Current Situation and Updates of QMS Inspection in Japan

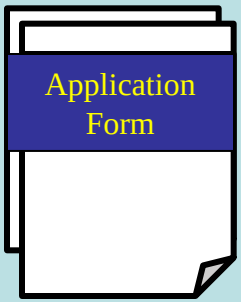
Office of GMP/QMS Inspection
Pharmaceuticals and
Medical Devices Agency

Pharmaceuticals and Medical Devices Agency

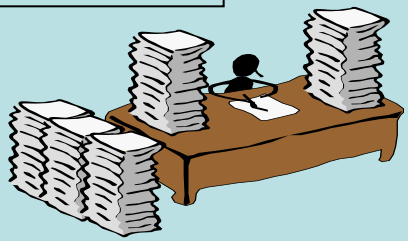
Framework of Approval Review and QMS Inspection on Medical Device

Pre-approval

Post-approval



Approval Application Form



Review Divisions

Partial Change Application

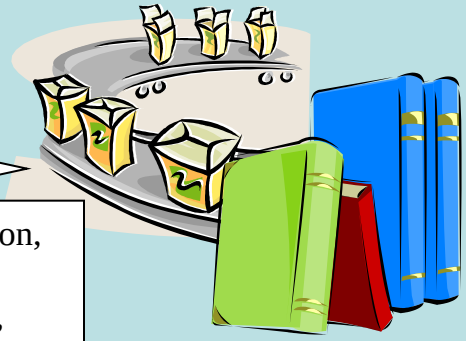
1) Review
2) QMS inspection

Minor Change Notification

1) Acceptance
2) Confirmation at regular inspection

Approval

Product realization,
Measurement,
Analysis of data,
Improvement



QMS inspection before approval

QMS inspection every 5 years after approval

Design transfer to manufacturing site

Actual production

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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	・New drugs ・Radioactive drugs	PMDA	PMDA
	Products without CS*	Prefectures	PMDA
	Products with CS*	Registered certification body	Registered certification body
Medical Devices	・New medical devices ・Cell / Tissue-based medical devices ・Class Ⅳ products	PMDA	PMDA
	Class Ⅲ and Class Ⅱ products (without CS*)	Prefectures	PMDA
	Class Ⅱ products (with CS*)	Registered certification body	Registered certification body

*CS : Certification Standards

Compliance Inspection by PMDA

Target Products	Target Sites
1. New medical devices* 2. Cell-tissue-based medical devices 3. Class IV medical devices 4. Radioactive IVDs	1. Manufacturing Sites 2. Sterilization Facilities 3. Storage Facilities 4. Testing Laboratories 5. Design and development institutes

* 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)

Facility A

Major manufacturer concerned with the product for marketing approval application ※※

1st application of QMS inspection (Product "a")

On-site inspection

a: PTCA Catheter

2nd application (Product "b")

Document review ※

b: Pacemaker

3rd application (Product "c")

Document review ※

c: Stent

4th application (Product "d")

On-site inspection

d: Defibrillator

2 years * (time after the 1st notification of QMS compliance result)

※ Document review is confined to the facility not having experienced Class-1 recalls and field corrections.

※※ Major manufacturer of the product : Facility A is supposed.

Manufacturing sites concerned with the product for marketing approval application (Example)

Assembling	Facility A	On-site inspection
	Facility A' (backup of Facility A)	Document review
Contract Sterilization	Facility B	Document review
Packaging, Labeling or Storage	Facility C	Document review
Packaging, Labeling or Storage (domestic)	Facility D	On-site inspection

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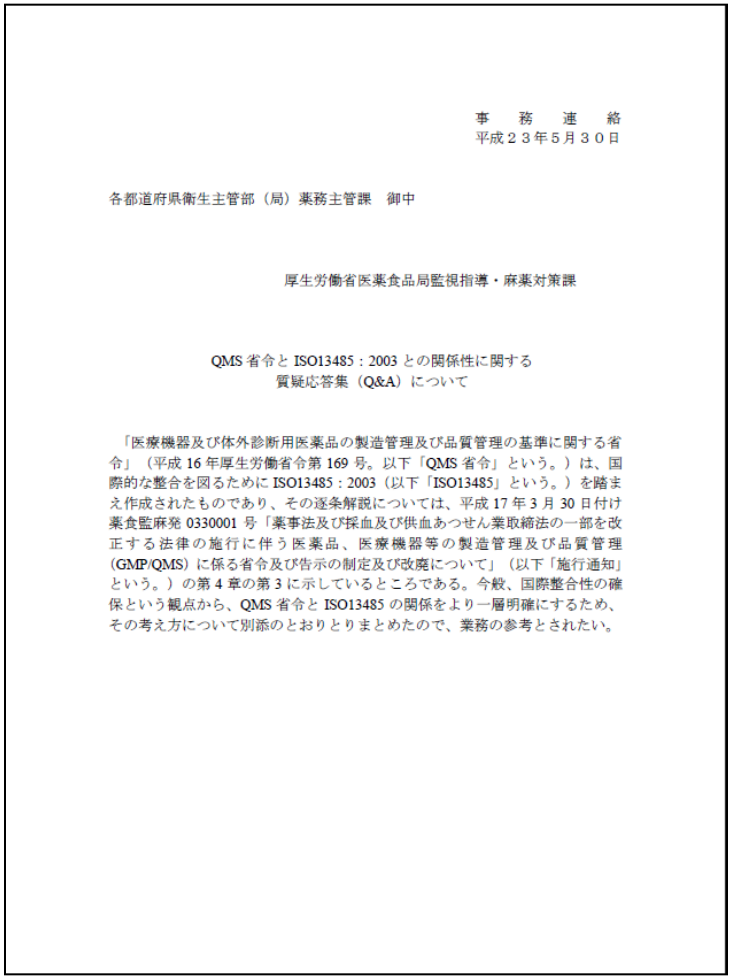
Relation between MHLW Ministerial Ordinance #169 and ISO13485:2003



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

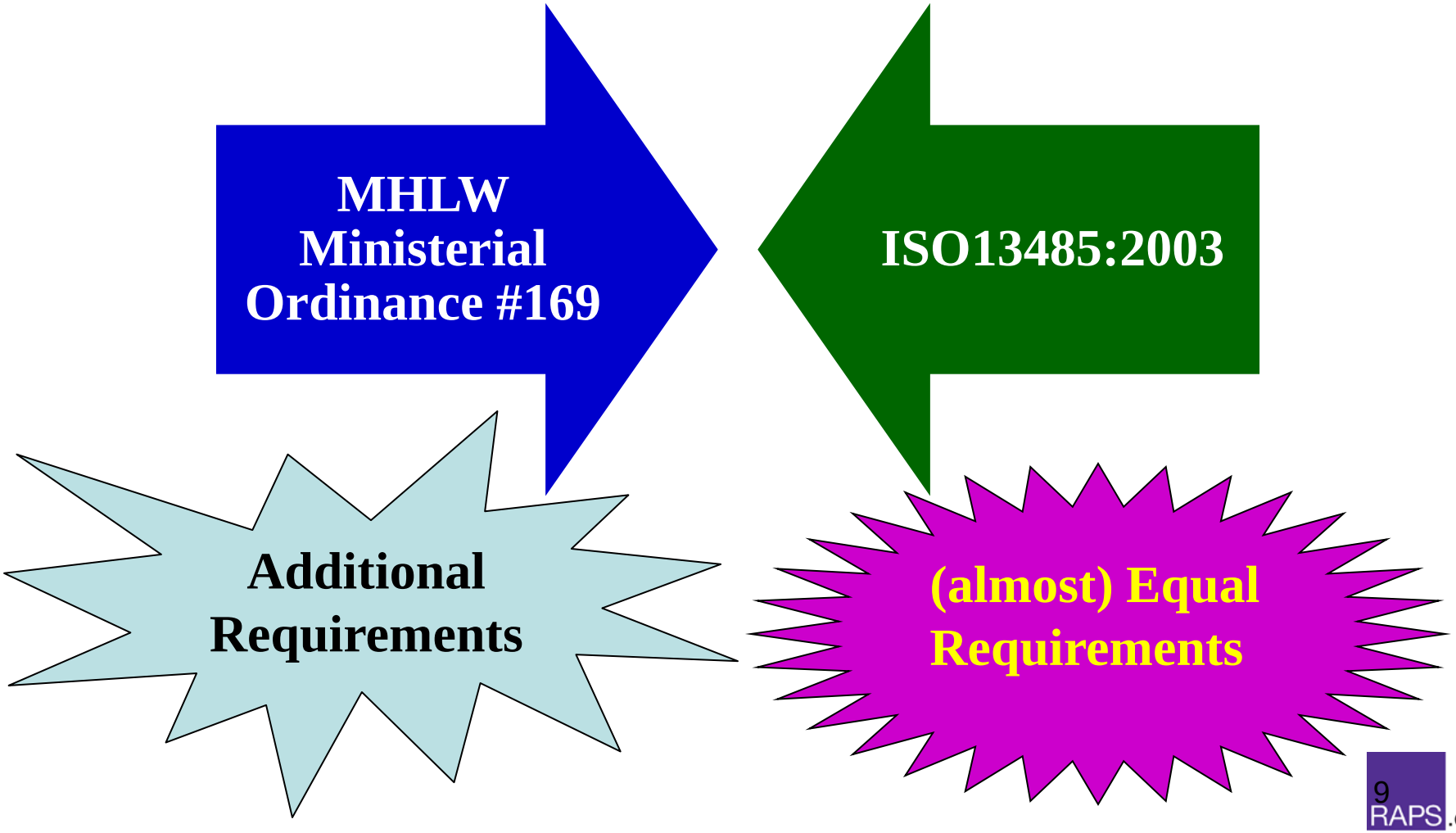
QMS 省令と ISO13485：2003 との関係性に関する
質疑応答集（Q&A）について

「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っ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



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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.)

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Relation between MHLW Ministerial Ordinance #169 and ISO13485:2003

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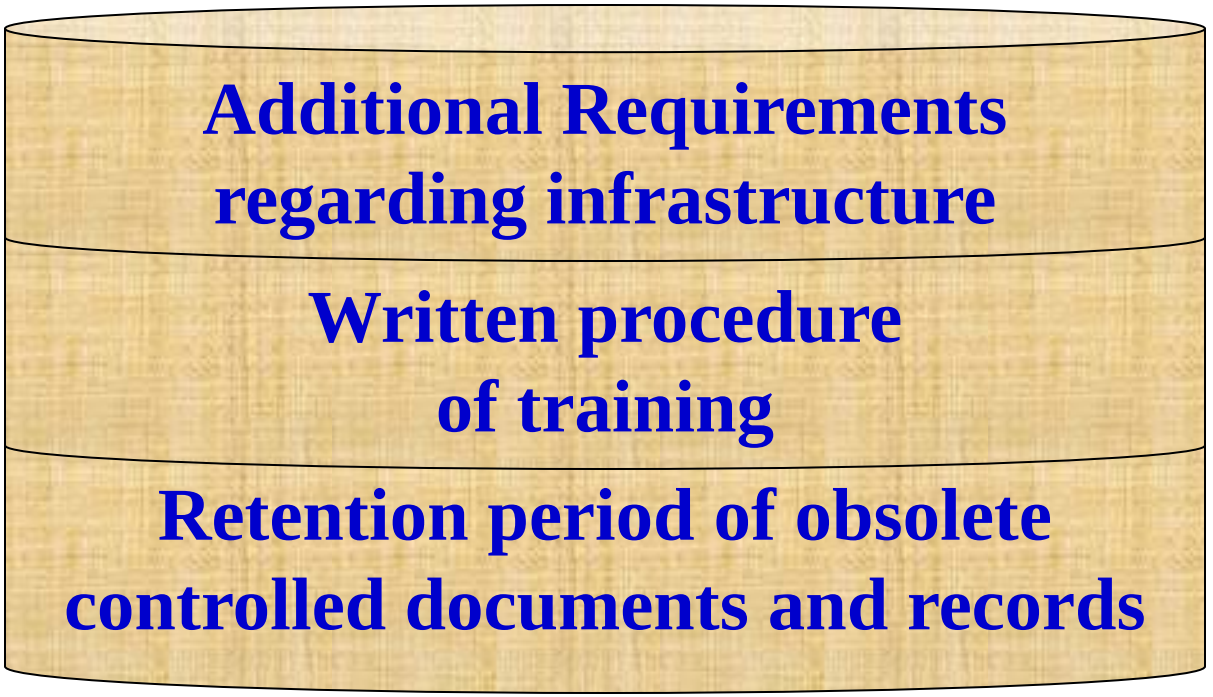
Additional Requirements

#169 Chapter 2
Additional Requirements



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Check!!
MHLW Ministerial Ordinance #169

Available PDF File: Ministerial Ordinance #169

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

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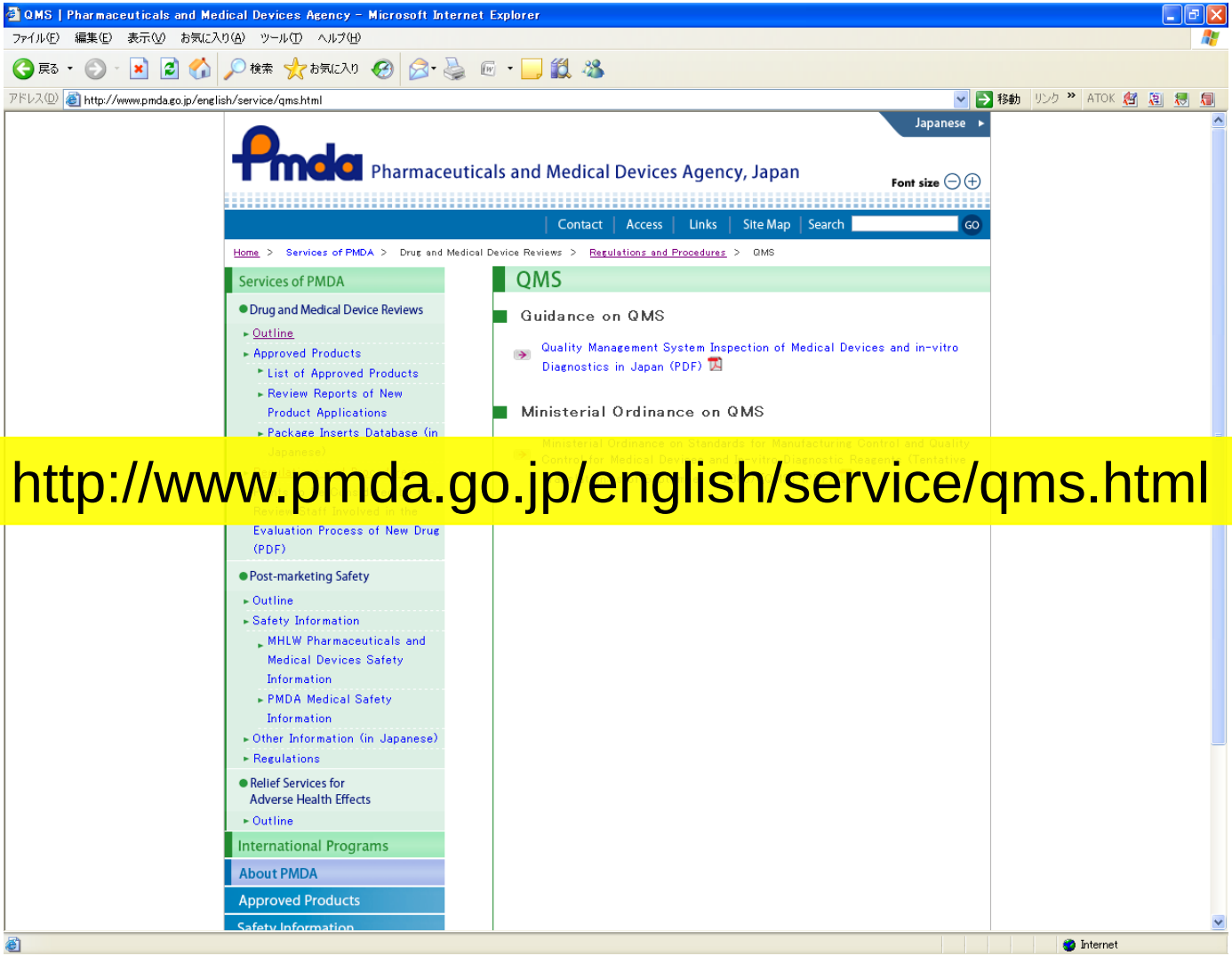
More information about details of PMDA's QMS Inspection



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

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Thank you very much for your kind attention!!

Pharmaceuticals and Medical Devices Agency

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