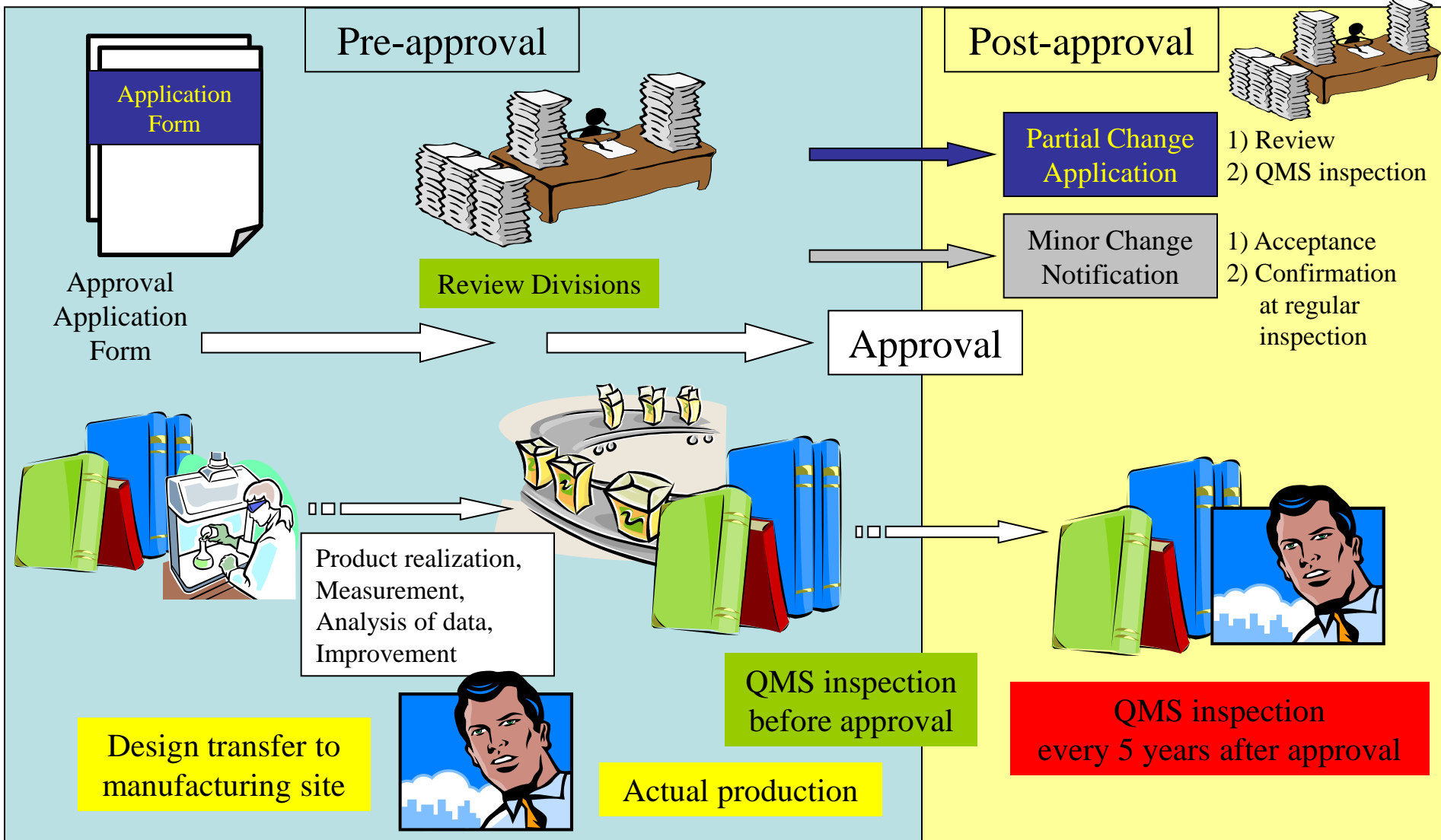


# Current Situation and Updates of QMS Inspection in Japan

Office of GMP/QMS Inspection  
Pharmaceuticals and  
Medical Devices Agency

# Framework of Approval Review and QMS Inspection on Medical Device



# Types of QMS Inspection

## **Compliance inspection**

- 1 Pre-approval inspection**
- 2 Post-approval inspection  
(periodic inspection)**

## **For-cause inspection**

# Authority of GMP/QMS Inspection

Site Location		Domestic	Foreign
IVDs	<ul style="list-style-type: none"> <li>• New drugs</li> <li>• Radioactive drugs</li> </ul>	<b>PMDA</b>	<b>PMDA</b>
	Products without CS*	Prefectures	<b>PMDA</b>
	Products with CS*	Registered certification body	Registered certification body
Medical Devices	<ul style="list-style-type: none"> <li>• New medical devices</li> <li>• Cell / Tissue-based medical devices</li> <li>• Class IV products</li> </ul>	<b>PMDA</b>	<b>PMDA</b>
	Class III and Class II products (without CS*)	Prefectures	<b>PMDA</b>
	Class II products (with CS*)	Registered certification body	Registered certification body

**\*CS : Certification Standards**

# Compliance Inspection by PMDA

Target Products	Target Sites
<ol style="list-style-type: none"><li>1. New medical devices*</li><li>2. Cell-tissue-based medical devices</li><li>3. Class IV medical devices</li><li>4. Radioactive IVDs</li></ol>	<ol style="list-style-type: none"><li>1. Manufacturing Sites</li><li>2. Sterilization Facilities</li><li>3. Storage Facilities</li><li>4. Testing Laboratories</li><li>5. Design and development institutes</li></ol>

\* New medical devices are, as a rule, limited to ones that have new principle or new functional characteristics.

# On-site Inspection and Document Review

Complexity of manufacturing processes

Risk associated with the use of products

Results of the previous on-site inspections

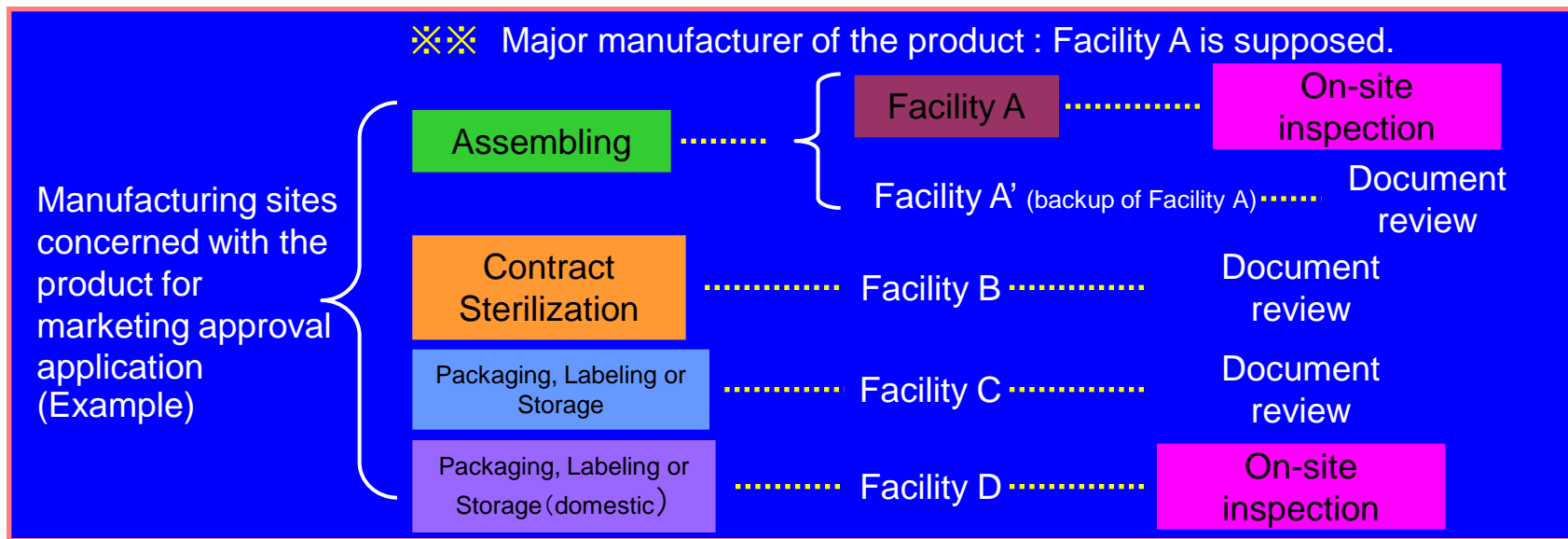
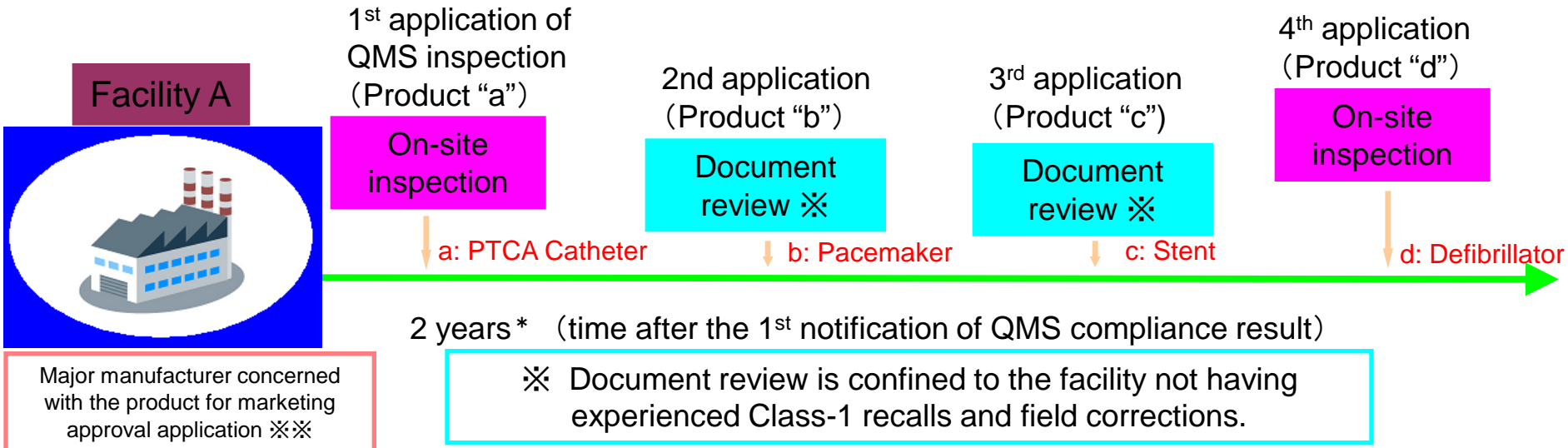
Previous nonconformity, recall, or the contents



On-Site Inspection

Document Review

# Principle of QMS On-site Inspection and Document Review (Concrete Example)





# Relation between MHLW Ministerial Ordinance #169 and ISO13485:2003

事務連絡  
平成23年5月30日

各都道府県衛生主管部（局）薬務主管課 御中

厚生労働省医薬食品局監視指導・麻薬対策課

QMS省令とISO13485：2003との関係性に関する  
質疑応答集（Q&A）について

「医療機器及び体外診断用医薬品の製造管理及び品質管理の基準に関する省令」（平成16年厚生労働省令第169号。以下「QMS省令」という。）は、国際的な整合を図るためにISO13485：2003（以下「ISO13485」という。）を踏まえ作成されたものであり、その逐条解説については、平成17年3月30日付け薬食監麻発0330001号「薬事法及び採血及び供血あつせん業取締法の一部を改正する法律の施行に伴う医薬品、医療機器等の製造管理及び品質管理（GMP/QMS）に係る省令及び告示の制定及び改廃について」（以下「施行通知」という。）の第4章の第3に示しているところである。今般、国際整合性の確保という観点から、QMS省令とISO13485の関係をより一層明確にするため、その考え方について別添のとおりとりまとめたので、業務の参考とされたい。

## MHLW Office Memorandum May 30, 2011

### Q & A regarding the relation between Ministerial Ordinance #169 and ISO13485:2003



# Relation between MHLW Ministerial Ordinance #169 and ISO13485:2003

**MHLW  
Ministerial  
Ordinance #169**

**ISO13485:2003**

**Additional  
Requirements**

**(almost) Equal  
Requirements**

# Contents of MHLW Ministerial Ordinance #169 (QMS Ordinance)

## Chapter 1 General Provisions

Chapter 2  
Medical Devices  
Manufacturers, etc.

Chapter 3  
Labeling, etc. – Category  
Medical Devices  
Manufacturers, etc.

Chapter 4  
Biological-origin Medical  
Device, etc. Manufacturers,  
etc.

\*Chapter 5 : In-Vitro Diagnostics Reagents  
Manufacturers, etc.  
(The provisions of Chapter 2 and 3  
shall be applied Mutatis Mutandis.)

# Relation between MHLW Ministerial Ordinance #169 and ISO13485:2003



# Additional Requirements

## #169 Chapter 2 Additional Requirements

**Additional Requirements  
regarding infrastructure**

**Written procedure  
of training**

**Retention period of obsolete  
controlled documents and records**

# Check!!

## MHLW Ministerial Ordinance #169

The screenshot shows the PMDA website interface. At the top left is the PMDA logo and the text 'Pharmaceuticals and Medical Devices Agency, Japan'. To the right of the logo are options for 'Japanese' and 'Font size'. Below the logo is a navigation bar with links for 'Contact', 'Access', 'Links', 'Site Map', and a search box with a 'GO' button. The main content area is titled 'Ministerial Ordinances' and contains a list of links to various PDF documents. A large blue arrow points from the text box on the right to the first link in the list.

Home > Services of PMDA > Drug and Medical Device Reviews > Regulations and Procedures > Ministerial Ordinances

### Services of PMDA

- Drug and Medical Device Reviews
  - ▶ Outline
  - ▶ Approved Products
    - ▶ List of Approved Products
    - ▶ Review Reports of New Drug
    - ▶ Applications
    - ▶ Package Inserts Database (in Japanese)
  - ▶ Regulations and Procedures
  - ▶ Points to Be Considered by the Review Staff Involved in the Evaluation Process of New Drug (PDF)
  - ▶ Record of Consultations on Pharmacogenomics/Biomarkers
- Post-marketing Safety
  - ▶ Outline
  - ▶ Safety Information
    - ▶ MHLW Pharmaceuticals and Medical Devices Safety Information
    - ▶ PMDA Medical Safety Information
    - ▶ PMDA Request for Proper Use of Drugs
    - ▶ Safety Information announced by MHLW
    - ▶ PMDA Risk Communications
  - ▶ Other Information (in Japanese)
  - ▶ MIHARI project
  - ▶ Regulations (in Japanese)

### Ministerial Ordinances

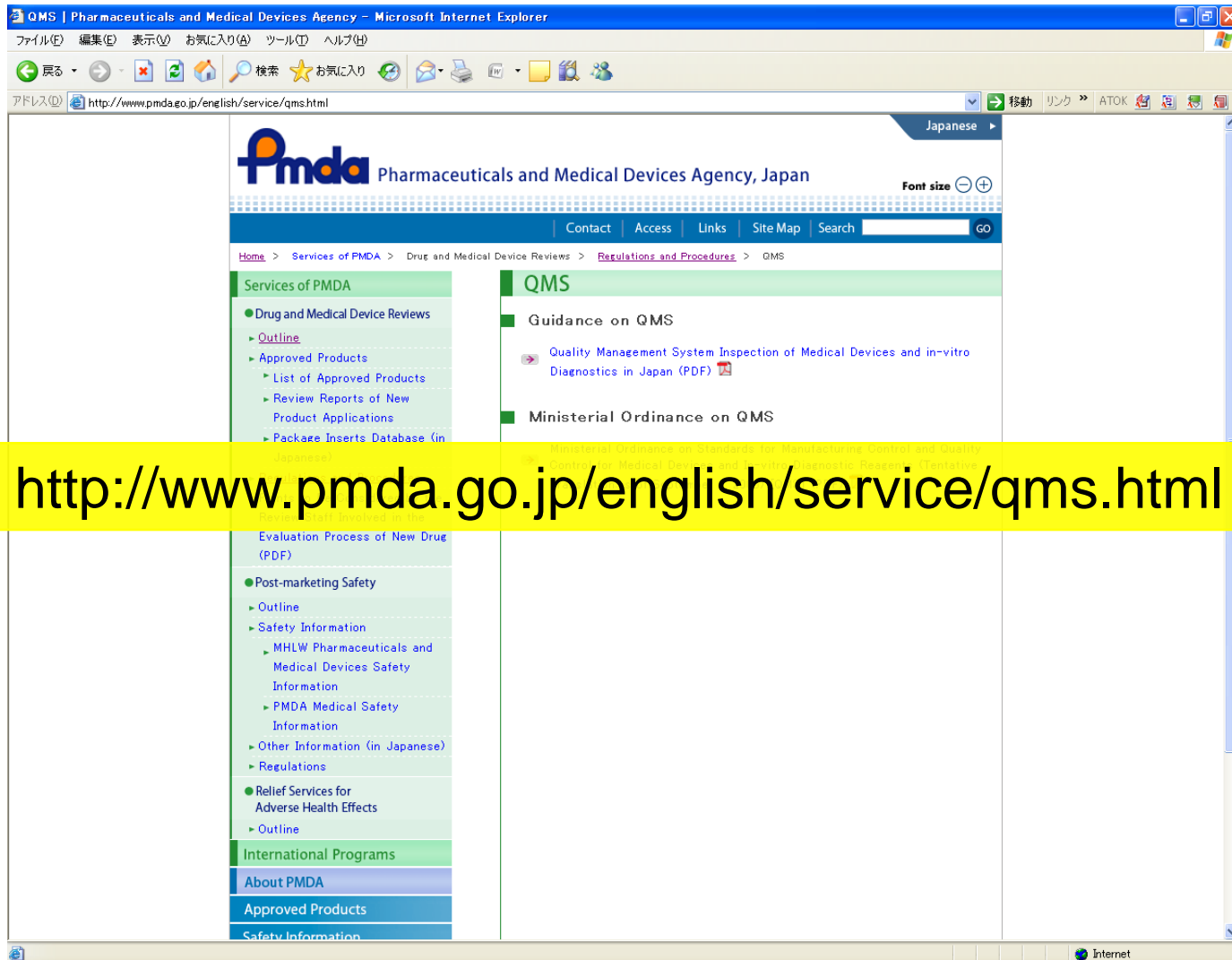
The following English translations of Japanese ministerial ordinances are intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese originals and the translations, the former shall prevail.

- ▶ Ministerial Ordinance on Good Clinical Practice for Drugs (PDF)
- ▶ Ministerial Ordinance on Good Clinical Practice for Medical Devices (PDF)
- ▶ Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices (Tentative Translation :as of September 9,2005) [GQP] (PDF)
- ▶ Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (Tentative Translation :as of September 9,2005) [GMP] (PDF)
- ▶ Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents (Tentative Translation :as of September 9,2005) [QMS] (PDF)
- ▶ Regulations for Buildings and Facilities of Pharmacies, etc. (Tentative Translation :as of September 9,2005) (PDF)

**Available PDF File:  
Ministerial  
Ordinance #169**

<http://www.pmda.go.jp/english/service/ministerial.html>

# More information about details of PMDA's QMS Inspection



The screenshot shows a Microsoft Internet Explorer browser window displaying the PMDA website. The address bar shows the URL: <http://www.pmda.go.jp/english/service/qms.html>. The website header includes the PMDA logo and the text "Pharmaceuticals and Medical Devices Agency, Japan". The main content area is titled "QMS" and contains the following sections:

- Guidance on QMS
  - Quality Management System Inspection of Medical Devices and in-vitro Diagnostics in Japan (PDF)
- Ministerial Ordinance on QMS

The left sidebar contains a navigation menu with the following items:

- Services of PMDA
  - Drug and Medical Device Reviews
    - Outline
    - Approved Products
      - List of Approved Products
    - Review Reports of New Product Applications
    - Package Inserts Database (in Japanese)
  - Evaluation Process of New Drug (PDF)
  - Post-marketing Safety
    - Outline
    - Safety Information
      - MHLW Pharmaceuticals and Medical Devices Safety Information
      - PMDA Medical Safety Information
      - Other Information (in Japanese)
    - Regulations
  - Relief Services for Adverse Health Effects
    - Outline
  - International Programs
  - About PMDA
  - Approved Products
  - Safety Information

<http://www.pmda.go.jp/english/service/qms.html>

**Thank you very much  
for your kind attention!!**

