Essential Requirements of Japanese PAL for API Business with Japan

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Necessary Matters

1. Accreditation
2. Registration of (D)MF
3. GQP Agreement
4. GMP Compliance Inspection by PMDA

Accreditation

Persons wishing to manufacture drugs exported to Japan from overseas (overseas manufacturers) must receive accreditation from the Minister.

The specifications for accreditation are the same as those for manufacturing licenses for Japanese manufacturers. It shall be renewed every 5 years.

Article 13

Registration of (D)MF

Manufacturers of APIs voluntarily register their data related to the quality and manufacturing method with the reviewing authority beforehand. In the marketing approval application review process, registered files are cited as information necessary for the review of the manufacturing method, etc.. The DMF system also aims at protecting intellectual property of relevant information.

(not applicable to OTC but only to ethical use)

Article 72,79 and 81 the PAL, Enforcement Regulations

GQP Agreement

Must be concluded concerning quality management between MAH and manufacturers. This is one of license requirements of MAH.

GQP Agreement, for example, makes MAH audit possible.

Ministerial Ordinance 136

GMP Compliance Inspection by PMDA

Must be received.
GMP Compliance Inspection concerning Pharmaceuticals of Foreign Manufacturers is an inspection on the compliance of manufacturing control and quality control methods at the relevant manufacturing sites with Japanese GMP. The GMP compliance is a requirement for marketing approval.

GMP Compliance Inspections include

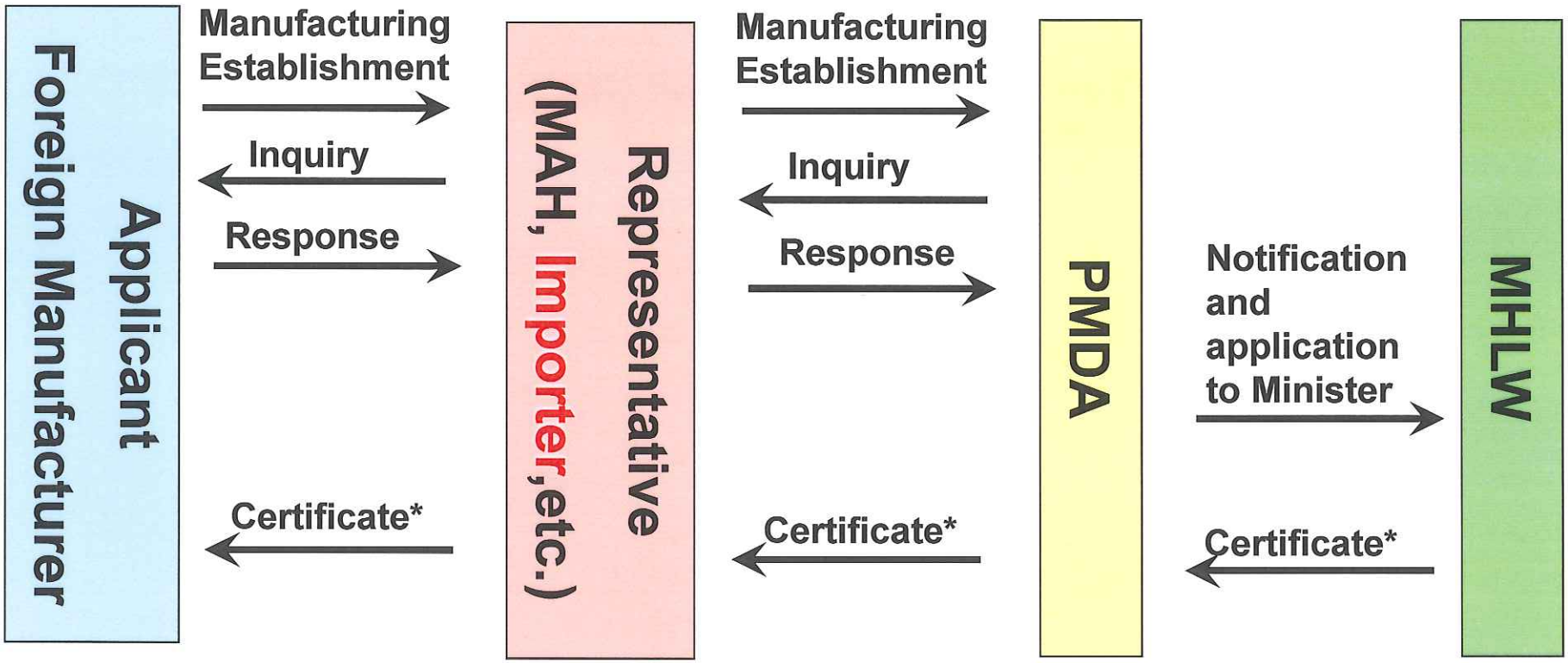
1) Inspections that are conducted at the point of application for new marketing approval or of application for partial changes of approved information, and

2) Inspections that are conducted periodically every five years following the obtainment of marketing approval.

(not applicable to OTC but only to ethical use)

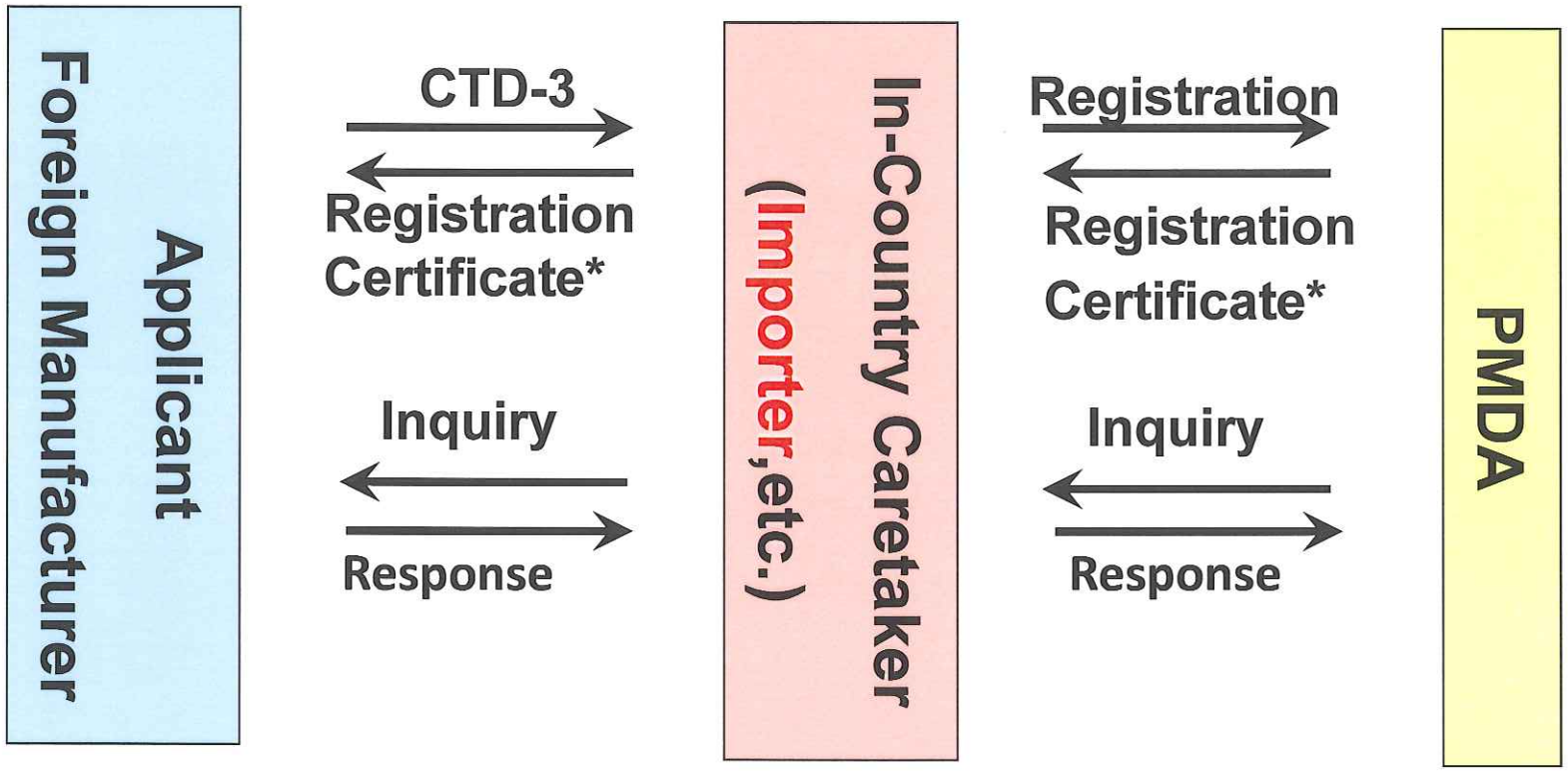
Notification No. 0330006

The Role of Importer in Application of Accreditation



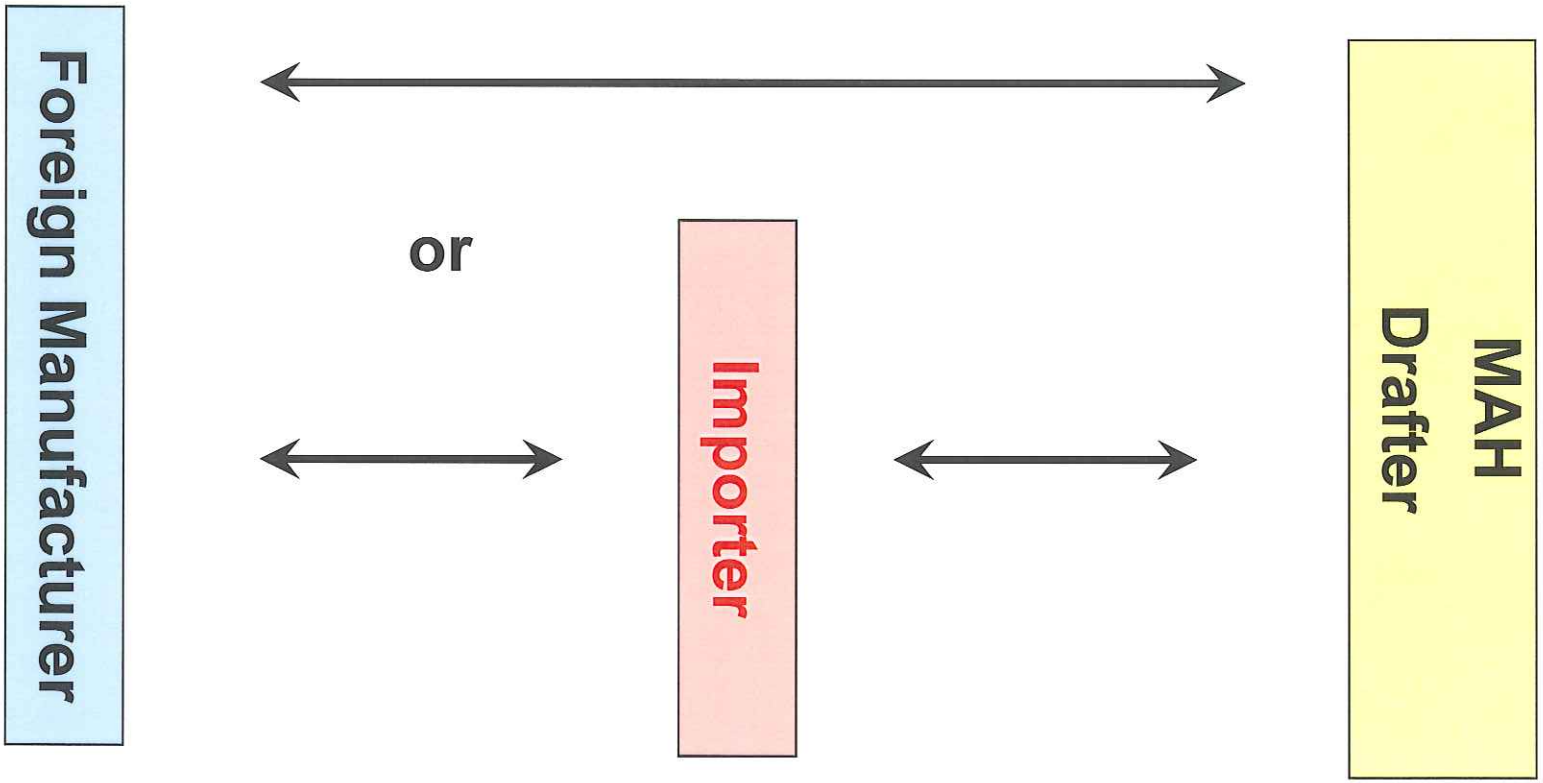
*Accreditation No.

The Role of Importer in Registration of (D)MF

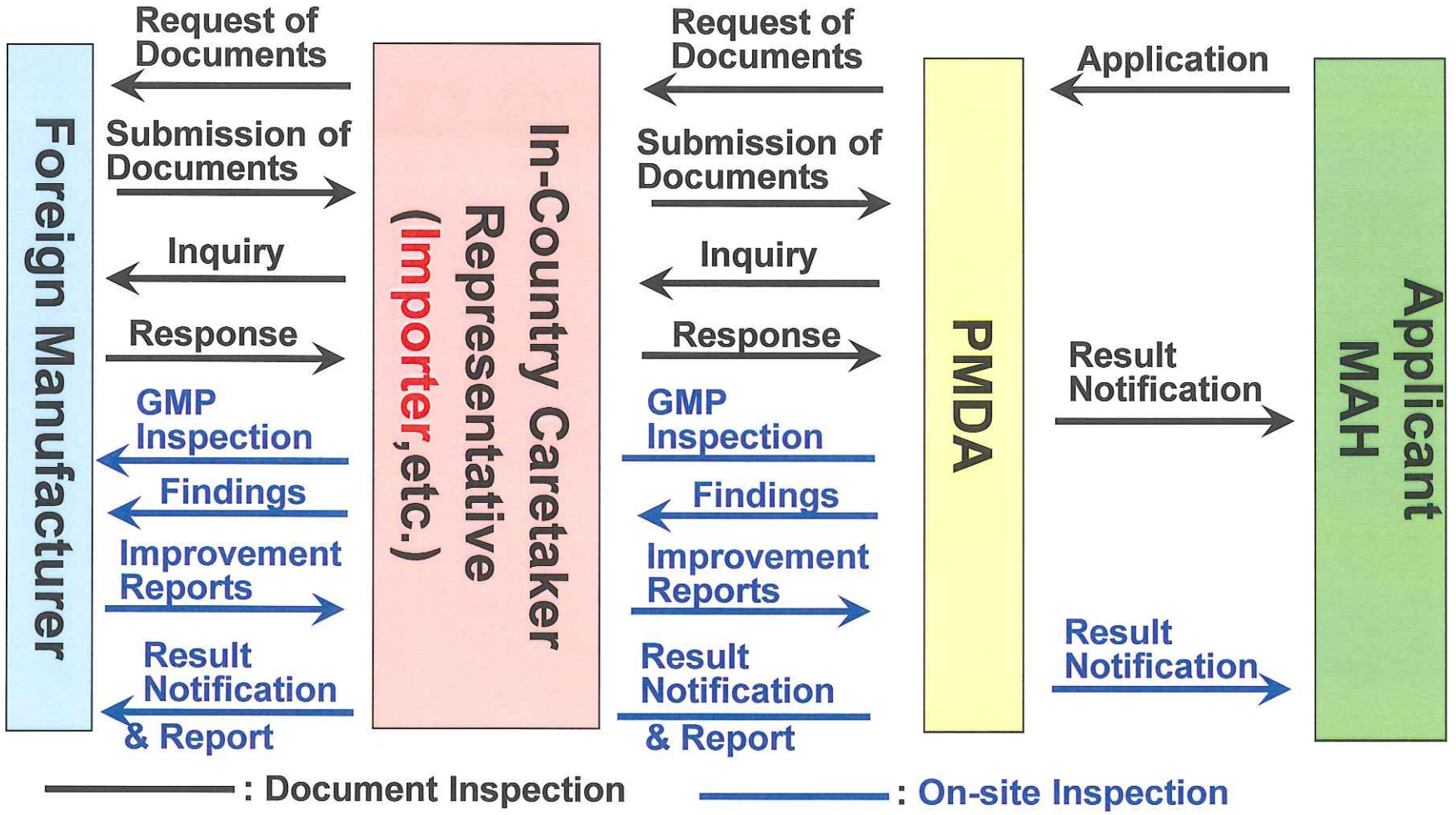


*MF No.

The Role of Importer in GQP Agreement



The Role of Importer in GMP Compliance Inspection by PMDA



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Booth of

Japan Pharmaceutical Traders' Association

CD ROM of
Laws, Ordinances and Administrative Notices relating to API Manufacturer Overseas
Renewal Date: December 16, 2009

¥ 5,000

The End

Thank you for your participation in the meeting.

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