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

Pre-approval

- Application Form
- Review Divisions
- Product realization, Measurement, Analysis of data, Improvement
- Design transfer to manufacturing site

Approval

- Partial Change Application
  - 1) Review
  - 2) QMS inspection
- Minor Change Notification
  - 1) Acceptance
  - 2) Confirmation at regular inspection

Post-approval

- QMS inspection before approval
- QMS inspection every 5 years after approval

Actual production
Types of QMS Inspection

Compliance inspection

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

For-cause inspection
### Authority of GMP/QMS Inspection

<table>
<thead>
<tr>
<th>Site Location</th>
<th>Domestic</th>
<th>Foreign</th>
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</thead>
<tbody>
<tr>
<td>IVDs</td>
<td></td>
<td></td>
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<tr>
<td>· New drugs</td>
<td>PMDA</td>
<td>PMDA</td>
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<tr>
<td>· Radioactive drugs</td>
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<tr>
<td>Products without CS*</td>
<td>Prefectures</td>
<td>PMDA</td>
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<tr>
<td>Products with CS*</td>
<td>Registered certification body</td>
<td>Registered certification body</td>
</tr>
<tr>
<td>Medical Devices</td>
<td></td>
<td></td>
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<tr>
<td>· New medical devices</td>
<td>PMDA</td>
<td>PMDA</td>
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<tr>
<td>· Cell / Tissue-based</td>
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<tr>
<td>· medical devices</td>
<td>Prefectures</td>
<td>PMDA</td>
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<tr>
<td>· Class IV products</td>
<td>Registered certification body</td>
<td>Registered certification body</td>
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<tr>
<td>Class III and Class II</td>
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<tr>
<td>products (without CS*)</td>
<td>Prefectures</td>
<td>PMDA</td>
</tr>
<tr>
<td>Class II products</td>
<td>Registered certification body</td>
<td>Registered certification body</td>
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<tr>
<td>(with CS*)</td>
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*CS : Certification Standards*
New medical devices are, as a rule, limited to ones that have new principle or new functional characteristics.

<table>
<thead>
<tr>
<th>Target Products</th>
<th>Target Sites</th>
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<tbody>
<tr>
<td>1. New medical devices*</td>
<td>1. Manufacturing Sites</td>
</tr>
<tr>
<td>2. Cell-tissue-based medical devices</td>
<td>2. Sterilization Facilities</td>
</tr>
<tr>
<td>3. Class IV medical devices</td>
<td>3. Storage Facilities</td>
</tr>
<tr>
<td>4. Radioactive IVDs</td>
<td>4. Testing Laboratories</td>
</tr>
<tr>
<td></td>
<td>5. Design and development institutes</td>
</tr>
</tbody>
</table>
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)

1\textsuperscript{st} application of QMS inspection (Product “a”)
2\textsuperscript{nd} application (Product “b”)
3\textsuperscript{rd} application (Product “c”)
4\textsuperscript{th} application (Product “d”)

On-site inspection

Document review ※

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

2 years* (time after the 1\textsuperscript{st} notification of QMS compliance result)

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

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

Facility A

Assembling

Facility A’ (backup of Facility A)

Contract Sterilization

Facility B

Packaging, Labeling or Storage

Facility C

Packaging, Labeling or Storage (domestic)

Facility D

On-site inspection

On-site inspection

Document review

Document review

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

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 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

#169
Chapter 4
Requirements

Additional
Requirements

ISO13485:2003
Requirements

#169 Chapter 3
Requirements

Ministerial Ordinance #169

#169 Chapter 2 Requirements
Additional Requirements

#169 Chapter 2 Additional Requirements

- Written procedure of training
- Retention period of obsolete controlled documents and records
- Additional Requirements regarding infrastructure
Check!!

MHLW Ministerial Ordinance #169

Ministerial Ordinances

http://www.pmda.go.jp/english/service/ministerial.html
More information about details of PMDA’s QMS Inspection

http://www.pmda.go.jp/english/service/qms.html
Thank you very much for your kind attention!!