Case Analysis of PMDA GCP Inspections and comparison with other regulatory inspections by JSQA

2025 international QA conference

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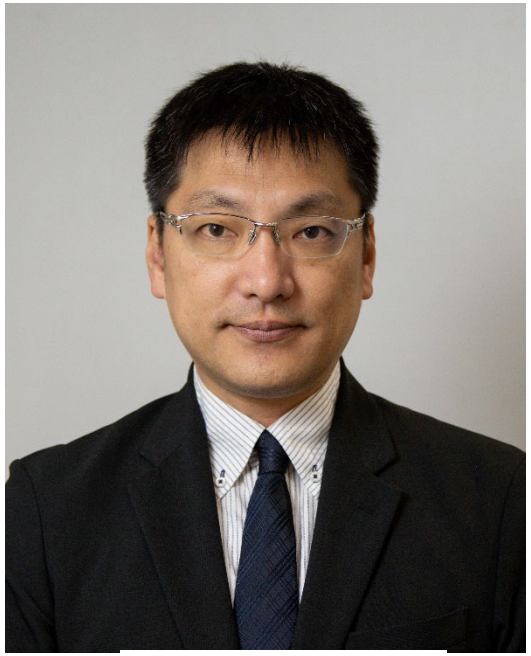


Daiichi-Sankyo

- Head of Audits & Compliance (Japan), Daiichi Sankyo Co., Ltd
- Working in Daiichi Sankyo for over 25 years and experiencing in GxP (GCP, GVP, GLP and CSV) Quality Assurance including over 200 Audits in multinational countries, and Clinical Development & Post-Marketing Study Manager
- Experienced EU Oncology QA Lead at United Kingdom in 2010-2013 as an ex-pat including MHRA/FDA/several EU Health Authority Inspection managements
- Chairperson of GCP Subcommittee#4 and International Affairs Committee in JSQA
- JSQA liaison with RQA GCP Committee, SQA and CQAF

Kaori Owada,

Member of GCP Subcommittee#4, JSQA

- Lead associate of Audits & Compliance (Japan), Daiichi Sankyo Co., Ltd
- Working Over 20 years for GCP/GMP Quality Assurance area in industry and CRO including Daiichi Sankyo for 5 years

AGENDA

1. Introduction -Japan Society of Quality Assurance (JSQA)-

2. Case Analysis of PMDA GCP Inspections and comparison with other regulatory inspections by JSQA

   2-1. Outline of Japan PMDA GCP Inspections

   2-2. Recent remarkable findings of PMDA on-site GCP inspection

   2-3. Comparison of common findings of medical institution (MHRA,FDA,EMA,PMDA)

1. Introduction:
Japan Society of Quality Assurance (JSQA)

Japan Society of Quality Assurance

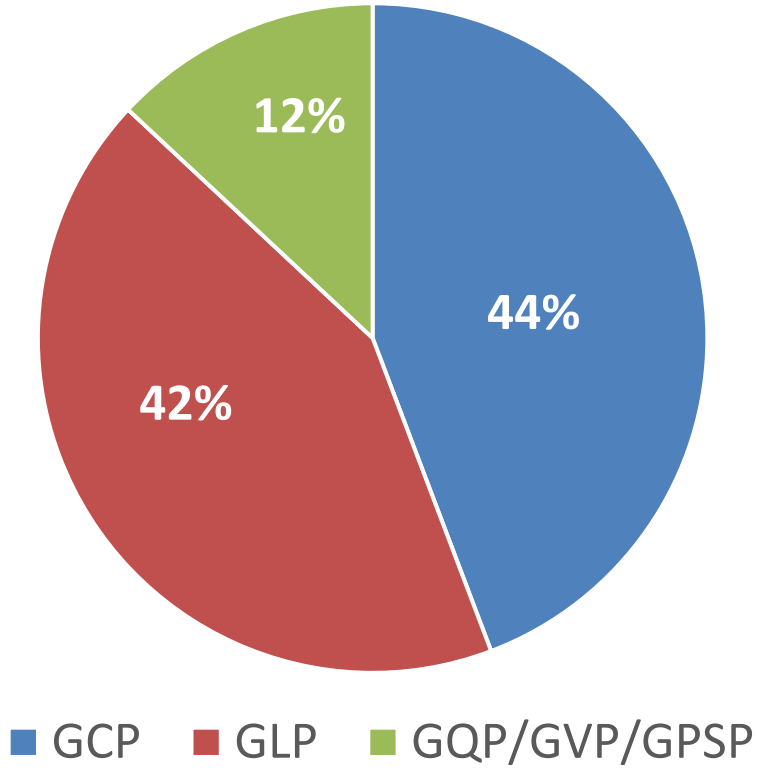
Vision

The Japan Society of Quality Assurance (JSQA) contributes to the improvement of the health and welfare of people by:

- disseminating relevant information,
- developing human resources, and
- presenting appropriate suggestions on specialized information concerning the quality assurance of drugs…etc.

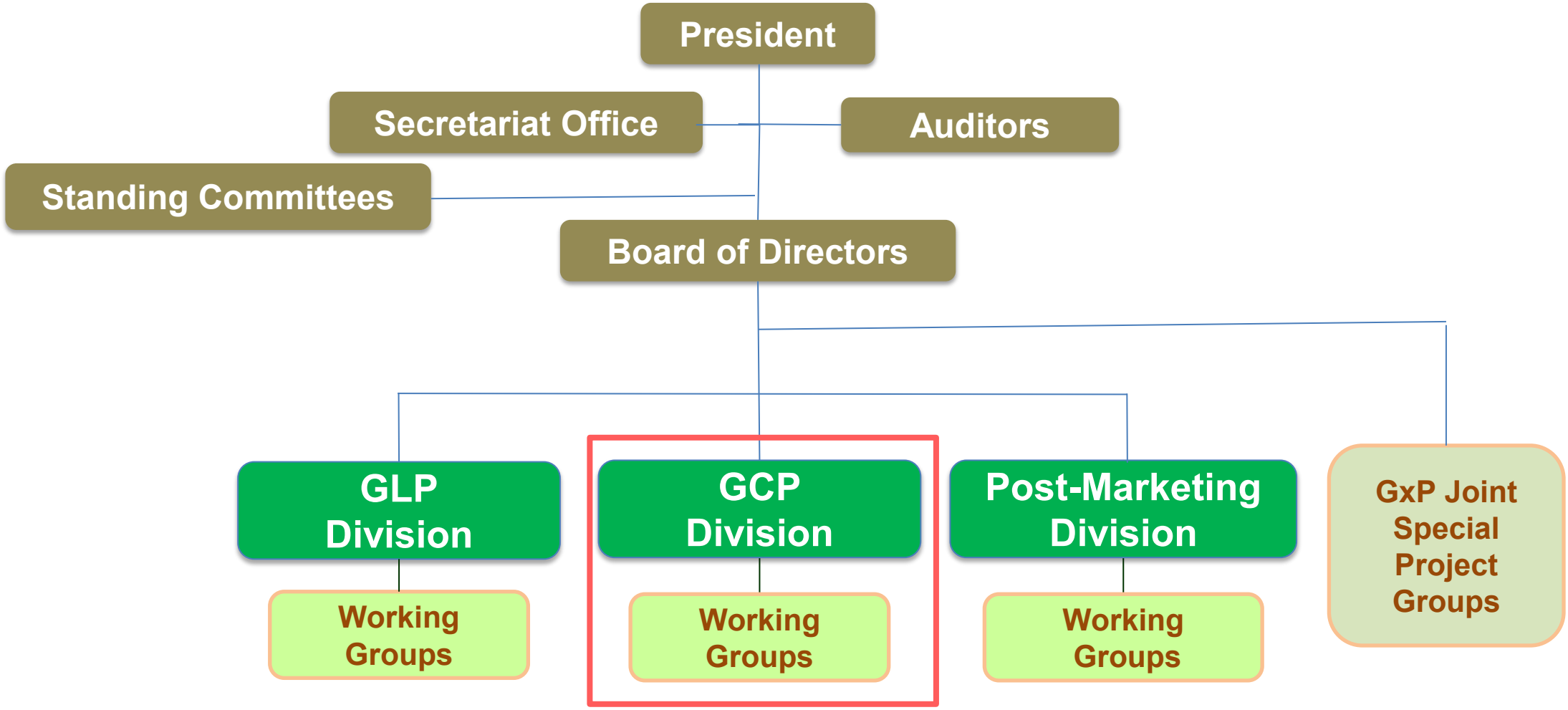
Division	Number of member companies	Number of members
GLP	146 companies	393 persons
GCP	153 companies	407 persons
GQP/GVP/GPSP	62 companies	120 persons

JSQA Composition of QA professionals



As of May 2025

JSQA Organization Chart



FY2024-2025
JSQA GCP Division Discussion Theme

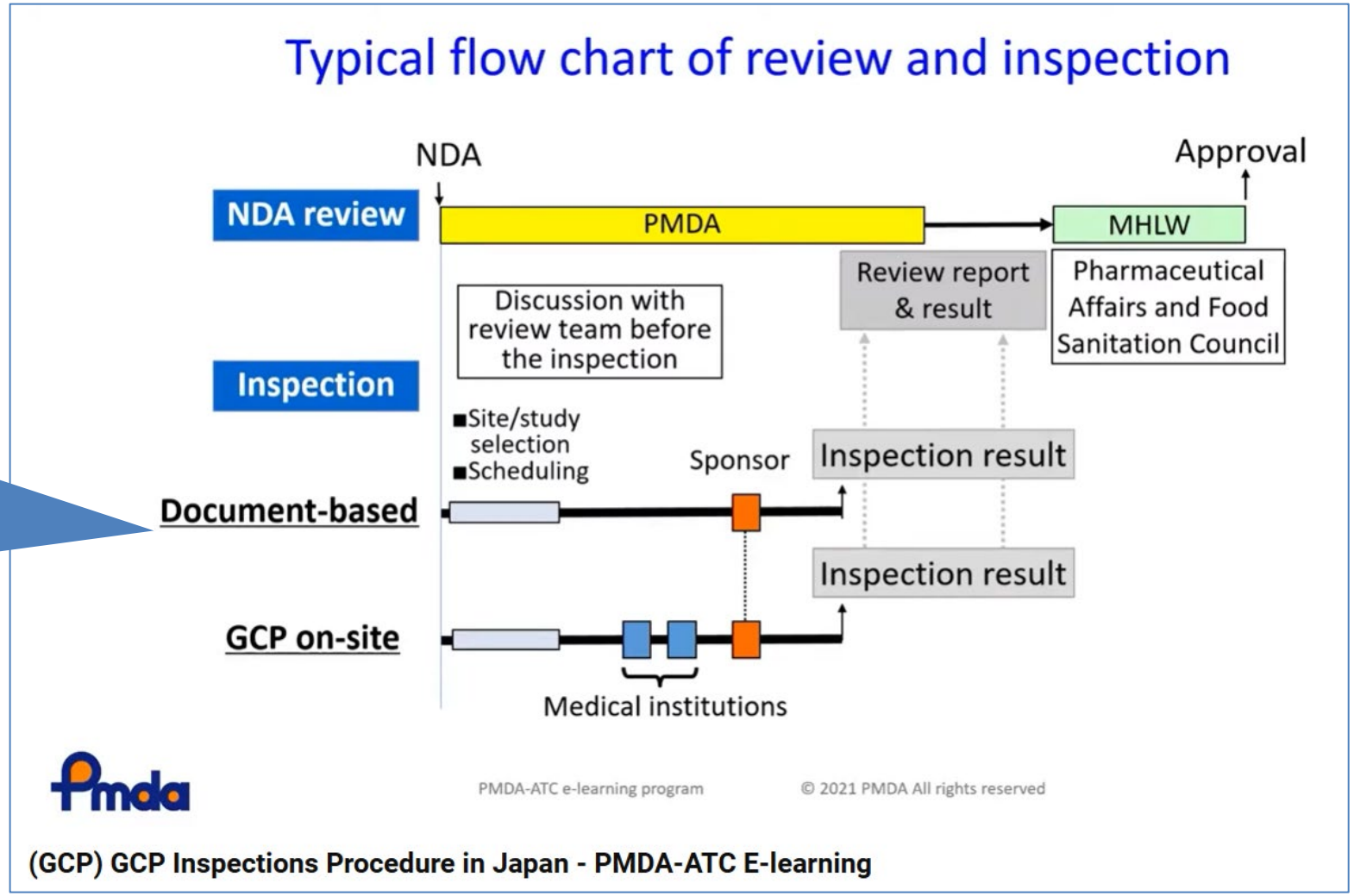
Sub-committee	Working Group
Sub-committee#1: Quality Assurance	Group A: ICH E6R3 Group B: Clinical Vendor Oversight
Sub-committee#2: Digital Transformation	Group A: Decentralized Clinical Trial Group B: Remote Monitoring/Remote Audit Group C: e-Trial Master File
Sub-committee#3: Medical Device/Investigator Site	Group A: Medical Device Group B: Quality Management of Investigator Site (including Investigator Initiated-Study/Clinical Research)
Sub-committee#4: Multi International Study	Group A: US/EU Group B: ASIA
Special project groups	Group 1: PMDA Inspection – case study Group 2: Organize-Training-Courses Group 3: Public Review Comment Group 4: Q&A for QA/QC representatives

2. Case Analysis of PMDA GCP Inspections and comparison with other regulatory inspections by JSQA

2-1.
Outline of Japan PMDA GCP Inspections

PMDA GCP Inspection Overview

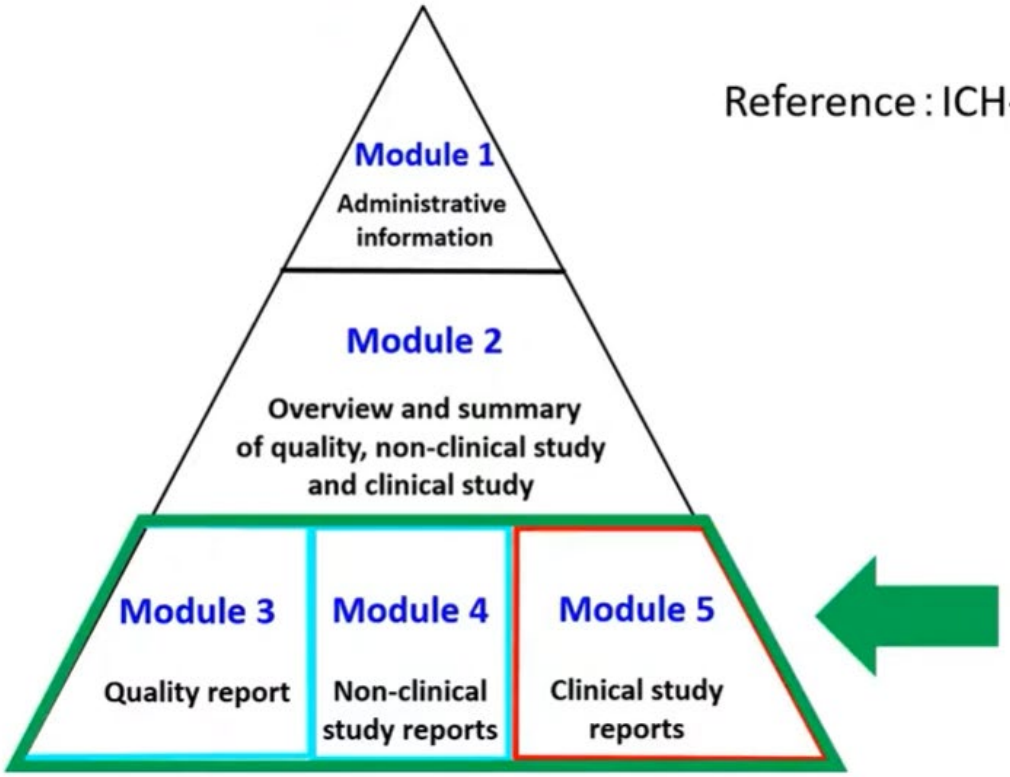
- PMDA conducts **two types** of GCP inspections.
- The **trigger is NDA submission**.



Source: '(GCP) GCP Inspections Procedure in Japan - PMDA-ATC E-learning'

PMDA Inspection Scope

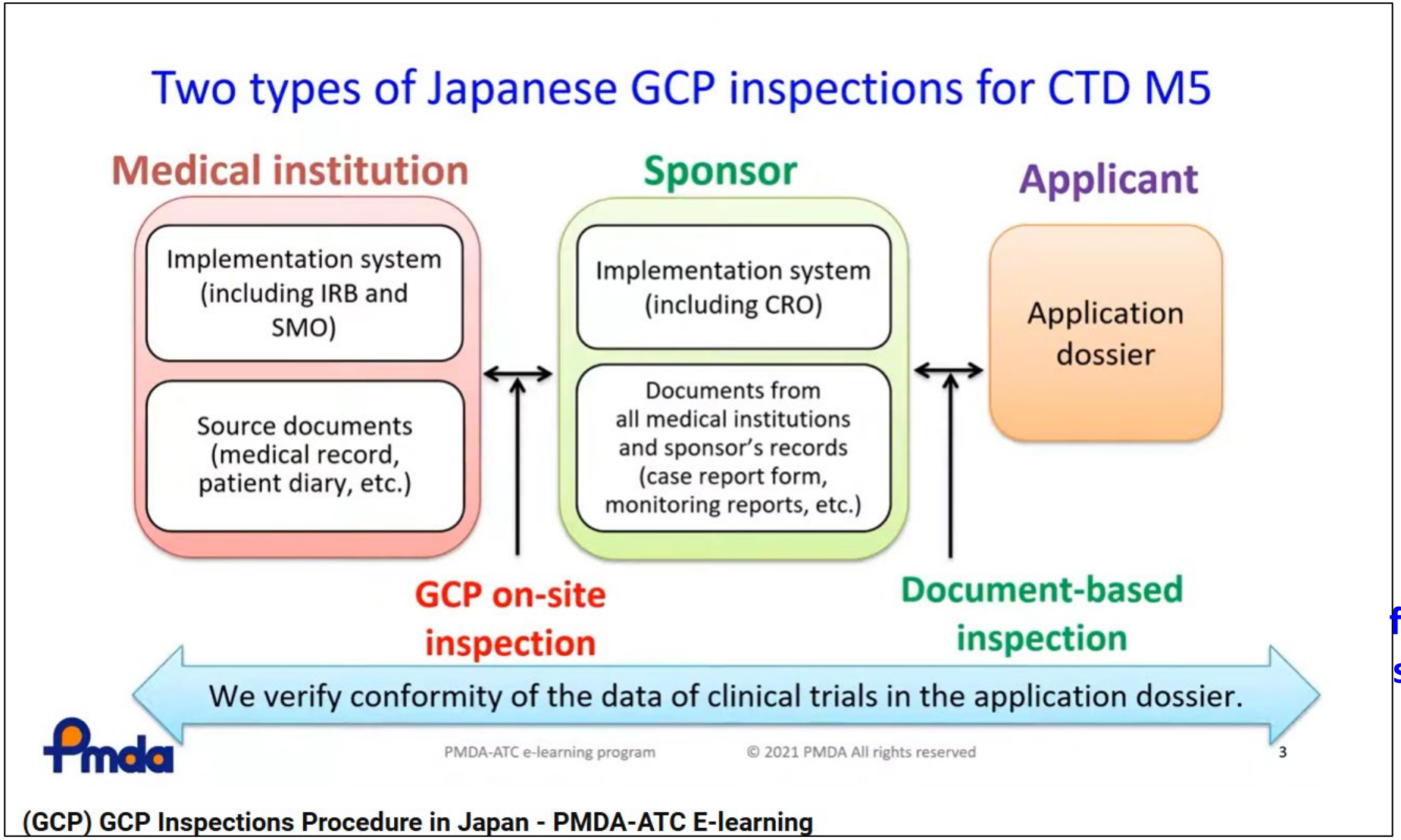
Structure of CTD (Common Technical Document)



(GCP) GCP Inspections Procedure in Japan - PMDA-ATC E-learning

Source: '(GCP) GCP Inspections Procedure in Japan - PMDA-ATC E-learning'

PMDA Inspection Types



※Remote or face to face : To be selected by PMDA

Source: '(GCP) GCP Inspections Procedure in Japan - PMDA-ATC E-learning'

Sources to learn about PMDA GCP inspections

Sources:

- PMDA uploads a video on YouTube to describe GCP inspection procedures.

‘(GCP) GCP Inspections Procedure in Japan - PMDA-ATC E-learning’,
Available at: https://www.youtube.com/watch?v=UMLTSkeiUBw (Accessed: 17 July 2025)

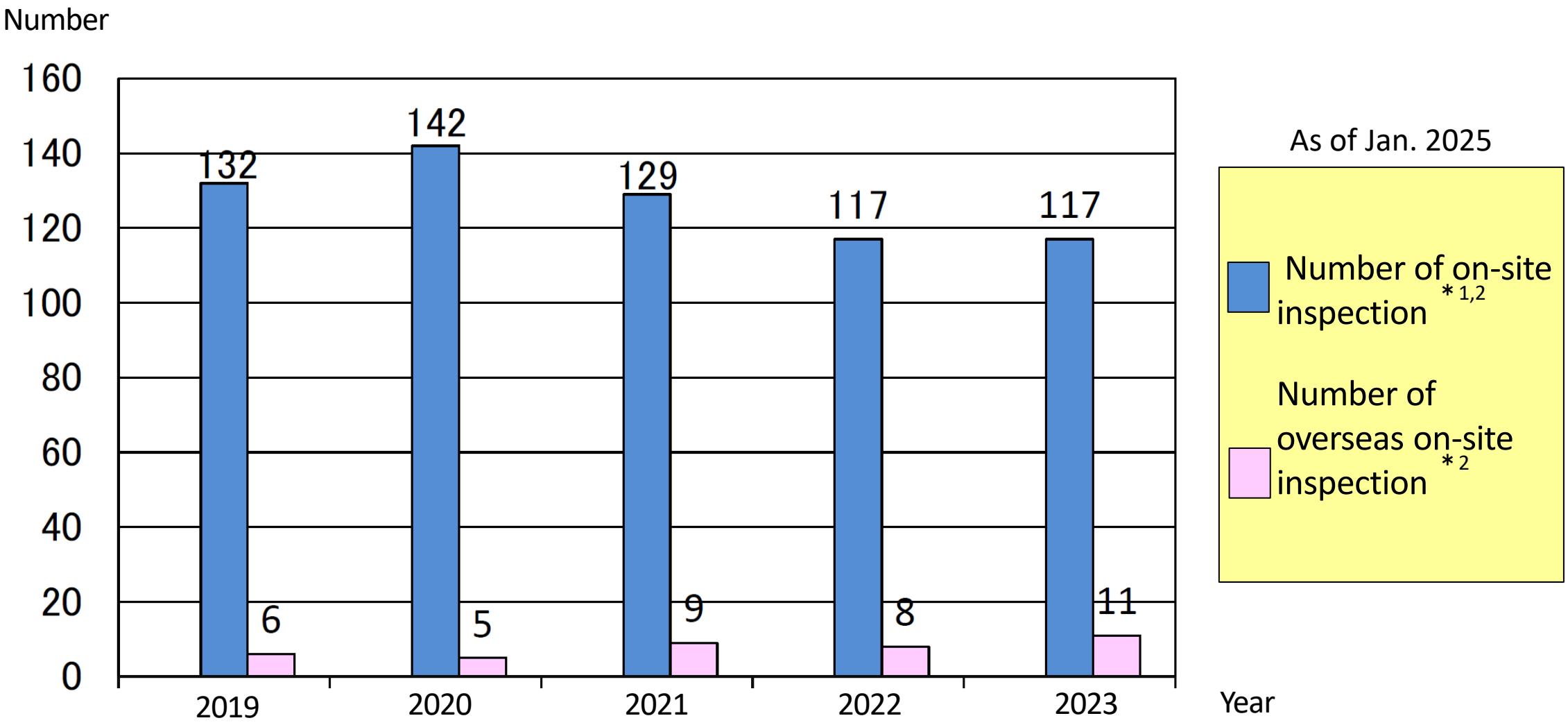
- ‘PMDA GCP Compliance Inspection Procedure’
  https://www.pmda.go.jp/files/000251862.pdf (Issued Feb. 2023)

- ‘Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products
  https://www.pmda.go.jp/files/000264393.pdf (Issued : 3 July 2023)

- 'Checklist for GCP On-site Inspection/Document-based Compliance Assessment for New Drug (for Sponsor)'
- 'Checklist for GCP On-site Inspection for New Drug (for Medical Institution)’
  https://www.pmda.go.jp/english/review-services/glp-gcp-gpsp/0003.html (Issued :1 July 2022)

2-2. Recent remarkable findings of PMDA on-site GCP inspection

Trend in GCP on-site inspection results for new drugs



*1: Number of notification letters issued for each fiscal year (per applicant), including on-site investigations overseas
*2: From fiscal year 2020 onwards, includes remote inspections

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Sponsor
on-site inspection

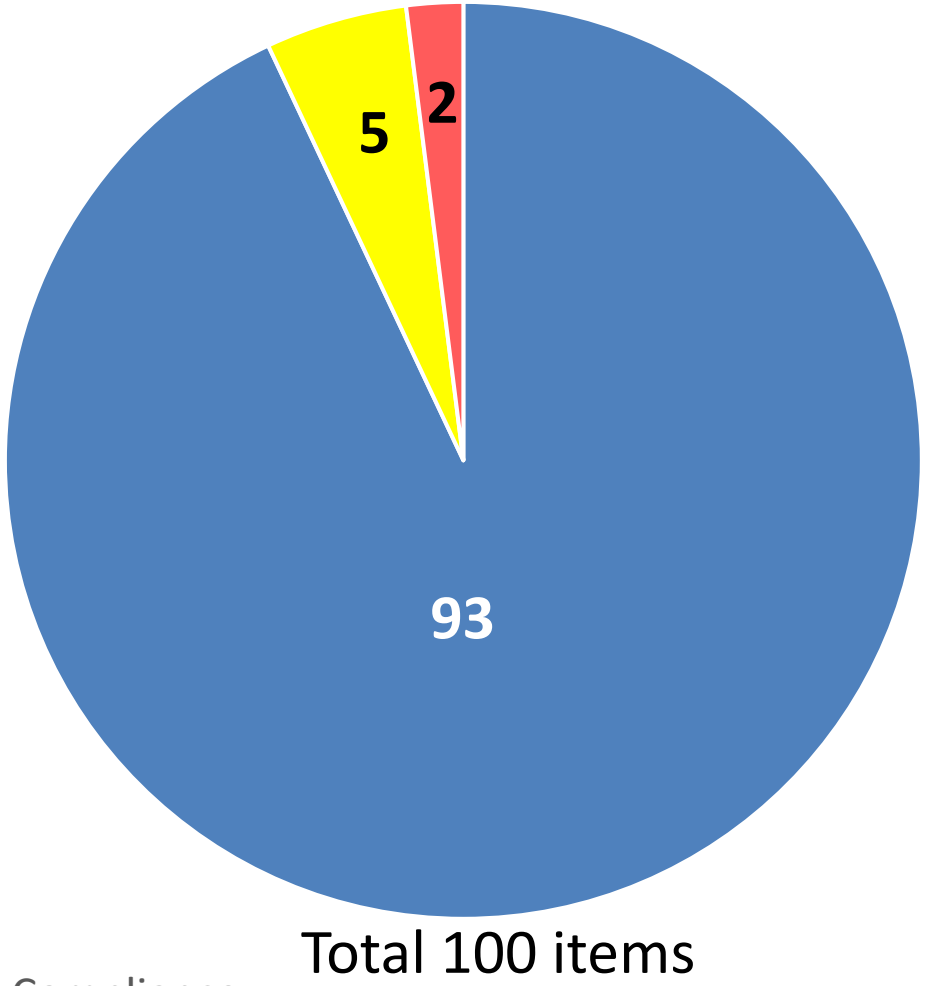
Results of GCP sponsor on-site inspections

- Compliance: 93 items

- Compliance with requiring improvement: 5 items→See next page

- Conditional compliance: 2 items
  - ✓ Partial non-compliance with GCP
  - ✓ Removal of GCP non-compliance case data

- Non-compliance: 0 items
  - ✓ Not conducted in accordance with GCP
  - ✓ Excluding all or part of the approval application documents from the scope of the approval review



* Items for which results notifications were issued between April 2023 and March 2024
* Number of results notifications issued (per applicant)
* New drugs conducted by companies, domestic inspection

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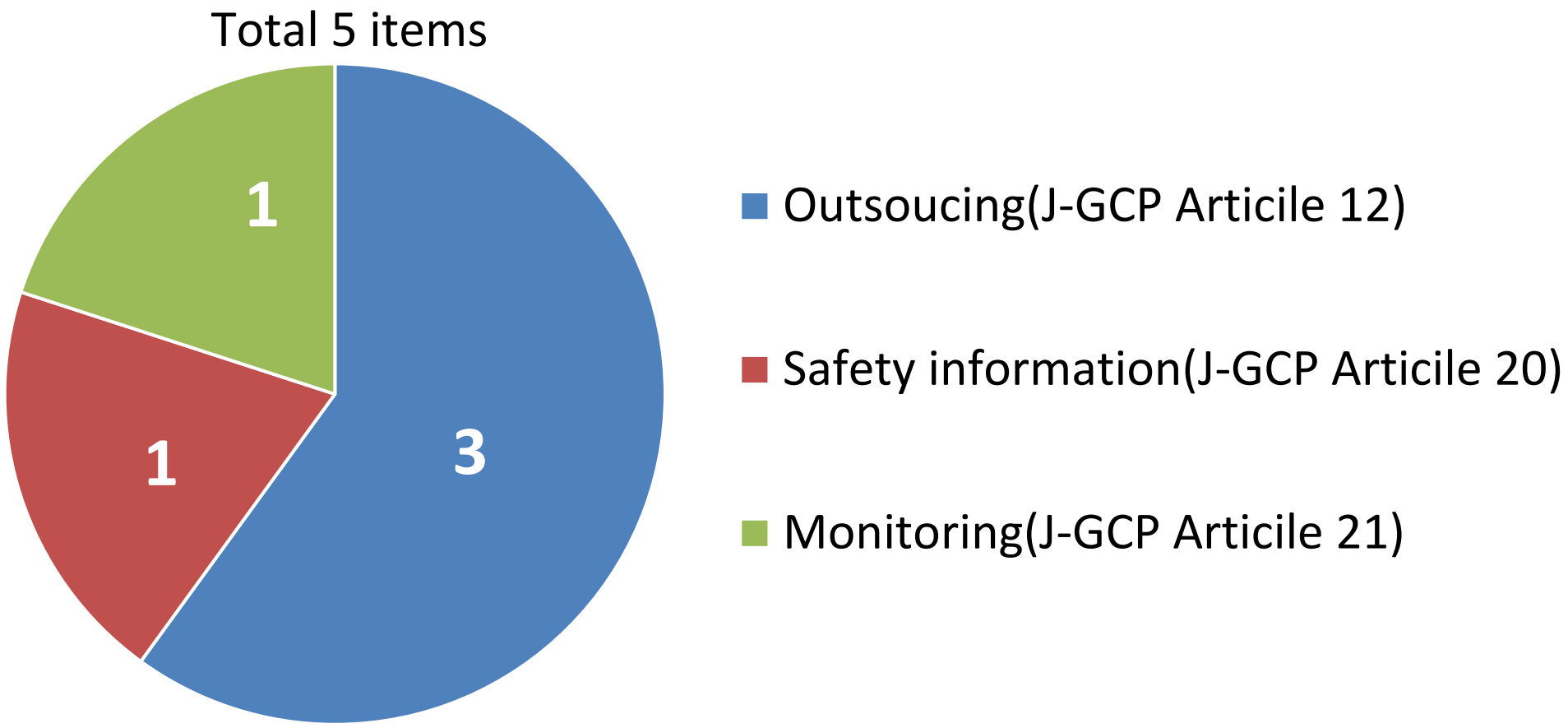
Compliance with Requiring improvement (sponsors)



※100 products for which results notifications were issued from April 2023 to March 2024

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Examples of GCP on-site inspection findings (sponsor)

1.Outsourcing (J-GCP Article 12)

The contract with CRO did not include provisions regarding Article 12, Paragraph 1.

2.Safety information (GCP Article 20)

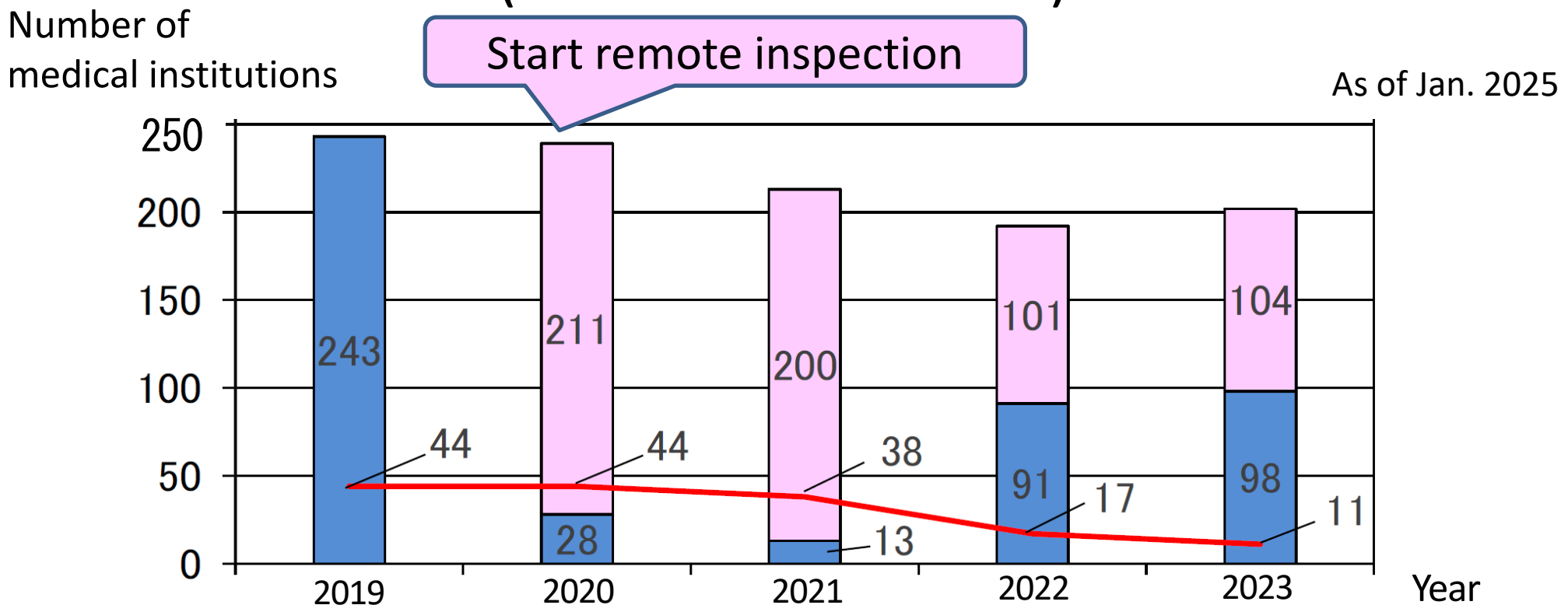
Delay of notification about Suspected Unexpected Serious Adverse Reactions(SUSAR) to the PI and the head of the institution

3.Monitoring (GCP Article 21)

AEs that should have been recorded in the CRF were not identified during monitoring.

Medical institutions on-site inspection

Trend in the number of GCP on-site inspections (Medical institutions)



Number of medical institutions conducted on-site inspection

Number of medical institutions that were inspected by focusing on the management status of sponsors. (Remote inspection)

Number of medical institutions requiring improvement.

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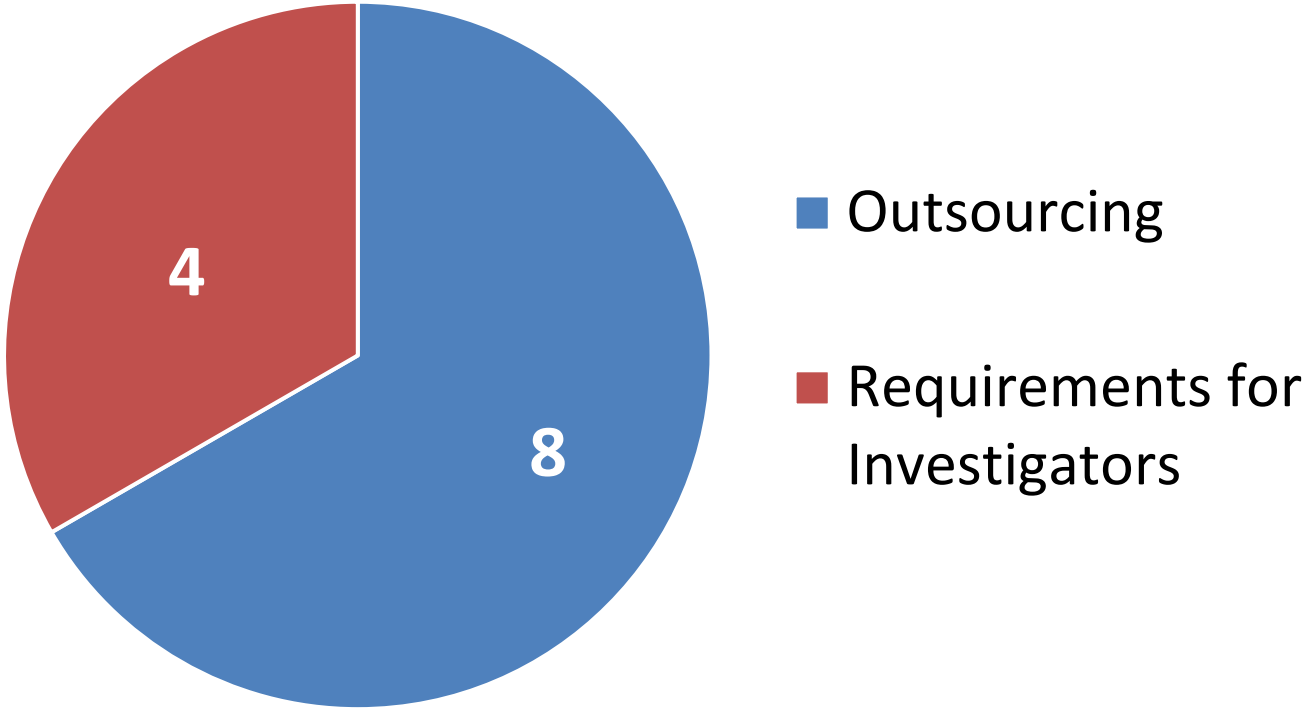
GCP on-site inspection findings
(Medical institution, Clinical Trial Management System)



(Total 12)

* Targeted at 98 medical institutions that issued notification of results between April 2023 and March 2024

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Examples of GCP on-site inspection findings (Medical institution, Clinical Trial Management System)

Outsourcing

◆ No contract stipulated in Article 39-2 of J-GCP with the IP logistics company. (Article 39-2 Outsourcing Duties).

◆ The contract did not stipulate that the PET scan provider needs to report the test conduct and test results to medical institution. (J-GCP Article 39-2, Item 6).

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J-GCP 39-2 Outsourcing Duties

Provision for the contract between medical institution and outsourced contractor

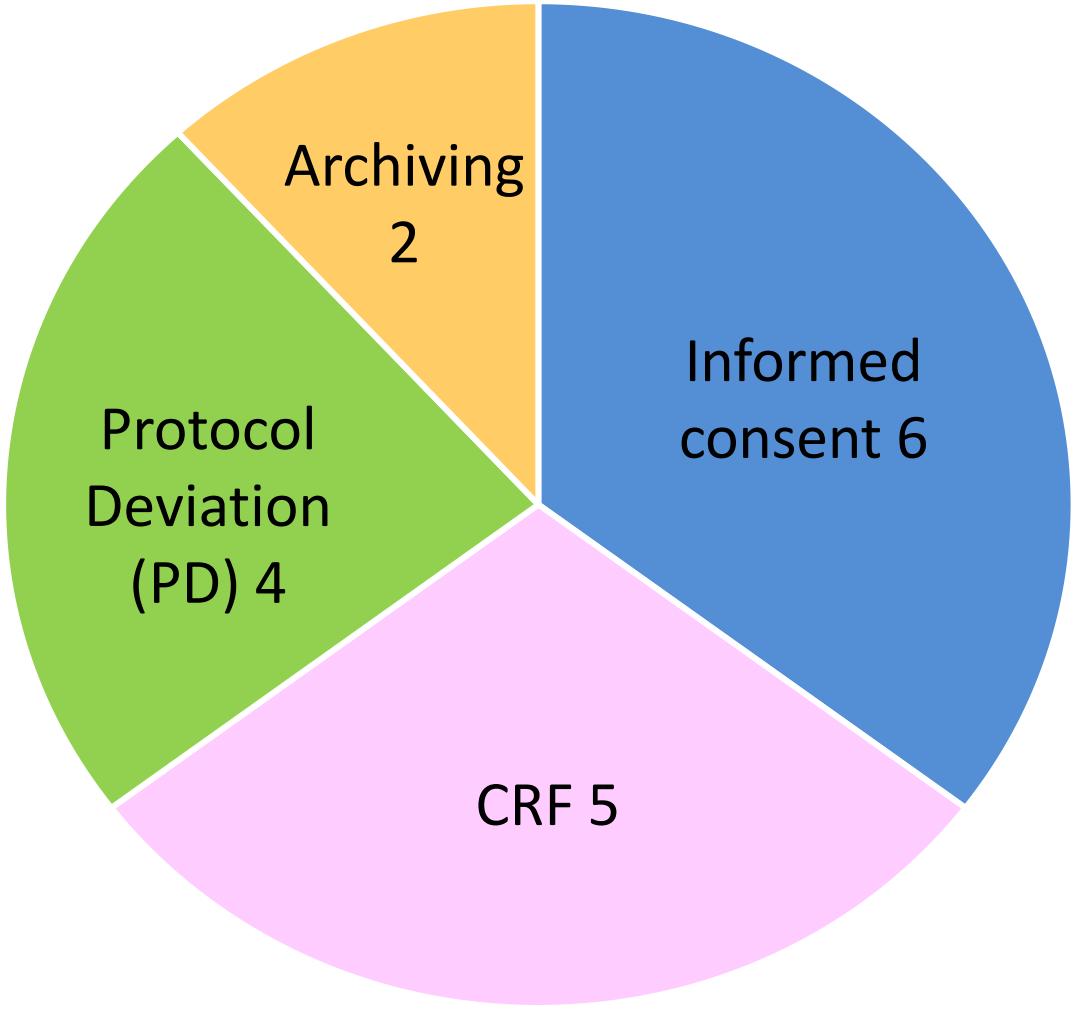
The medical institution shall execute a contract with a service provider by means of a document specifying the following information when outsourcing any of the duties related to the conduct of the clinical trial:

1. **Scope** of the duties outsourced
2. **Description of the operating procedures** for the duties outsourced
3. Statement that the **medical institution can ascertain whether the duties outsourced are conducted properly and smoothly** in compliance with the operating procedures specified in the preceding item
4. Description of the **instructions** to the contractor
5. Statement that if the instructions specified in the preceding item are given, **the medical institution is entitled to ascertain whether appropriate measures are taken** in response to the instructions
6. Description of the **reports** to be submitted by the contractor to the medical institution
7. Other necessary matters related to the duties outsourced

Ministerial Ordinance on Good Clinical Practice for Drugs as of 2023

GCP on-site inspection findings (Medical institution, individual cases)

(Clinical trials of new drugs conducted by companies, domestic investigations)



(Total 17)

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* Targeted at 98 medical institutions that issued result notification between April 2023 and March 2024

Examples of GCP on-site inspection findings (Medical institutions, individual cases)

1. Informed consent (J-GCP Article 50-54)

Informed consent was not obtained from participants using the revised consent form.

2. CRF(J-GCP Article 47)

Adverse events that should have been recorded in the CRF were not recorded.

3. Protocol deviations (J-GCP Article 46)

Administration of the wrong dose of the Investigational Products.

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2-3 Comparison of common findings of medical institution (MHRA,FDA,EMA,PMDA)

Comparison of common findings for Investigator site inspections

	MHRA	EMA	FDA	PMDA
Metrics Period	2019–2020	FY2023	FY2023	FY2023 ※Apr. 2023-Mar. 2024
Common 5 findings	✓ CRF/source data ✓ Medical oversight by PI ✓ IMP management/Pharmacy ✓ Staff delegation & responsibility ✓ Essential document	✓ General ✓ Investigational site ✓ IMP ✓ Informed consent ✓ Trial management (Sponsor)	✓ Failure to Investigational plan/Form1572 ✓ Case/source record ✓ Informed consent ✓ IP handling ✓ Safety report	✓ Outsourcing ✓ Informed consent ✓ CRF/source record ✓ PD ✓ Requirement for investigators

MHRA:https://assets.publishing.service.gov.uk/media/64357bfe89f19f00133cfb40/GCP_inspection_metrics_2019-2020.pdf
EMA:https://www.ema.europa.eu/en/documents/report/annual-report-good-clinical-practice-inspectors-working-group-2023_en.pdf
FDA:https://www.fda.gov/media/178661/download
PMDA:000273412.pdf

Summary

- PMDA inspections, the total number hasn't changed significantly, but remote inspections have increased since the pandemic.
- Trends in PMDA findings : **outsourcing** is key.
- Comparison among MHRA/EMA/FDA/PMDA findings : **basically same**. Findings concerning **Sponsor/PI Oversight and outsourcing** are trending.

Thank you for listening.
Any questions?