utilization of regulatory information under established relationships of trust.

	FY	2021	2022	2023	2024	2025
	Count	5	9	22	15	6
Information provided from Japan to overseas	Authorities	USA, EMA	EMA, EDQM(European Directorate for the Quality of Medicines), Italy, Germany, Canada, Argentina, Ukraine	EMA, Singapore, EDQM, Korea, Canada, France, WHO	EMA, Canada, Switzerland, Taiwan, USA, EDQM, Peru	Korea, Taiwan, Singapore, EMA, Canada
	Count	11	13	20	3	7
Information provided from overseas to Japan	Authorities	USA, EMA, Korea, Brazil	USA, Canada, Argentina, Germany, EMA	USA, Argentina, EDQM, Korea, Germany, Hungary, Singapore, Taiwan	EMA, Korea, Taiwan	Canada, WHO, USA, Singapore

Mutual observer programs

To promote mutual understanding and enhance inspection capabilities with overseas regulatory authorities, PMDA conducts mutual observer programs during GMP inspections (on-site inspections). The achievements over the past three years are summarized in the table below. No PMDA participation in overseas authorities' on-site inspections was recorded in FY2025, primarily due to scheduling constraints associated with inspections conducted by overseas regulatory authorities. With respect to cooperation with the Health Sciences Authority (HSA) of Singapore, HSA inspectors participated in multiple PMDA on-site inspections during the fiscal year. Through these observer activities and the ongoing exchange of information between GMP inspectors of both authorities, mutual understanding of each authority's approaches and methodologies for GMP compliance inspections was further enhanced. These efforts are considered to have contributed to the smooth technical coordination leading to the conclusion of a Memorandum of Cooperation between the Ministry of Health, Labour and Welfare (MHLW) of Japan and the Singapore authority on April 20, 2026. Regarding cooperation with US FDA, since FY2024 there has been an increasing use of a collaborative approach in which PMDA and US FDA conduct inspections independently during the same period, in addition to the traditional observer-based model. As of FY2026, this trend continues, with more mature forms of cooperation becoming established, including the sharing of inspection plans and key discussion points through advance meetings, where appropriate. Although the number of observer activities in FY2025 decreased compared with previous years, the qualitative improvement in regulatory cooperation has facilitated more efficient and advanced inspection activities based on enhanced mutual trust. Taken as a whole, these developments may be viewed positively.

	FY	2022	2023	2024	2025
Observing inspections by PMDA	Count	8	7	5	0
	Authorities	USA	USA, Korea, Taiwan	USA, Korea, Taiwan	-
Observing inspections by Overseas	Count	4	19	8	6
	Authorities	Malaysia, Taiwan, Singapore	Taiwan, Korea, Singapore, South Africa	Canada, Thailand, Malaysia, Korea, Taiwan	Singapore, Canada, Belgium, Turkey, USA

4-3-2 Other international activities

Training support to Asian regulatory authorities (PMDA-ATC(Asia Training Center) GMP Seminar)

The Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) utilizes the knowledge and experience accumulated by PMDA to provide training for regulatory authority personnel in Asian countries, supported by PIC/S, in response to their requests.

OMQD delivers lectures on inspection systems and regulatory frameworks related to pharmaceutical manufacturing and quality control. In addition, with cooperation from actual manufacturing facilities, it provides practical programs that allow participants to experience simulated on-site inspections.

Recent seminar activities and upcoming plans are as follows:

- PMDA-ATC GMP Inspection Webinar 2023 (February 6–7, 2024)
- PMDA-ATC GMP Inspection Seminar 2024 (October 8–10, 2024)
- PMDA-ATC GMP Inspection Seminar 2025 (September 17–19, 2025)
- PMDA-ATC GMP Inspection Seminar 2026 (Scheduled for September 15–17, 2026)

API Programme (Active Pharmaceutical Ingredient Programme)

The API Programme was launched in 2012 to streamline international GMP inspections of active pharmaceutical ingredient manufacturers. OMQD has participated in this program since 2016. The current participants comprise 14 organizations: AIFA, ANSM, ANVISA, DKMA, US FDA, Health Canada, HPRA, MHRA, PMDA, TGA, EDQM, EMA, WHO, and EC.

Under this program, all GMP inspection information (inspection plans and results) of API manufacturers already inspected or scheduled to be inspected by participating authorities is registered and shared in a master list (database) under confidentiality agreements. Monthly web meetings allow authorities to utilize this information to identify overlapping inspection targets, coordinate inspection schedules, plan joint inspections, and mutually use inspection results, thereby enhancing efficiency and international reliability of inspections.

OMQD uses information obtained through this program to identify issues at inspection target manufacturing sites in advance, set prioritized confirmation items, and allocate inspection resources preferentially to high-risk facilities. Additionally, joint inspections with other authorities are conducted as needed to improve efficiency and quality of inspections. Furthermore, sharing inspection information via the API Programme also serves as a means to verify GMP inspection capabilities of participating authorities, thereby strengthening the foundation of mutual trust among organizations.

EMA GMDP Inspectors Working Group

The EMA GMDP Inspectors Working Group (EMA GMDP-IWG(Inspectors Working Group)) is a group mainly composed of EU member states and MRA partner countries, holding meetings every three months for information sharing among participants. OMQD participates in these meetings as an observer under the Japan-EU MRA.

OMQD regularly attends these meetings to stay informed of the latest regulatory trends related to pharmaceutical manufacturing and quality control in the EU, and actively promotes international mutual understanding and cooperation by sharing information on Japan's pharmaceutical regulatory system and engaging in discussions.

5 Future vision

At present, oversight of pharmaceutical manufacturers in Japan is conducted primarily through GMP compliance inspections in collaboration with prefectural governments. However, the expansion of global supply chains and the increasing diversity of regulated entities have made it increasingly difficult to address emerging challenges through conventional uniform inspection approaches alone. Consequently, there is a growing need to transition to a more advanced and flexible oversight framework that enables the prioritized allocation of regulatory resources according to risk and the efficient use of information to support inspection activities. PMDA considers it essential to play a leading role in advancing this transition toward a risk-based inspection framework.

To address these challenges, the Notification entitled “Promulgation of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and Related Acts,” issued on May 21, 2025, outlined the direction of regulatory reforms aimed at strengthening risk-based inspections. [As highlighted in this Annual Report](#), measures have been introduced to improve both the efficiency and layering of the inspection framework, including the streamlining of periodic inspections for low-risk manufacturing sites and the establishment of a mechanism for PMDA’s additional involvement in category-specific compliance inspections conducted by prefectural governments.

Against this background, the PMDA is advancing not only the enhancement of risk-based inspection methodologies, but also the development of infrastructure that enables the integrated and cross-functional use of inspection results, inspection findings, and other relevant information. As part of these efforts, operation of the GMP/GCTP Manufacturing Quality Data System, which centrally manages and visualizes inspection information held by PMDA and all prefectural authorities, commenced in April 2026. The establishment of this system was formally incorporated into the regulatory framework through the “Partial Revision of the Guidelines for GMP Inspections” (Pharmaceutical Regulatory and Narcotics Affairs Bureau Notification No. 0319-2, dated March 19, 2026).^{※16} By enabling PMDA and prefectural authorities to centrally access and share inspection information through this system, it supports not only the evaluation of individual cases but also trend analysis and the early identification of risk signals. As a result, the system contributes to more refined inspection planning and more sophisticated risk assessment. Furthermore, the knowledge and insights generated through the use of such data are expected to be utilized as inputs for the publication of GMP inspection results and risk communication activities. In turn, this will strengthen the feedback mechanism provided to the pharmaceutical industry as a whole. Going forward, PMDA will continue to share common challenges and explore potential solutions through initiatives such as the GMP Roundtable Meetings, thereby promoting effective improvement activities that go beyond the provision of information alone.

Furthermore, as the use of artificial intelligence (AI) in pharmaceutical manufacturing continues to advance rapidly, inspection authorities are increasingly required to establish appropriate regulatory approaches and strengthen their inspection capabilities in this area. To address this challenge, PMDA has established an Advanced Technologies (AT) Task Force and is advancing its work in collaboration with relevant domestic and international organizations. In addition, PMDA is directly involved in international discussions on AI in Manufacturing through presentations at PIC/S seminars and participation in the PIC/S-EMA Joint Guideline Working Group. PMDA will continue to contribute to the development of guidelines that facilitate the early implementation of technologies essential for the growth and competitiveness of Japan’s pharmaceutical industry.

PMDA is also actively engaged in promoting regulatory harmonization, sharing inspection information, and strengthening reliance through activities such as PIC/S. As described in [Chapter 4, “International Activities,”](#) the Memorandum of Cooperation on Strengthening Regulatory Collaboration concluded with the Health Sciences Authority (HSA) of Singapore on April 20, 2026, is a prime example of these efforts. Through this cooperation, further initiatives are expected to be advanced with HSA, including enhanced information sharing and joint training programs for inspectors. In line with PMDA’s Mid-Term Plan, PMDA will continue to strengthen collaboration with regulatory authorities across the Asian region. Recognizing that such cooperation contributes to enhancing the inspection capabilities and technical expertise of PMDA, as well as supporting a stable pharmaceutical supply and the development of an efficient inspection framework, PMDA will continue to strengthen effective collaborative relationships with overseas regulatory authorities.

Building a more effective and efficient inspection framework will require the integrated advancement of risk-based inspections, enhanced utilization of data, and strengthened international collaboration. PMDA is committed to steadily implementing these initiatives in order to further improve the quality of inspections and the effectiveness of regulatory oversight, while contributing to the establishment of a quality management framework that earns and maintains the trust of stakeholders both in Japan and internationally.

※16 Partial Revision of the “Guidelines for GMP Inspections” (Pharmaceutical Regulatory and Narcotics Affairs Bureau Notification No. 0319-2, dated March 19, 2026)

https://www.mhlw.go.jp/web/t_doc?dataId=00tc9859&dataType=1&pageNo=1

What's on your mind now? Let us know! -PMDA Annual Report 2025 Survey-



QR code

Scan here using your mobile device.
The survey is also accessible from [here](#).

The content of GMP/GCTP Annual report is continuously improved based on feedback collected through surveys from our readers. For example, in the FY 2024 edition, we analyzed other deficiencies related to requirements stipulated in ministerial ordinances. In the FY 2025 edition, we analyzed identified deficiencies after classifying manufacturing sites into categories such as domestic and overseas sites.

As we consider the contents of future GMP/GCTP Annual Reports, we kindly ask for your cooperation in completing a short survey so that we can better address your needs and provide more useful information. The summary of the survey results will be used as a reference in discussions about the future direction of the Annual Report. Please be assured that individual responses will remain anonymous.

We sincerely appreciate your honest and constructive feedback.

PMDA GMP / GCTP Annual Report FY 2025

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Notice

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We, PMDA, continue to create “Tomorrow’s Normal” together,
as a “life platform” that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA’s “Safety Triangle” of review, safety and relief,
with “intelligence” weaved through science and information, and
with “human resourcefulness” accompanying
and bringing the world and the future into harmony.



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