Pharmaceutical Regulations in Japan

(MF System, Accreditation of Foreign Manufacturing Site, GMP Inspection etc.)

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This is a tentative translation for the convenience of participants in this seminar.

Drugs, quasi drugs, medical devices etc.

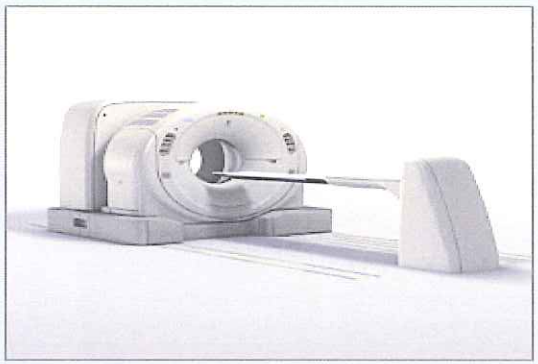
⇨ Regulated under the Pharmaceutical Affairs Law (Law No. 145, 1960)

Ethical drugs { **New drugs** / **Generic drugs**

OTC drugs

Quasi drugs

Medical devices



Key points in the 2002 revision of the Pharmaceutical Affairs Law etc.

July 31, 2002 Revised Pharmaceutical Affairs Law was proclaimed

(April 1, 2005 Took full effect)

- **Improved post-marketing safety measures and changed approval and license systems**

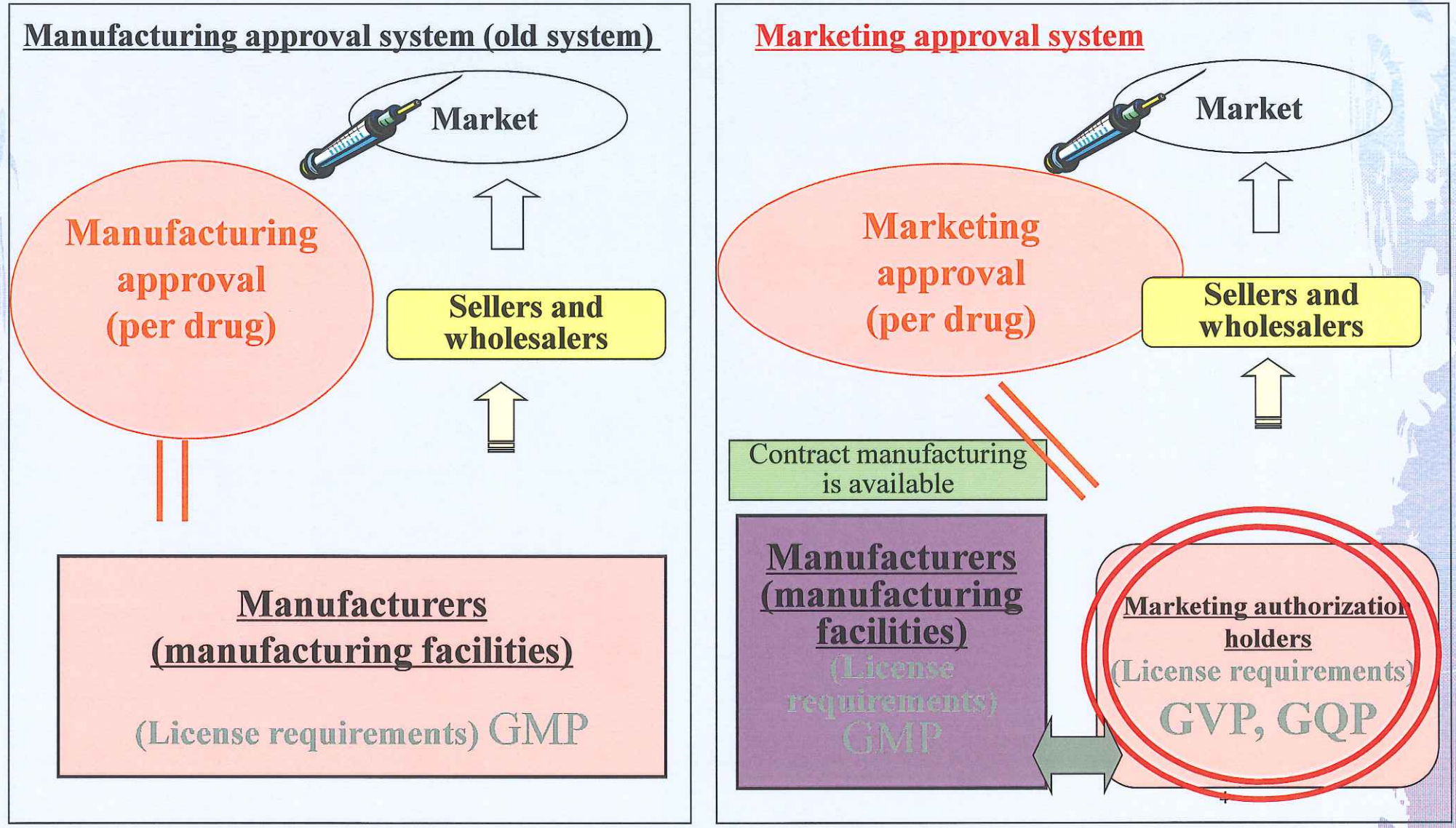
  (Shifted to marketing approval and license systems, introduced minor change notification system etc.)

- **Introduced Master File (MF) registration system etc.**

April 1, 2004 Law for the Pharmaceuticals and Medical Devices Agency took effect

- **PDMA was established; Changed the approval review system (entrusted with PMDA)**

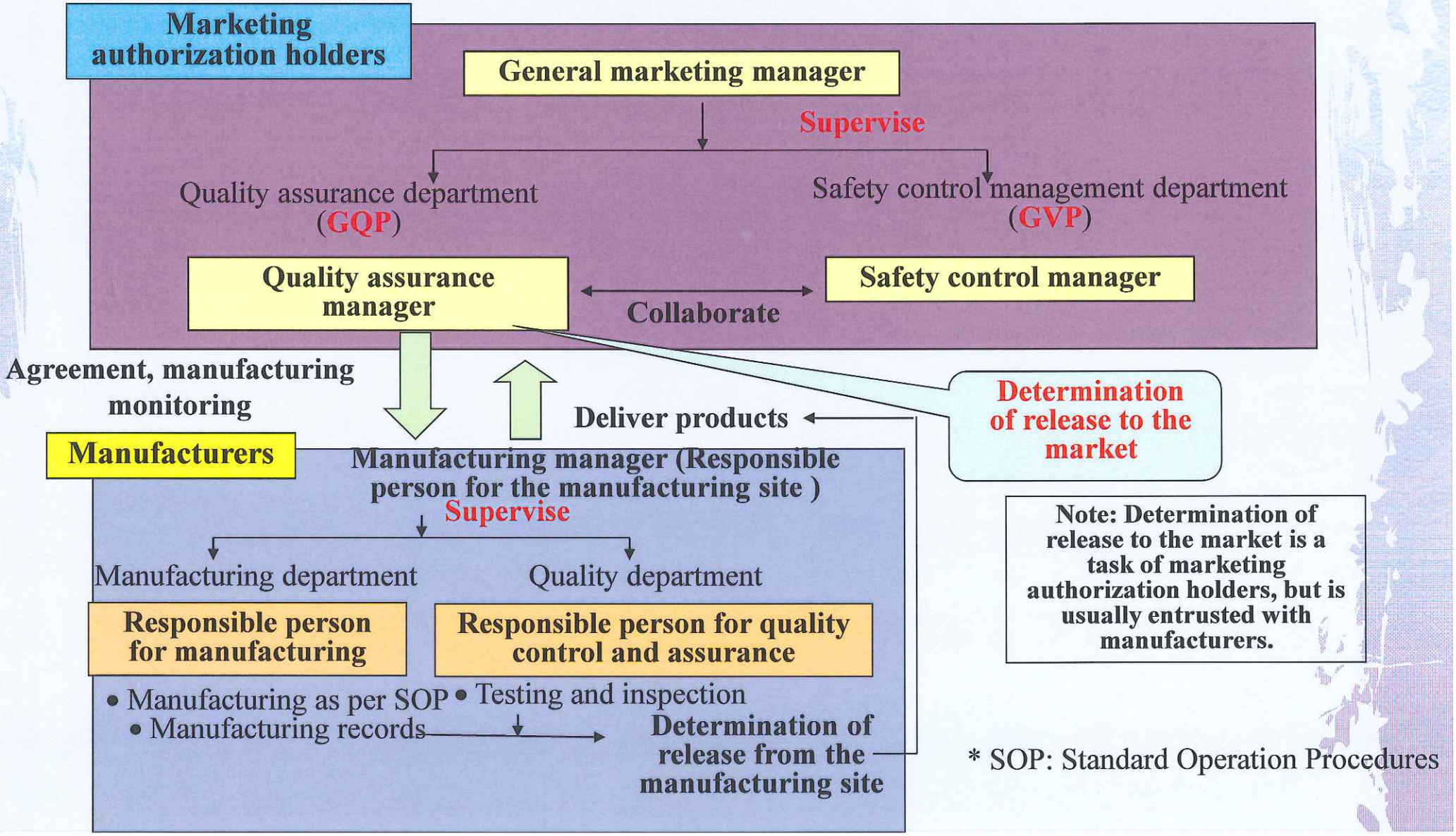
Approval & License System following the 2002 Revision



Regulations concerning the marketing of drugs

- "Marketing" refers to the marketing and/or provision of manufactured (which includes contract manufacturing) and/or imported pharmaceutical products (which excludes APIs).
- Marketing authorization holders of pharmaceutical products shall be responsible from their manufacturing through to post-marketing, under provisions of the Pharmaceutical Affairs Law.

Collaboration between Marketing Approval Holders and Manufacturers



For the marketing of pharmaceutical products

- **License for marketing authorization holder is required**

  Obtain license by demonstrating that the business entity is capable of responsible manufacturing, quality control and post-marketing safety control of pharmaceutical products.

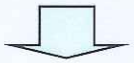
- **Marketing approval is required**

  Collect data on the quality, efficacy and safety of pharmaceutical products, receive review, and obtain approval as pharmaceutical products by the Minister of Health, Labour and Welfare etc.

(○ **For in-house manufacturing of pharmaceutical products, license for manufacturer is also required for each manufacturing site.)**

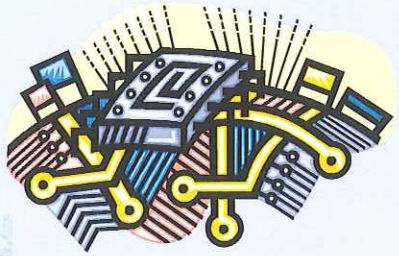
Marketing approval requirements for pharmaceutical products (Section 2, Article 14 of the Law)

- Manufacturing sites satisfy the compliance with standards for **manufacturing control and quality control (GMP: Good Manufacturing Practice)**
- License for marketing authorization holder
- License (accreditation) for manufacturer at each manufacturing site
- Quality, efficacy and safety of pharmaceutical products



In addition to the conventional emphasis on specifications, detailed description is also required on manufacturing methods under the Revised Pharmaceutical Affairs Law

Marketing approval and its requirements



Approval requirements

*Quality, efficacy and safety ←◎ Review

*Marketing authorization holder license and manufacturer license (accreditation)
← License/accreditation requirements inspection

*GMP compliance ← GMP inspection to factory

Marketing approval application

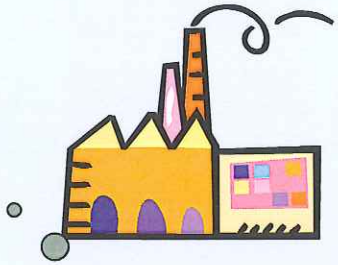
Review & inspection

Marketing approval

Shipment

Marketing authoriaztion holder or appointed marketing authorization holder

Manufacturer



License requirements
*Personnel requirements
*GQP/GVP compliance

License (Accreditation) requirements
*Personnel requirements
*Buildings and facilities

Required compliance
*GMP compliance

Specific description example in the manufacturing method Column

Step1 (Critical process)

Stir 2 - (1 - Triphenylmethyl - 1H - tetrasol - 5 - yl) - 4' - bromomethylbiphenyl [1] <(21.6 kg) >, 2 - formyl - 5 - [(1E, 3E) - 1, 3 - pentadienyl] - 1H - imidazol [2] <(6.9 kg) >, potassium carbonate <(11.8 kg) >, and dimethylformaldehyde <(60 L) > for <24 hours at 25°C>. Add sodium borohydride <(3.2 kg) >, and stir for another <24 hours at 25°C >. Filter the reacted solution and remove the insolubles. Apply vacuum concentration to the filtrate. Add to the residuals water <(50 L) >, and extract with acetic ether<(50 L) >. Wash the organic layer with water <(50 L) > and "10% saline" <(30 L) >. Apply vacuum concentration to the organic layer to approximately half the volume. Stir residuals for <3 hours at 5°C >. Apply centrifugal separation to precipitated crystals, and clean them with acetic ether <(10 L) >. Apply vacuum drying to the crystals for eight to ten hours **<<40°C>>**, and obtain 1 - [2' - (1 - trityl - 1H - tetrasol - 5 - yl) - 4 - biphenylmethyl] - 5 - [(1E, 3E) - 1, 3 - pentadienyl] - 2 - hydroxymethylimidazol [3].

Step2

Stir [3] obtained in Step1 <(approx. 22 kg) >, "10%" hydrochloric acid <(200 L) > and tetrahydrofuran <(400 L) > for <24 hours at 25°C >. Add to the reacted solution "10%" sodium hydroxide solution <(200 L) >. Apply vacuum concentration to the mixture. Add to the residuals water <(100 L) >. Filter it and remove the insolubles. Adjust the filtrate to pH ±0.5 with "35%" hydrochloric acid. Apply centrifugal separation to precipitated crystals, and clean them with water. Apply vacuum drying to the crystals at **<<40°C>>**, and obtain rough crystals of 1 - [2' - (1H - tetrasol - 5 - yl) biphenyl - 4 - yl] methyl) - 5 - [(1E, 3E) - 1, 3 - pentadienyl] - 2 - hydroxymethyl - 1H - imidazol [4].

Scope of minor change notification

Scope of partial change approval application

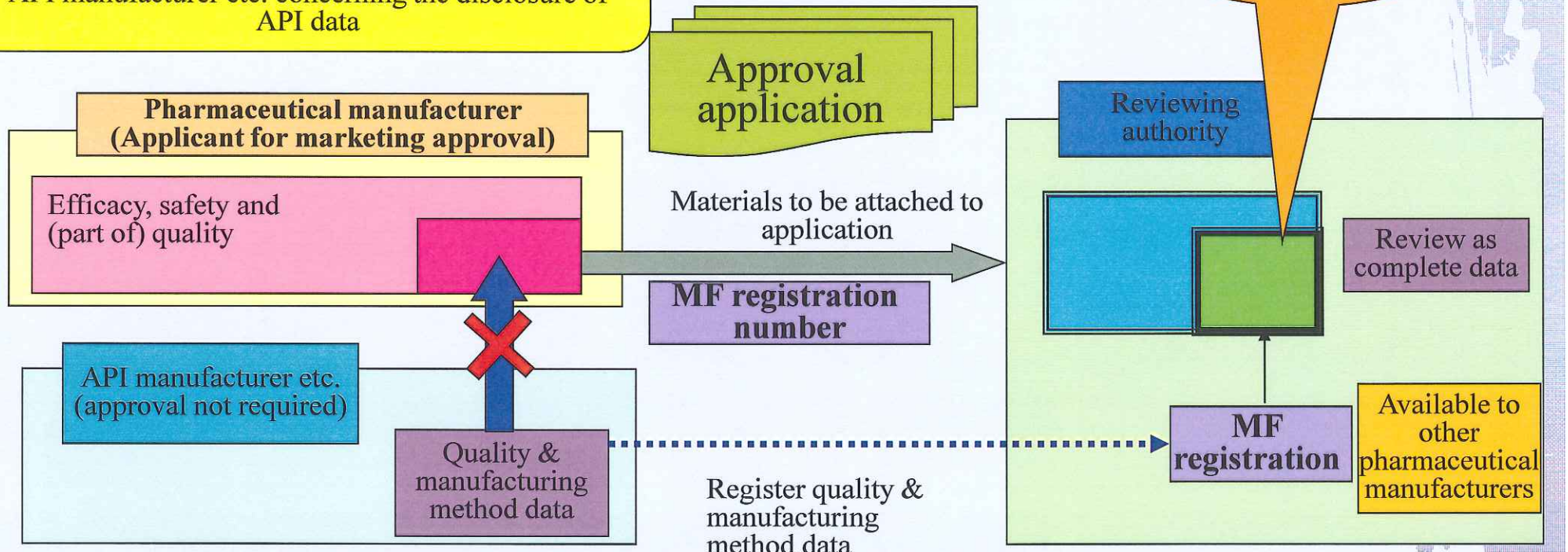
Master File (MF) System

MF is used both in USA and EU – international harmonization

A system that admits separate submission of quality and manufacturing method information, from a manufacturer other than the approval applicant for marketing the pharmaceutical product etc. (optional submission)

Manufacturing method is reviewed in detail in the approval review, which leads to the avoidance of troubles between pharmaceutical manufacturer and API manufacturer etc. concerning the disclosure of API data

Non-disclosed information (which excludes information concerning public health safety, as required specifically)



Eligibility of MF registration

- Manufacturers of drug substances(APIs) etc. in Japan and overseas

- Foreign businesses who apply for MF registration shall assign an in-country caretaker for drug substances(APIs) etc., who undertake clerical affairs for the relevant registration etc. in Japan. Ensure to assign an in-country caretaker for drug substances(APIs) etc. before applying for MF registration.

(Reference)

Section 2, Article 72, Enforcement Regulations for the Pharmaceutical Affairs Law

Items targeted for Master File (MF) Registration

- **(Ethical) drug substances(APIs), intermediates and pharmaceutical product materials (materials of pharmaceutical products with special dosage form, etc.)**
- **Excipients (new excipients, new pre-mix excipients)**
- **Materials for medical devices ・・・*Currently under consideration***
- **Containers, packaging materials ・・・ *Currently under consideration for medical devices***

* The use of MF shall be refrained for the time being for drug substances(APIs), intermediates and pharmaceutical product materials for OTC drugs (excluding those containing new active ingredients). (This excludes TSE materials)

Details registered in Master Files (MF)

(1) Name of the drug substance(API) etc.

(2) Name of the manufacturing site etc.

(3) Information concerning the ingredients, contents and/or inherit properties

(4) Manufacturing method, manufacturing process control and quality control test

(5) Specifications and test method

(6) Stability test, preservation method and shelf life

(7) Nonclinical test (mainly for new excipients)

(8) Information concerning safety

(9) Category of manufacturer license or foreign manufacturer accreditation

(10) Manufacturer license number or foreign manufacturer accreditation number and date

(11) In-country caretaker for the drug substance(API) etc.

Issuance and publication of Master File (MF) registration certificate

Once MF is registered…

[To MF registrants]

Master File registration certificate and copy of registration application are issued

[To the public]

- **Publication based on provisions under Section 3, Article 14-11 of the Pharmaceutical Affairs Law**

  → Published on the website of PMDA (http://www.pmda.go.jp/)

- **Published information:**

  MF registration number, date of registration (of change), name and address of registrant, name of registered item, category of registration

(Reference notification)

- Notification of Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MH LW; yakushoku shinsa-hatsu No.0210004, February 10 2005

Information that MF registrant shall disclose to pharmaceutical product approval applicant etc.

Items Targeted for MF Registration, Description of Each Item and Disclosure Status

Attachment

Item for registration		Data items that can be registered as reference materials		Restricted part (example)	Disclosed part (example)	
Items targeted for Master File (MF) registration, as specified in Section 1, Article 14-11 of the Law, are as follows:			Statement that any change concerning manufacturing and control of the drug substance etc. be reported			
			Data items based on the CTD			
Name of the drug substance etc.		3.2.S.1	General information			
Name of the manufacturing site		3.2.S.1.1	Name (INN, chemical name, development code etc.)		○	
Location of the manufacturing site		3.2.S.1.2	Structure (structural formula, molecular formula, molecular weight)		○	
Category and number (as appropriate) of manufacturing license / accreditation		3.2.S.1.3	General characteristics (properties, physicochemical qualities such as solubility)		○	
		3.2.S.2	Manufacturing			
Ingredients, contents or inherent property		3.2.S.2.1	Manufacturer		○	
		3.2.S.2.2	Manufacturing method and process control (Manufacturing flow and its description, process control etc.)	○	○	*Note
Manufacturing method		3.2.S.2.3	Control of raw materials	○		
		3.2.S.2.4	Control of critical processes and intermediates	○		
Specifications and test methods		3.2.S.2.5	Process validation / process evaluation	○		
		3.2.S.2.6	Development history of the manufacturing process	○		
Stability information		3.2.S.3	Characteristics			
		3.2.S.3.1	Clarification of structure and other characteristics (elemental analysis concerning structural determination, NMR etc.)		○	
Storage method and shelf life		3.2.S.3.2	Impurities (analogs, decomposition channels, residual solvents etc.)		○	
Safety information		3.2.S.4	Control of the drug substance			
		3.2.S.4.1	Specifications and test methods		○	
		3.2.S.4.2	Test/analysis methods		○	
		3.2.S.4.3	Validation of test/analysis methods		○	
		3.2.S.4.4	Lot analysis		○	*Note
		3.2.S.4.5	Validity of /rationale for the specifications and test methods	○	○	*Note
		3.2.S.5	Reference material or standard substance	○	○	
		3.2.S.6	Container closure system			
		3.2.S.7	Stability			
		3.2.S.7.1	Summary and conclusion of stability		○	
		3.2.S.7.2	Formulation and implementation of post-approval stability test plan		○	
		3.2.S.7.3	Stability data			

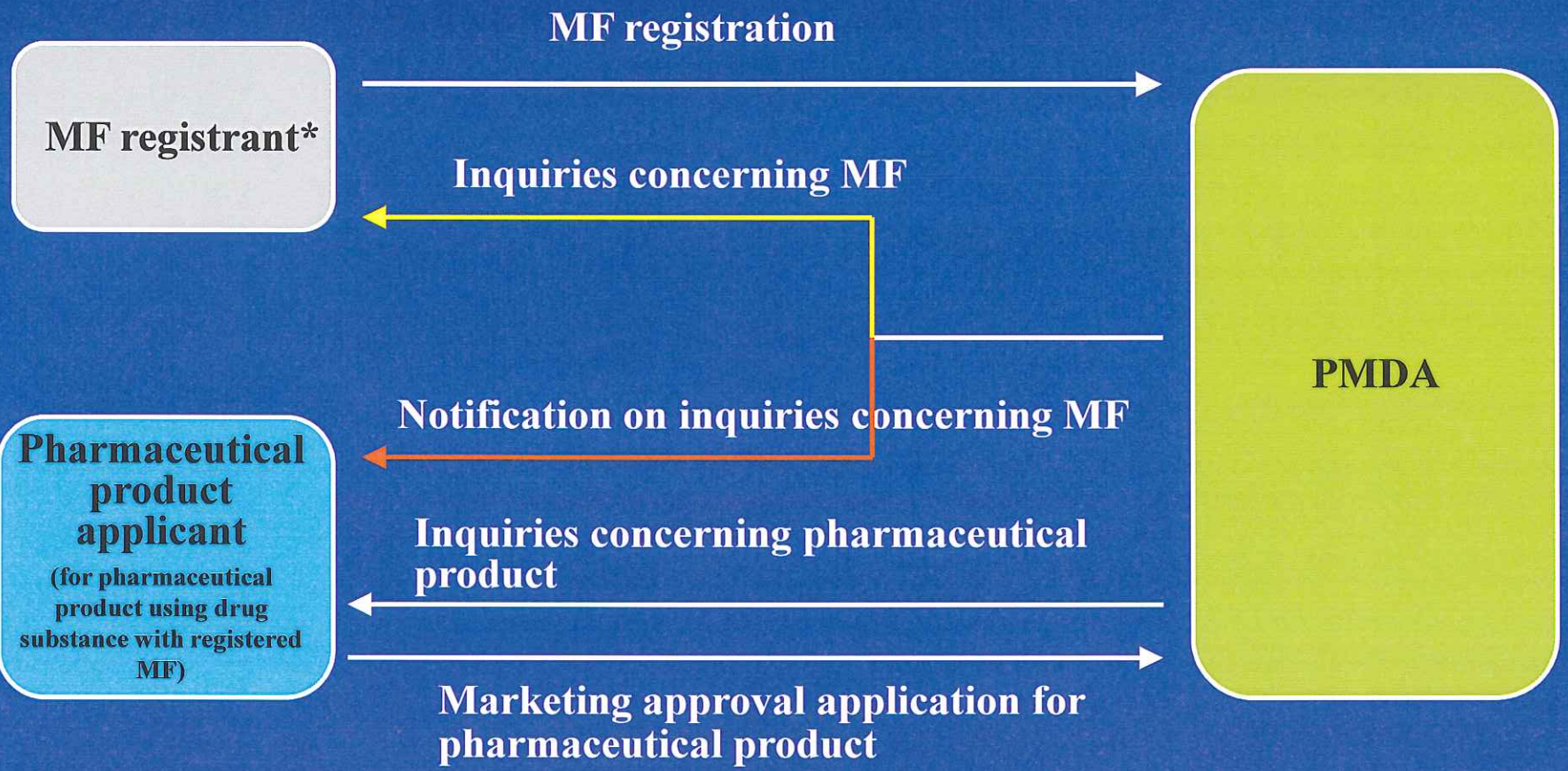
(Note) shown in both parts are basically disclosed. But information related to intellectual properties of MF registrant may not be disclosed

"Data related to the safety and efficacy of analogs etc. should be indicated in the approval application itself as necessary."

Status of information registered in Master File (MF)

- Information registered in MF
  - > Partial substitution for marketing approval application for a pharmaceutical product
  - > Partial substitution for attached materials for marketing approval application for a pharmaceutical product
- The registered information is reviewed in the approval review for the pharmaceutical product using the relevant MF. In the review of the pharmaceutical product, materials listed in Module 3 of CTD and materials equivalent to Module 2 of CTD (overview of attached materials) are also required.

[Overview of approval review for pharmaceutical product quoting MF]



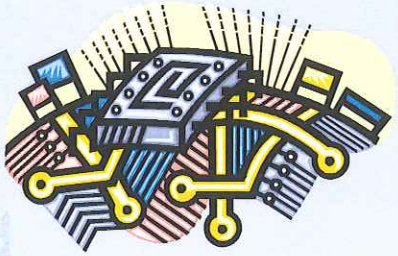
MF registrant* : If the registrant is an overseas manufacturer, inquiries are made by way of in-country caretaker for drug substances(APIs) etc.

Points to consider for MF registrants

(1) While MF registration is optional, registration check only verifies whether specified formats are observed, and required materials are attached. Note that validity of the registered information is not reviewed, and that acceptance of MF registration does not signify approval by the review authority.

(2) An MF registrant (**in-country caretaker for overseas manufacturer of APIs etc.**) shall **notify any change to the registered information (which includes minor change notifications) to the marketing approval applicant and marketing approval holder of the relevant pharmaceutical product.**

Marketing approval and its requirements (same as the previous slide (No9))



Approval requirements

*Quality, efficacy and safety ← Review

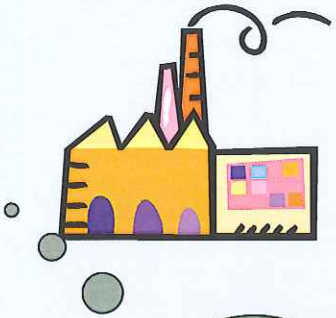
*Marketing authorization holder license and manufacturer license (accreditation) ← ◎License/accreditation requirements inspection

*GMP compliance ←◎GMP inspection to factory

Marketing approval application → Review & inspection → **Marketing approval** → Shipment

Marketing authorization holder or appointed marketing authorization holder

Manufacturer



License requirements
*personnel requirements
*GQP/GVP compliance

License (Accreditation) requirements
*Personnel requirements
*Buildings and facilities

Required compliance
*GMP compliance

Ministerial Ordinances concerning GMP and License (Accreditation)

●GMP

"Ministerial Ordinance concerning Standards for Manufacturing Control and Quality Control for Drugs and Quasi Drugs"

・・・Drugs and Quasi Drugs GMP Ministerial Ordinance

(MHLW Ordinance No.179, 2004)

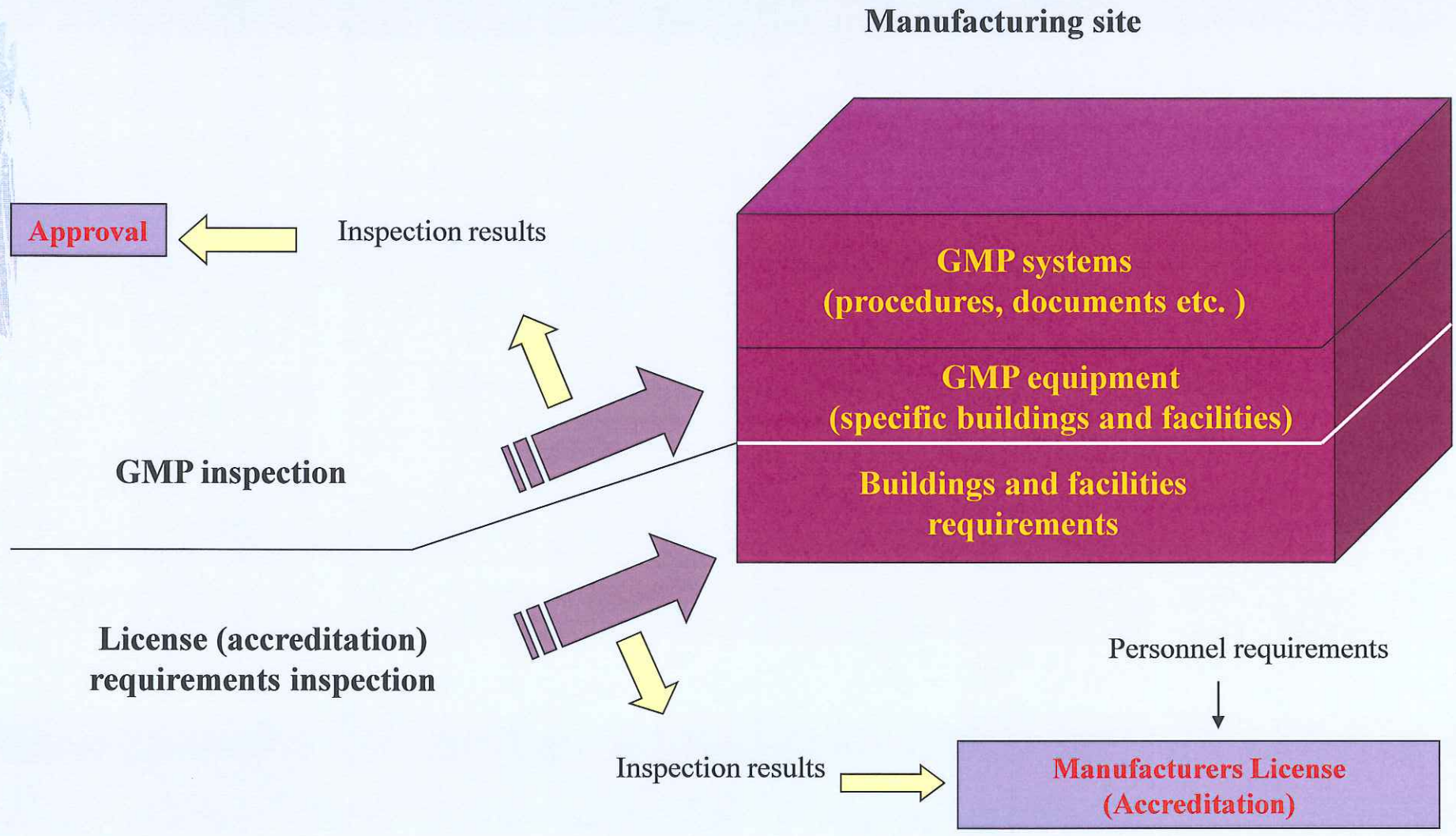
●License (Accreditation)

"Regulations for Buildings and Facilities for Pharmacies etc."

(MHW Ordinance No.2, 1961)

→ Both GMP and Accreditation requires renewal every five years.

GMP inspection and license (accreditation) requirements inspection



GMP compliance inspection (pharmaceutical products) by PMDA*

- Domestic facilities for manufacturing of the following items
  - New drugs (Shifted from prefectural authorities to PMDA in April 2005)

    (* New drugs before the publication of re-evaluation)
  - Biological products
  - Drugs designated by the Minister for national assay
  - Radiopharmaceuticals
  - Drugs manufactured by application of recombination DNA technology
  - Drugs manufactured by application of cell culture technology
  - Specified biological products
  - Cell/tissue-based drugs
- Overseas facilities in the scope of GMP (New since April 2005)

* Inspection is conducted by prefectural authorities for other manufacturing sites.

Flow of on-site GMP inspection for new drugs

Applicant (Marketing authorization holder)

Marketing approval application

GMP compliance inspection application

PMDA

(Receive application) Office of Review Administration

Offices of Review

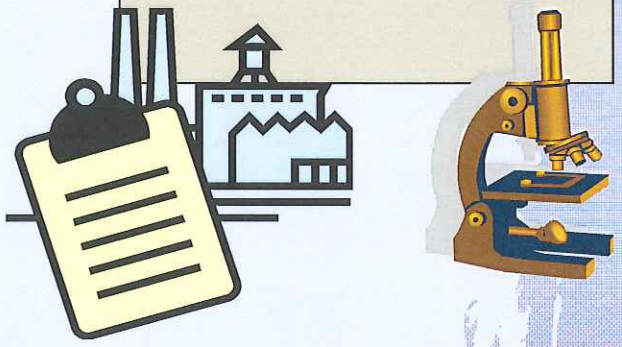
Office of Compliance and Standards

GMP inspection

Domestic & overseas manufacturers (Pharmaceutical factories)

Manufacturing

Quality control



Review results

GMP inspection results

Approval authority (MHLW)

Approval certificate

Points to be considered for on-site GMP inspection for overseas manufacturing sites (overview)

1 In principle, inspection equivalent to that for domestic manufacturing sites shall be conducted.

2 In advance, the GMP Ministerial Ordinance of Japan and other information shall be provided to the relevant manufacturer.

3 Drug product master formula, standard codes, procedures and other documents required in the GMP Ministerial Ordinance of Japan shall be prepared.

4 Documents that verify agreements between the marketing authorization holder and manufacturer based on the GQP Ministerial Ordinance of Japan shall be prepared.

5 Assign a contact person who can reply to inspection inquiries (ensure preparations at the targeted manufacturing site for the planned inspection).

6 Assign an appropriate interpreter.

7 Translate the materials as necessary.

8 Formulate an efficient inspection schedule.

Typical findings at overseas manufacturing sites

- Discrepancy from approval application (ingredient and/or content specifications, manufacturing conditions etc.)
- Inadequacies concerning GQP agreements (agreements on technological conditions, change control etc.)
- Nonconformities with the GMP Ministerial Ordinance of Japan, noncompliance with standards (in particular, Standards for Biological Ingredients, retention period for records etc.)

Accreditation

Accreditation of foreign manufacturers:

- **Is issued by the Minister of Health, Labour and Welfare.**
- **Is issued separately for each manufacturing site, and for each category.**
- **Is valid for five years.**
- **Requires application procedures and accreditation fee.**
- **PMDA inspects whether the site is in conformity with the standards specified by the MHLW Ordinance (Regulations for Buildings and Facilities for Pharmacies etc.).**
  → At present, only document inspection is conducted.

Five types for pharmaceutical products (excluding *in vitro* diagnosis)

1. **Biological products etc.** (Item 1, Section 1, Article 36 of the Enforcement Regulations)
   Those who undertake whole or part of the manufacturing process for biological products, drugs for national assay, drugs manufactured by application of recombination DNA technology, drugs manufactured by application of cell culture technology, cell/tissue-based drugs, and specified biological products
2. **Radiopharmaceuticals** (Item 2, Section 1, Article 36 of the Enforcement Regulations)
   Those who undertake whole or part of the manufacturing process for radiopharmaceuticals
3. **Sterile drugs** (Item 3, Section 1, Article 36 of the Enforcement Regulations)
   Those who undertake whole or part of the manufacturing process for sterile drugs
4. **General** (Item 4, Section 1, Article 36 of the Enforcement Regulations)
   Those who undertake whole or part of the manufacturing process for pharmaceutical products other than those listed in 1 through 3 above
5. **Packaging, labeling and storage** (Item 5, Section 1, Article 36 of the Enforcement Regulations)
   Those who undertake only packaging, labeling and storage

Materials to be submitted for application (Article 35, Enforcement Regulations)

(1) Medical certificate by physician for the applicant

(2) Personal history of responsible persons for the manufacturing site

(3) List of manufactured items and documents concerning the manufacturing process

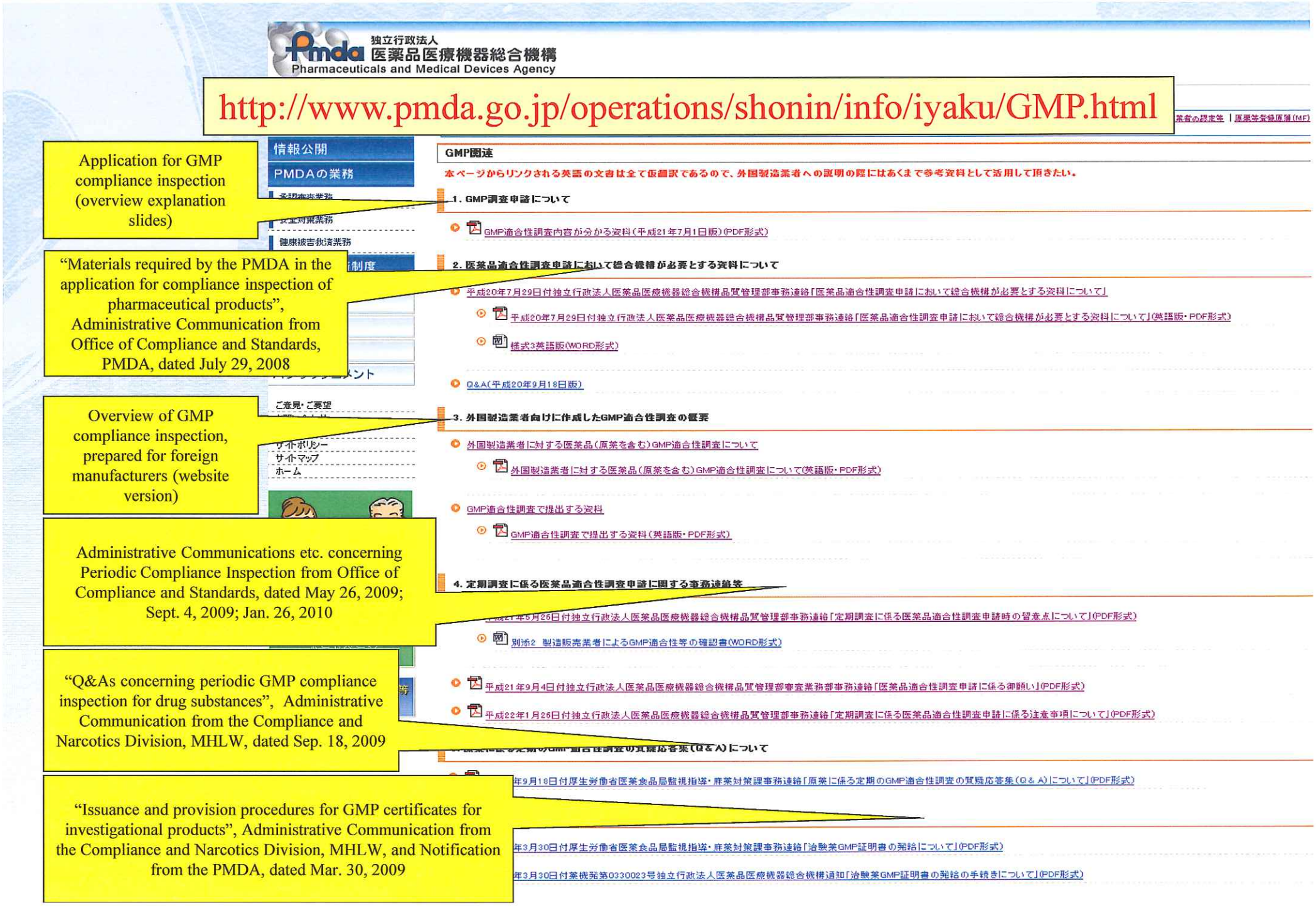
(4) Documents concerning the buildings and facilities of the manufacturing site

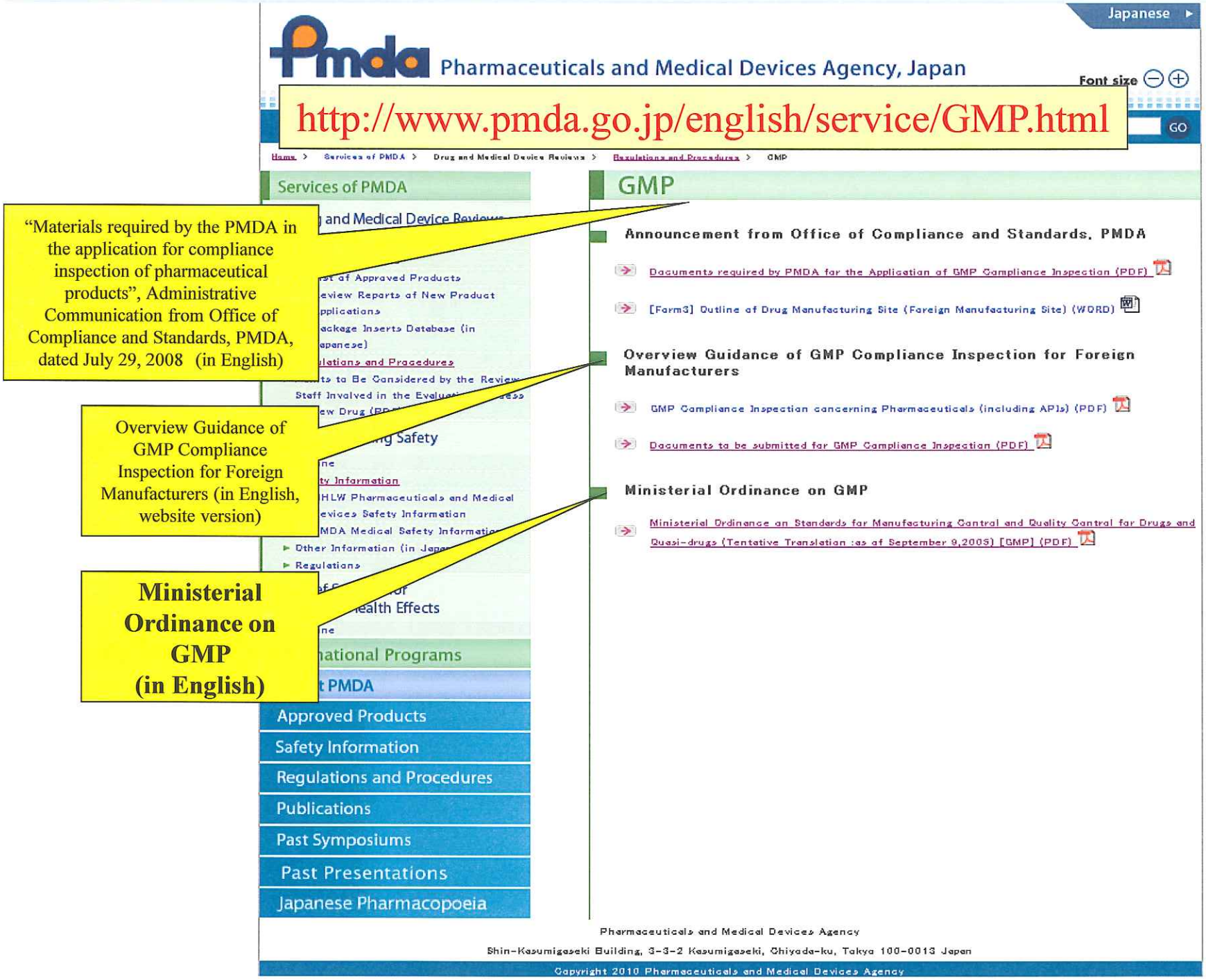
List of buildings and facilities (form to be attached to the application form, as indicated by the Notification from the Director-General of the Pharmaceutical and Food Safety Bureau, Yakushoku Hatsu No.0619002, dated June 19, 2007; http://www.pmda.go.jp/operations/shonin/info/foreign/gaikokuseizou.html)

(5) When radiopharmaceuticals are handled, overview of facilities required for handling such radiopharmaceuticals

(6) Copy of license certificate etc. issued by the government of the country in which the relevant foreign manufacturer operates

Reference materials follow.


独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency
http://www.pmda.go.jp/operations/shonin/info/iyaku/GMP.html
Application for GMP compliance inspection (overview explanation slides)
"Materials required by the PMDA in the application for compliance inspection of pharmaceutical products", Administrative Communication from Office of Compliance and Standards, PMDA, dated July 29, 2008
Overview of GMP compliance inspection, prepared for foreign manufacturers (website version)
Administrative Communications etc. concerning Periodic Compliance Inspection from Office of Compliance and Standards, dated May 26, 2009; Sept. 4, 2009; Jan. 26, 2010
"Q&As concerning periodic GMP compliance inspection for drug substances", Administrative Communication from the Compliance and Narcotics Division, MHLW, dated Sep. 18, 2009
"Issuance and provision procedures for GMP certificates for investigational products", Administrative Communication from the Compliance and Narcotics Division, MHLW, and Notification from the PMDA, dated Mar. 30, 2009
情報公開
PMDAの業務
GMP関連
本ページからリンクされる英語の文書は全て仮翻訳であるので、外国製造業者への説明の際にはあくまで参考資料として活用して頂きたい。
1. GMP調査申請について
GMP適合性調査内容が分かる資料（平成21年7月1日版）(PDF形式)
2. 医薬品適合性調査申請において総合機構が必要とする資料について
平成20年7月29日付独立行政法人医薬品医療機器総合機構品質管理部事務連絡「医薬品適合性調査申請において総合機構が必要とする資料について」
平成20年7月29日付独立行政法人医薬品医療機器総合機構品質管理部事務連絡「医薬品適合性調査申請において総合機構が必要とする資料について」(英語版・PDF形式)
様式3英語版(WORD形式)
Q&A（平成20年9月18日版）
3. 外国製造業者向けに作成したGMP適合性調査の概要
外国製造業者に対する医薬品（原薬を含む）GMP適合性調査について
外国製造業者に対する医薬品（原薬を含む）GMP適合性調査について(英語版・PDF形式)
GMP適合性調査で提出する資料
GMP適合性調査で提出する資料（英語版・PDF形式）
4. 定期調査に係る医薬品適合性調査申請に関する事務連絡等
別添2　製造販売業者によるGMP適合性等の確認書(WORD形式)
平成21年9月4日付独立行政法人医薬品医療機器総合機構品質管理部審査業務部事務連絡「医薬品適合性調査申請に係る御願い」(PDF形式)
平成22年1月26日付独立行政法人医薬品医療機器総合機構品質管理部事務連絡「定期調査に係る医薬品適合性調査申請に係る注意事項について」(PDF形式)
年9月18日付厚生労働省医薬食品局監視指導・麻薬対策課事務連絡「原薬に係る定期のGMP適合性調査の質疑応答集（Q＆A）について」(PDF形式)
年3月30日付厚生労働省医薬食品局監視指導・麻薬対策課事務連絡「治験薬GMP証明書の発給について」(PDF形式)
年3月30日付薬機発第0330023号独立行政法人医薬品医療機器総合機構通知「治験薬GMP証明書の発給の手続きについて」(PDF形式)
サイトポリシー
サイトマップ
ホーム


"Materials required by the PMDA in the application for compliance inspection of pharmaceutical products", Administrative Communication from Office of Compliance and Standards, PMDA, dated July 29, 2008 (in English)
Overview Guidance of GMP Compliance Inspection for Foreign Manufacturers (in English, website version)
Ministerial Ordinance on GMP (in English)
Japanese
Pharmaceuticals and Medical Devices Agency, Japan
Font size
http://www.pmda.go.jp/english/service/GMP.html
GO
Home > Services of PMDA > Drug and Medical Device Reviews > Regulations and Procedures > GMP
Services of PMDA
GMP
Announcement from Office of Compliance and Standards, PMDA
Documents required by PMDA for the Application of GMP Compliance Inspection (PDF)
[Form3] Outline of Drug Manufacturing Site (Foreign Manufacturing Site) (WORD)
Overview Guidance of GMP Compliance Inspection for Foreign Manufacturers
GMP Compliance Inspection concerning Pharmaceuticals (including APIs) (PDF)
Documents to be submitted for GMP Compliance Inspection (PDF)
Ministerial Ordinance on GMP
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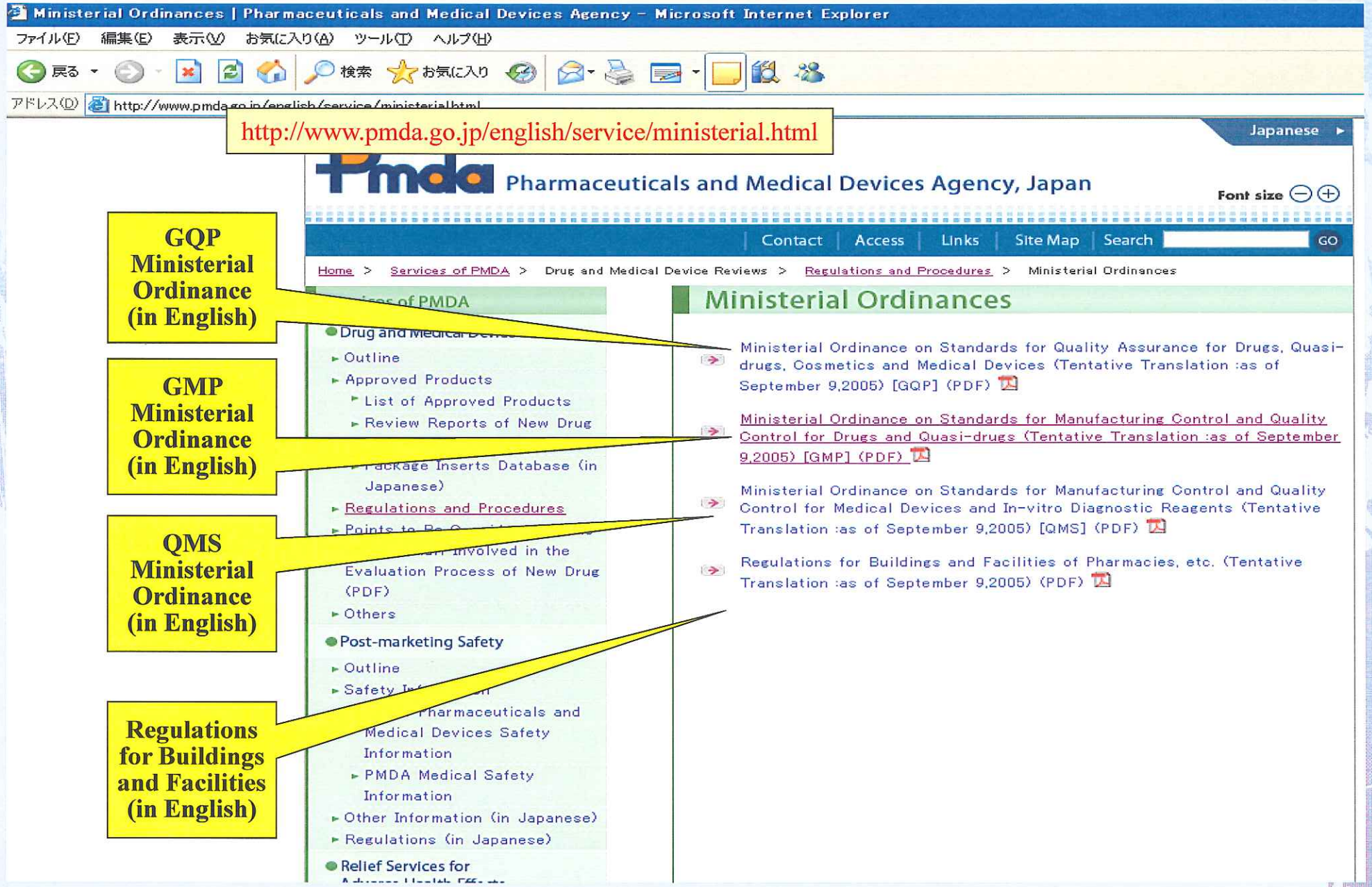
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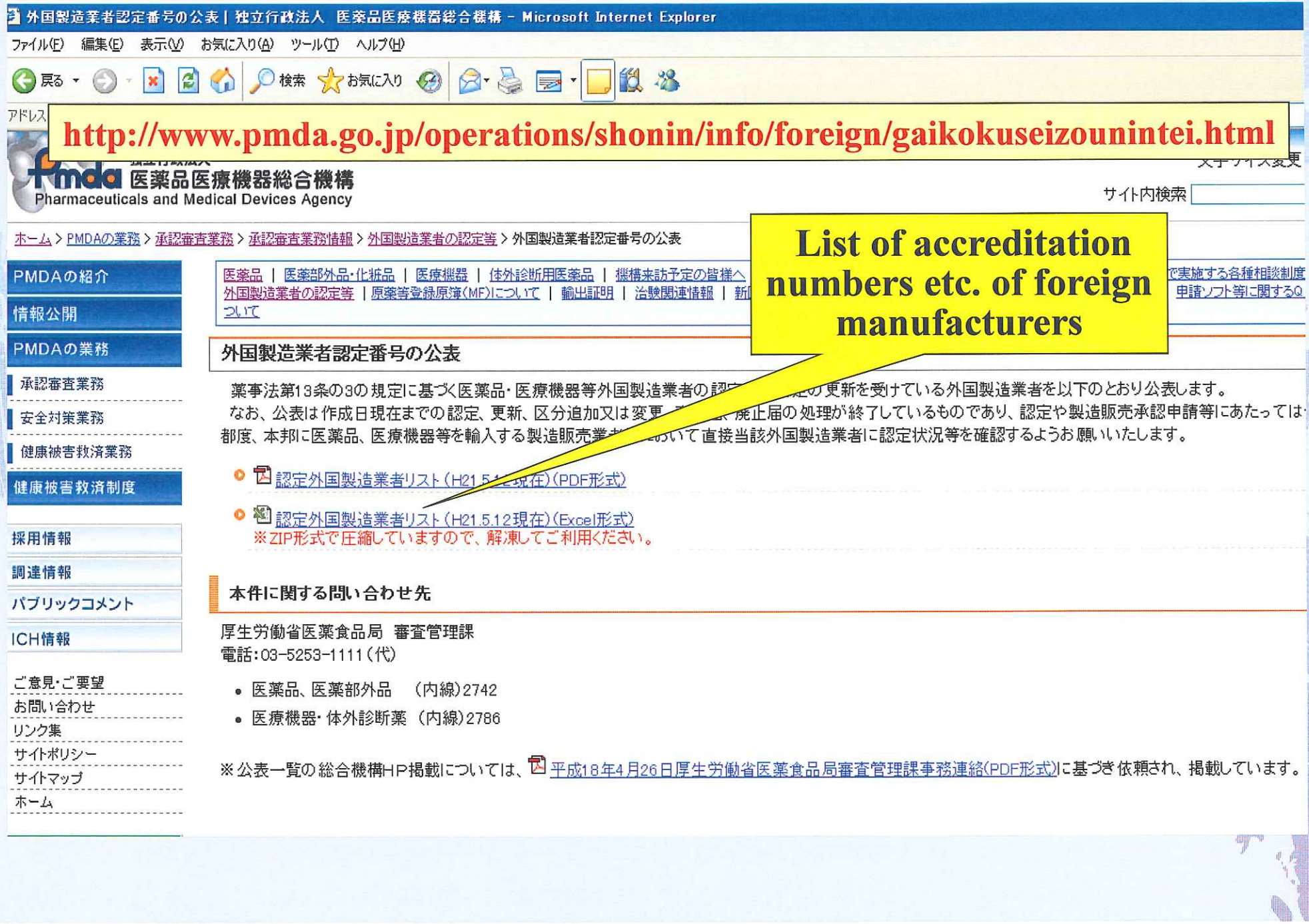
Regulations for Buildings and Facilities of Pharmacies, etc. (Tentative Translation :as of September 9,2005) (PDF)
GQP Ministerial Ordinance (in English)
GMP Ministerial Ordinance (in English)
QMS Ministerial Ordinance (in English)
Regulations for Buildings and Facilities (in English)


外国製造業者認定番号の公表 | 独立行政法人 医薬品医療機器総合機構 - Microsoft Internet Explorer
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申請ソフト等に関するQ
外国製造業者認定番号の公表
薬事法第13条の3の規定に基づく医薬品・医療機器等外国製造業者の認定
なお、公表は作成日現在までの認定、更新、区分追加又は変更
都度、本邦に医薬品、医療機器等を輸入する製造販売業者
認定外国製造業者リスト(H21.5.12現在)(PDF形式)
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※ZIP形式で圧縮していますので、解凍してご利用ください。
本件に関する問い合わせ先
厚生労働省医薬食品局 審査管理課
電話:03-5253-1111(代)
医薬品、医薬部外品 (内線)2742
医療機器・体外診断薬 (内線)2786
※公表一覧の総合機構HP掲載については、平成18年4月26日厚生労働省医薬食品局審査管理課事務連絡(PDF形式)に基づき依頼され、掲載しています。


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医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency
Explanation on application for accreditation of foreign manufacturers (in Japanese)
外国製造業者の認定申請について
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Application for Accreditation of Foreign Manufacturers
(This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail. For further information, please contact Ministry of Health, Labour and Welfare (MHLW) or PMDA.)
1. What is Accreditation of Foreign Manufacturers?
A foreign manufacturer (a person/a company) intending to manufacture drugs, quasi-drugs, or medical devices in foreign countries and export them to Japan, is required to be accredited by the Minister of Health, Labour, and Welfare as an "Accredited Foreign Manufacturer", specified in Article 13-3 of PAL, in the same way that a Japanese manufacturer is licensed. The person or the company who intends to apply for the accreditation is hereinafter referred to as an "Applicant".
However, a foreign manufacturer of the drug or medical device, etc. whose marketing approval holder has an effective importing license granted under the old PAL as of April