

Responsibilities of MHLW, PMDA and Prefectures

Delegation of legal authorities of GMP inspection and other administrative scope

- The Act on Securing Quality, Efficacy and Safety of Products including Pharmaceutical and medical Devices(PMD Act) defines the authorities related to GMP inspection and other pharmaceutical administration and regulations as a single comprehensive rule.
- Cabinet Ordinance defines the scope of the authorities and delegates the domestic authorities to Prefectures.

Delegation of MHLW's authority of GMP inspection to PMDA and prefectural inspectorates

Products manufactured	Domestic Manufacturing Site	Foreign Manufacturing Site
Medicinal products other than generic products, Biological Products and Radiopharmaceuticals	MHLW Delegated to PMDA	MHLW Delegated to PMDA
Other Medicinal Products Including OTC products	Prefectural Inspectorate Where the site locates	MHLW Delegated to PMDA
Medicinal Products for export, Other than Biological Products and Radiopharmaceuticals	Prefectural Inspectorate Where the site locates	—

Delegation of MHLW's authority of Manufacturers' License / Accreditation to PMDA and Prefectures

License/Accreditation Categories	Domestic Site License	Foreign Site Accreditation
Biological Products, Radiopharmaceuticals	MHLW Delegated to PMDA	MHLW Delegated to PMDA
Other Medicinal Products	Prefectural Authority Where the site locates	MHLW Delegated to PMDA

Scope of GMP inspection (medicinal products) by PMDA*

- **Domestic manufacturing sites for the following products**
 - **Medicinal products other than generic products**
 - **Biological products**
 - **Medicinal Products designated by the Minister for national assay**
 - **Radiopharmaceuticals**
 - **Medicinal Products manufactured by utilizing recombination DNA technology**
 - **Medicinal Products manufactured by utilizing cellculture technology**
 - **Designated biological products**
 - **Cell/tissue-based Medicinal Products**

- **Foreign manufacturing sites for the products to be imported into Japan**

* Inspection by Prefectural Inspectorates for other manufacturing sites. 5

Administrative scope of GMP inspectorates (PMDA and Prefectures)

- Prefectures have legal authorities on both GMP inspection and administrative action, such as administrative orders, suspension or revocation of license.
- PMDA has only the authority of GMP inspection, while MHLW has the legal authority on administrative actions based on the results of GMP inspections conducted by PMDA

On-site inspection or Desk-top inspection

- Article 14.6 of PMD Act provides that GMP inspection is to be conducted either by on-site inspection or desk-top inspection
- The inspectorate has responsibility to decide either on-site inspection or desk-top inspection for each inspection, based on risk based assessment
- GMP Inspection Manual issued by MHLW provides procedure for both on-site and desk-top inspection.

* SOPs for risk based selection of on-site or desk-top inspection are to be in place at each inspectorate