ISO 13485 and Japanese QMS Ordinance

2nd Korea-Japan Joint Symposium on Medical Product

Hideki Asai
Vice-chairman of ISO/TC210 Japanese National Committee
Agenda

1. ISO/TC210
   a) ISO/TC210 Structure and Activities
   b) ISO/TC210 Japanese National Committee
2. History of QMS standards
3. Structure of Present Japanese QMS Ordinance
4. Major difference between ISO 13485:2016 and Japanese QMS ordinance
5. ISO 13485:2016 certification in Japanese regulation
6. Future of Japanese QMS Ordinance
ISO/TC210

ISO/TC 210
"Quality management and corresponding general aspects for medical devices"

- Established in 1994
- Member
  - P member 38 countries (including KOREA and JAPAN)
  - O member 17 countries
WG 01  "Application of quality systems to medical devices"

WG 02  "General aspects stemming from the application of quality principles to medical devices"

WG 03  "Symbols and nomenclature for medical devices"

WG 06  "Application of post market surveillance systems to medical devices"

JWG 01  "Joint ISO/TC 210-IEC/SC 62A WG ; Application of risk management to medical devices"

JWG 02  "Joint ISO/TC 210-IEC/SC 62A WG ; Medical device software"

JWG 03  "Joint ISO/TC 210-IEC/SC 62A WG ; Medical device usability"

JWG 04  "Joint ISO/TC 210-IEC/SC 62D; Small bore connectors"

WG 05  "Connectors for reservoir delivery systems"

ISO 13485
History of QMS Standards

1959
US Military Standard
MIL-Q-9858

1979
BS 5750 Pt 1
BS 5750 Pt 2
BS 5750 Pt 3

1987
ISO 9001
ISO 9002
ISO 9003

1987
EN 29001
EN 29002
EN 29003

1994
ISO 9001
ISO 9002
ISO 9003

1993
EN 46001
EN 46002
EN 46003

1996
ISO 13485
ISO 13488

1997
USA QSR

2000
ISO 9001

2003
ISO 13485

2004 / 2014
Japanese QMS Ordinance

2008
ISO 9001

2015
ISO 9001

2016
ISO 13485

QMS for Medical Devices
TC210 Japanese National Committee

- Same Committee/WG Structure as TC210
  - TC210 Japanese National Committee
    - TC210/WG1 Japanese National Sub-Committee
    - TC210/WG2 Japanese National Sub-Committee

- Chairman: Dr. Tei (Prof of Tokyo Univ.)
- Secretary: JFMDA
- Members: Academia, Government (MHLW, PMDA), Industry (JFMDA)
Japanese QMS ordinance

- Present Japanese QMS ordinance is based on ISO 13485:2003 and have additional requirements.
- Design Control applies to class 2, 3, and 4
- QMS ordinance is also applied to class 1 device but no pre-market inspection.
- QMS ordinance is applied both MAH and manufacturing site.
# Structure of Japanese QMS Ordinance

<table>
<thead>
<tr>
<th>Chapter 1.</th>
<th>General Provisions (Article 1~3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 2.</td>
<td><strong>Medical Devices Manufacturing</strong> (Article 4~64)</td>
</tr>
<tr>
<td></td>
<td><strong>Identical to ISO13485:2003</strong></td>
</tr>
<tr>
<td>Chapter 3.</td>
<td><strong>Additional Requirements</strong> (Article 65~72-3)</td>
</tr>
<tr>
<td>Chapter 4.</td>
<td>Biological-origin Medical Device, etc. Manufacturers (Domestic, Foreign) (Article 73~79)</td>
</tr>
<tr>
<td>Chapter 5.</td>
<td>In-Vitro Diagnostic Radioactive Reagents Manufacturers (Domestic, Foreign) (Article 80~81)</td>
</tr>
<tr>
<td>Chapter 6.</td>
<td>Provisions Applied Mutatis Mutandis of Medical Device, etc. Manufacturing Sites, etc.(Article 82~84)</td>
</tr>
</tbody>
</table>
## Chapter 2 of Japanese QMS ordinance

<table>
<thead>
<tr>
<th>Section</th>
<th>QMS Ordinance (Chapter 2)</th>
<th>ISO 13485:2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1</td>
<td>General Requirements (Article 4)</td>
<td>1. Scope</td>
</tr>
<tr>
<td>Section 2</td>
<td>Quality Management System (Article 5 to Article 9)</td>
<td>4. Quality management system</td>
</tr>
<tr>
<td>Section 3</td>
<td>Management responsibility (Article 10 to Article 20)</td>
<td>5. Management Responsibility</td>
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<tr>
<td>Section 4</td>
<td>Resource Management (Article 21 to Article 25)</td>
<td>6. Resource management</td>
</tr>
<tr>
<td>Section 5</td>
<td>Product Realization (Article 26 to Article 53)</td>
<td>7. Product realization</td>
</tr>
<tr>
<td>Section 6</td>
<td>Measurement, Analysis and Improvement (Article 54 to Article 64)</td>
<td>8. Measurement, analysis and improvement</td>
</tr>
</tbody>
</table>
ISO 13485:2016

• Purpose of the change
  – To reflect changes in regulatory requirements and expectations, current practices employed by medical device providers (e.g., manufacturers, distributors, and service providers) to ensure safe and effective medical devices that meet customer requirements.
  – To reflect changes to the ISO 9001:2008 standard on which this Standard is based.
Structure of New revision of ISO 13485

- New Revision of ISO 13485 is not followed Annex SL of ISO Directive because of this is not match Regulatory Purpose.
- Basic structure is identical to ISO 13485:2003.
- Correlation Matrix of ISO 9001:2015 and ISO 13485:2016 are described in Annex B.
- No. of Sub clause changed for MDSAP grading issue. (7.5.1 – 7.5.11)
Contents of ISO 13485:2016

Foreword
Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Quality management system
5. Management Responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement
Bibliography
4.1 General requirements

4.1.2 (QMS Processes)

<Risk based thinking>

• The organization shall:
  a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;

  b) apply a risk based approach to the control of the appropriate processes needed for the quality management system;

  c) determine the sequence and interaction of these processes.
4.1 General requirements

4.1.6
New Requirement (Expanded)
(Validation of the application of QMS software)

• The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.
• The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.
• Records of such activities shall be maintained (see 4.2.5).
4.2.3 Medical Device File

New requirement

= “SEIHIN HYOJUNSYO” in Japanese QMS ordinance

(concept is already in 2003 version /New sub-clause)

• For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

• The content of the file(s) shall include, but is not limited to:
  a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
  b) specifications for product;
  c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
  d) procedures for measuring and monitoring;
  e) as appropriate, requirements for installation;
  f) as appropriate, procedures for servicing.
Major difference between ISO 13485:2016 and QMS ordinance

7.3 Design and development
  7.3.1 General
  7.3.2 Design and development planning
  7.3.3 Design and development inputs
  7.3.4 Design and development outputs
  7.3.5 Design and development review
  7.3.6 Design and development verification
  7.3.7 Design and development validation
  7.3.8 Design and development transfer (New Sub-clause)
  7.3.9 Control of design and development changes
  7.3.10 Design and development files (New Sub-clause)
7.5.8 Identification

Added requirement for unique device identification (UDI).

- The organization shall document procedures for product identification and identify product by suitable means throughout product realization.
- The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.
- **If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.**
- The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.
8 Measurement, analysis and improvement

8.1 General.
8.2 Monitoring and measurement
  8.2.1 Feedback
  8.2.2 Complaint handling (New Sub-clause)
  8.2.3 Reporting to regulatory authorities (New Sub-clause)
  8.2.4 Internal audit
  8.2.5 Monitoring and measurement of processes
  8.2.6 Monitoring and measurement of product

8.3 Control of nonconforming product (re-arranged)
  8.3.1 General
  8.3.2 Actions in response to nonconforming product detected before delivery
  8.3.3 Actions in response to nonconforming product detected after delivery
  8.3.4 Rework

8.4 Analysis of data
8.5 Improvement
  8.5.1 General
  8.5.2 Corrective action
  8.5.3 Preventive action

Major difference between ISO 13485:2016 and QMS ordinance
ISO 13485:2016 certification in Present Japanese Regulation

• Compliance to ISO 13485:2016 is considered to comply to the Chapter 2 of Japanese QMS Ordinance. (Administrative Circular 2016/July)
Future of Japanese QMS ordinance

- JIS Q 13485:201X(=ISO 13485:2016) will be issued soon.
- Health Labor Science Research Study Group for Medical Device QMS （Chair: Dr Sakurai/PMDA）
  - Recommend to introduce ISO 13485:2016 to Japanese QMS ordinance to MHLW.
- It is expected that Japanese QMS ordinance will harmonize with ISO 13485:2016 / Global QMS standard soon.

- The draft version of this Handbook circulated for CIB and passed CIB (positive 28, negative 1)
- Handbook Writing Team is working to resolve the comment for draft version now.

- This handbook draft will issue for final 1 month ballot soon and final version will be published in June 2017.

- ISO/TC210/WG1 Japanese National sub-committee will translate this handbook to Japanese and issue it soon after the final version is published.
Questions?

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Quality Management System (QMS) for Medical Devices in Korea

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Korea Ministry of Food and Drug Safety
Jangyong Choi
Deputy Director of Medical Device Safety Evaluation Division in Korea MFDS

• Medical device policy, medical device inspection & QMS
• AHWP WG member
Quality Management System (QMS)

Table of Contents

I. Status of Korea Medical Device Industry

II. Organization and Regulations for medical device QMS

III. History and Regulation in detail of Korea QMS

IV. Future Plan
I. Status of Korea Medical Device Industry

※ Ref: Espicom. The World Medical Markets Fact Book 5, Forecasts to 2018
   Unit: US Million Dollars

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>2013 Market scale (Mn)</th>
<th>2014 Market scale (Mn)</th>
<th>2015 Market scale (Mn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>127,159</td>
<td>133,593</td>
<td>140,143</td>
</tr>
<tr>
<td>2</td>
<td>Japan</td>
<td>28,208</td>
<td>28,100</td>
<td>26,012</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>25,554</td>
<td>26,256</td>
<td>22,667</td>
</tr>
<tr>
<td>4</td>
<td>China</td>
<td>16,075</td>
<td>17,207</td>
<td>17,773</td>
</tr>
<tr>
<td>11</td>
<td>Korea</td>
<td>5,083</td>
<td>5,441</td>
<td><strong>5,503</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ranking it 9th in global market</td>
</tr>
</tbody>
</table>
I. Status of Korea Medical Device Industry

About 5,800 medical device manufacturers & importers in 2016

Number of medical device business entities

<table>
<thead>
<tr>
<th>Year</th>
<th>Manufacturer</th>
<th>Importer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>2,168</td>
<td>1,626</td>
<td>3,794</td>
</tr>
<tr>
<td>2011</td>
<td>2,245</td>
<td>1,662</td>
<td>3,907</td>
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<tr>
<td>2012</td>
<td>2,550</td>
<td>1,898</td>
<td>4,448</td>
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<tr>
<td>2013</td>
<td>2,711</td>
<td>2,027</td>
<td>4,738</td>
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<tr>
<td>2014</td>
<td>2,993</td>
<td>2,239</td>
<td>5,232</td>
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<tr>
<td>2015</td>
<td>3,272</td>
<td>2,365</td>
<td>5,637</td>
</tr>
<tr>
<td>2016.6</td>
<td>3,406</td>
<td>2,459</td>
<td>5,865</td>
</tr>
</tbody>
</table>
I. Status of Korea Medical Device Industry

Statistic Result on KQMS Audit

- Manufacturer
- Importer
- Total

<table>
<thead>
<tr>
<th>Year</th>
<th>Manufacturer</th>
<th>Importer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>2,979</td>
<td>1,202</td>
<td>4,181</td>
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<tr>
<td>2008</td>
<td>1,530</td>
<td>500</td>
<td>2,030</td>
</tr>
<tr>
<td>2009</td>
<td>2,770</td>
<td>1,908</td>
<td>4,678</td>
</tr>
<tr>
<td>2010</td>
<td>1,908</td>
<td>1,885</td>
<td>3,793</td>
</tr>
<tr>
<td>2011</td>
<td>1,885</td>
<td>1,885</td>
<td>3,770</td>
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<tr>
<td>2012</td>
<td>2,372</td>
<td>1,762</td>
<td>4,134</td>
</tr>
<tr>
<td>2013</td>
<td>1,762</td>
<td>2,403</td>
<td>4,165</td>
</tr>
<tr>
<td>2014</td>
<td>1,762</td>
<td>2,403</td>
<td>4,165</td>
</tr>
<tr>
<td>2015</td>
<td>1,762</td>
<td>2,403</td>
<td>4,165</td>
</tr>
</tbody>
</table>
II. Organization and Regulations for medical device QMS
- Changed responsibility of MFDS & KFDA -

- Clinical Trials - Approval, Manufacturing - Distribution - Patient (Consumer)

- MFDS
  Make regulations and policies as a control tower of medical device safety management

- (MoH)
  To establish policies and draft laws regarding medical device safety management

- (KFDA)
  GCP - QMS - GSP - Post-market surveillance

Before 2013:
Only responsible for legal enforcement and management related to medical devices

2013:
Combination of policy and enforcement
II. Organization and Regulations for medical device QMS
- Organizational Chart for QMS Control of MD in Korea MFDS –

Medical device Safety Evaluation Division
(QMS Control tower_MFDS, 2)

Third-party Organization (40)
- Korea Testing Laboratory (KTL, 9)
- Korea Testing & Research Institute (KTR, 13)
- Korea Testing Certification (KTC, 11)
- Korea Conformity Laboratory (KCL, 7)

Cooperation Group (MFDS, 40)

Six Regional Branch Offices (15)
(Medical Product Safety Division)

NIFDS (25)
(National Institute of Food & Drug Safety Evaluation)

High-tech medical devices division
- Cardiovascular devices division
- Orthopedic & Restorative devices division
- Dental & Gastroenterology devices division
- In vitro diagnostic device division
II. Organization and Regulations for medical device QMS

- Medical Device Regulations at Four Hierarchical Orders -

- Medical Device Act (MDA)
- Enforcement Regulations of MDA
- Implementing Regulations of MDA
- MFDS Notifications of MDA
  - QMS Notification for medical device is also included
III. History and Regulation of Korea QMS

1. **04.05.30**: First Introduced the MD QMS regulation
2. **07.05.31**: QMS audits including S/W validation and risk management were set to be mandatory
3. **12.04.08**: QMS audits have been conducted on oversea manufacturing companies
4. **13.09.16**: Class 1 medical device were exempted from QMS audits
5. **16.01.28**: QMS conformity assessment before medical device approval
III. History and Regulation of Korea QMS

- Korea QMS regulation in details -

🔹 **Applied standard** : The standard for Korea QMS conformity assurance audit, equivalent to **ISO 13485 : 2003**.

🔹 **Target** :
  ① A person who is going to manufacture or import medical devices (including overseas manufacturer company) => Initial audits
  ② Periodic audits every 3 years on manufactures where initial audits were conducted

🔹 **Audit types** :
  ① Initial audit : An initial audit to approve QMS conformity assurance
  ② Periodic audit : After the initial audit, at least one audit will be conducted in 3 years
  ③ Audit of approval changes : Audits to be conducted again if manufacturers notify changes of manufacturing sites.
  ④ Supplementary audit : Audits to be conducted if a product is added from a different product group.
III. History and Regulation of Korea QMS
- Korea QMS regulation in details -

- Audit method: Conducting on-site audits and document review for each product groups of manufacturing company
  ※ Product group: Products whose raw materials, manufacturing process and quality management system are similar to those of which have been classified into 26 group

- Certification period: 3 years (QMS conformity certification should be renewed)

- Miscellaneous information:
  ① Low-risk class 1 medical devices excluded
  ② 6 regional offices and 4 medical device quality evaluation institutions are jointly conducting on-site audit and document review
### III. History and Regulation of Korea QMS

*<The list of 26 product groups for Korea QMS conformity assurance>*

<table>
<thead>
<tr>
<th>No.</th>
<th>Product Groups of Medical Devices</th>
<th>No.</th>
<th>Product Groups of Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General Equipment for Treatment</td>
<td>14</td>
<td>Syringes and Needles</td>
</tr>
<tr>
<td>2</td>
<td>Surgical Devices</td>
<td>15</td>
<td>Instruments for Dental Treatment</td>
</tr>
<tr>
<td>3</td>
<td>Medical Chambers</td>
<td>16</td>
<td>Sight Corrective Ophthalmic Lens</td>
</tr>
<tr>
<td>4</td>
<td>Life-support System</td>
<td>17</td>
<td>Hearing Aid</td>
</tr>
<tr>
<td>5</td>
<td>Artificial Internal Organ</td>
<td>18</td>
<td>Medicinal Substance-Producing Equipment</td>
</tr>
<tr>
<td>6</td>
<td>Diagnostic Devices</td>
<td>19</td>
<td>Implantable Medical Supplies</td>
</tr>
<tr>
<td>7</td>
<td>Medical Stimulating Instruments</td>
<td>20</td>
<td>Human Tissue and Organ Substitute</td>
</tr>
<tr>
<td>8</td>
<td>Surgical Instruments</td>
<td>21</td>
<td>In Vitro Medical Supplies</td>
</tr>
<tr>
<td>9</td>
<td>Patient Transport</td>
<td>22</td>
<td>Contraceptive Device</td>
</tr>
<tr>
<td>10</td>
<td>Physiological Measuring Instruments</td>
<td>23</td>
<td>Dental Alloy</td>
</tr>
<tr>
<td>11</td>
<td>In Vitro Diagnostics</td>
<td>24</td>
<td>Materials for Dental Treatment</td>
</tr>
<tr>
<td>12</td>
<td>Speculums for Medical Use</td>
<td>25</td>
<td>Analyzing Products for In Vitro Diagnosis</td>
</tr>
<tr>
<td>13</td>
<td>Instruments for Medical Treatment</td>
<td>26</td>
<td>U-Healthcare Medical Device</td>
</tr>
</tbody>
</table>

2,200 Product items classified Re-categorized 26 Product groups
### III. History and Regulation of Korea QMS

*Class I medical devices are not required to have a QMS conformity assessment.*

<table>
<thead>
<tr>
<th>Manufacturer or Importer of M.D</th>
<th>Classification</th>
<th>Initial Audit</th>
<th>Supplementary audit</th>
<th>Audit of approval change</th>
<th>Periodic Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II</td>
<td></td>
<td></td>
<td></td>
<td>3rd party organizations</td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td></td>
<td></td>
<td></td>
<td>MFDS + 3rd party organizations</td>
<td></td>
</tr>
<tr>
<td>Class IV</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
III. Medical Device QMS audit process

1. Application of KQMS audit

2. Receipt of application

3. Pre-review

4. Confirmation of third-party auditor and audit date

5. Notifying to MFDS auditor about audit schedule

6. Notice for schedule of KQMS audit

7. Preparation of KQMS audit

8. Audit

9. MFDS review

10. Issuing KQMS certification

10. Correction request for indicated deficiency

10. Notice to applicant for prohibition of distribution

- Conformity
- Minor-Nonconformity (correction)
- Major-Nonconformity (incorrection)
List of Published Guidelines for QMS

MFDS Guidelines describes specific requirements for QMS audits.

<table>
<thead>
<tr>
<th>No.</th>
<th>The Title of Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Guidelines for <strong>Software Validation</strong> of Medical Devices</td>
</tr>
<tr>
<td>2</td>
<td>Guidelines for <strong>Sterilization Validation</strong> of Medical Devices</td>
</tr>
<tr>
<td>3</td>
<td>Guidelines for <strong>Risk Management</strong> of Medical Devices</td>
</tr>
<tr>
<td>4</td>
<td>Handbook for QMS audit of Medical Devices</td>
</tr>
<tr>
<td>5</td>
<td>Guidelines for Installation Medical Devices</td>
</tr>
<tr>
<td>6</td>
<td>Guidelines for Packaging Process Validation of Medical Devices</td>
</tr>
<tr>
<td>7</td>
<td>Guidelines for Design Control of Medical Devices</td>
</tr>
<tr>
<td>8</td>
<td>Guidelines for Washing Process Validation of Medical Devices</td>
</tr>
<tr>
<td>9</td>
<td>Guidelines for Cleanliness Control of Medical Devices</td>
</tr>
<tr>
<td>10</td>
<td>Guidelines for Corrective action and Preventive action of Medical Devices</td>
</tr>
<tr>
<td>11</td>
<td>Guidelines for Raw Material Purchasing and Outsourcing Process Quality Control of Medical Devices</td>
</tr>
</tbody>
</table>

etc.
IV. Future Plan

- MFDS promotes to apply new ISO 13485, which was revised in March, 2016 to Korea QMS for medical devices.
- To promote harmonization and communication with global partners
  - MFDS is going to publish an English version of “Standard of Medical Device Manufacturing and Quality Management (MFDS QMS Notification)” in early 2017
    ※ Requirement for QMS audits and audit methods & process will be described in this Standard.
- To harmonize and improve professionalism in QMS audit
  - “Class 2 medical device” is going to be fully outsourced to third parties for QMS audit
Thank you.

Jang yong Choi
E-mail: navante1@korea.kr
Japanese QMS system/
Overview of MDSAP

Office of Manufacturing/Quality and Compliance
Division of Medical Devices
Pharmaceuticals and Medical Devices Agency
Junichi Ohishi, Ph.D.
Manufacturing/Quality and Compliance

Division of Medical Devices (QMS)

Division of Pharmaceuticals (GMP)

Division of Registered Certification Body Supervision

Division of Administration
1. QMS Inspection
Outline of QMS Inspection

Marketing Authorization Holder (MAH) → QMS Application → PMDA → MAH and Manufacturing Sites → Inspection (On-site or Desktop) → Report → MHLW Minister
Types of QMS Inspection

1. Pre-Marketing Approval Inspection
   Required before the marketing approval.

2. Pre-partial Change Approval Inspection
   Required before the partial change approval.

3. Periodic Post-approval Inspection
   Required for maintaining marketing approval every 5 years since the initial marketing approval.

4. Additional Inspection
   Required for the notified cases. ex) biological products, micro machine and medical devices utilizing nano-materials etc.
Pre-Marketing Approval Inspection

Periodic Post-approval Inspection

- Application for Marketing Approval
- Regulatory Review
- Pre-approval Inspection

- Marketing Approval
- Post-approval Inspection

- Marketing

- 5 years
- 5 years
- 5 years

- Inspection scope: MAH and all the manufacturing sites.

- If the product is applicable to notified cases, the additional inspection is simultaneously conducted.
Pre-partial Change Approval Inspection

- Pre-partial Change Approval Inspection
- Post-approval Inspection

Marketing Approval

Pre-partial change Application

Pre-partial change Approval

Every 5 years

- Inspection scope: MAH and the change-related sites.

ex) Main assembling site

Change
## QMS Inspection Authority

<table>
<thead>
<tr>
<th>Product</th>
<th>Inspection Authority</th>
</tr>
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<tbody>
<tr>
<td>Medical Devices</td>
<td></td>
</tr>
<tr>
<td>• Class IV</td>
<td>PMDA</td>
</tr>
<tr>
<td>• Class III and Class II <strong>without CS</strong></td>
<td>PMDA</td>
</tr>
<tr>
<td>• Class III and Class II <strong>with CS</strong></td>
<td>Registered certification body</td>
</tr>
<tr>
<td>IVDs</td>
<td></td>
</tr>
<tr>
<td>• Products <strong>without CS</strong></td>
<td>PMDA</td>
</tr>
<tr>
<td>• Products <strong>with CS</strong></td>
<td>Registered certification body</td>
</tr>
</tbody>
</table>

*CS : Certification Standards*
### Manufacturing Site Registration

<table>
<thead>
<tr>
<th>Manufacturing Site</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design Facility</strong></td>
<td>(1) maintains records of design and development, and</td>
</tr>
<tr>
<td></td>
<td>(2) the responsible person should work here.</td>
</tr>
<tr>
<td><strong>Main Assembly Plant</strong></td>
<td>(1) is mainly responsible for QMS or product realization, and</td>
</tr>
<tr>
<td></td>
<td>(2) implement assembling (filling) processes.</td>
</tr>
<tr>
<td><strong>Sterilizer</strong></td>
<td>(1) implement sterilization process.</td>
</tr>
<tr>
<td><strong>Domestic (Japan) Distribution Center</strong></td>
<td>(1) store and release the products into Japanese market.</td>
</tr>
</tbody>
</table>
Example of Mfg. Site Registration

Outside of Japan

- Design
- Supplier
- Sub-Assembly
- Main Assembly
- Packing
- Sterilize
- Distribution

In Japan

- Distribution

Registration

- Required
- Not Required
- Not Required
- Required
- Not Required
- Required
## Scope of QMS Inspection

<table>
<thead>
<tr>
<th>Facility</th>
<th>QMS Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAH</td>
<td>Required</td>
</tr>
<tr>
<td>Design Facility</td>
<td>Required</td>
</tr>
<tr>
<td>Main Assembly Plant</td>
<td>Required</td>
</tr>
<tr>
<td>Sterilizer</td>
<td>Required</td>
</tr>
<tr>
<td>Domestic (Japan)</td>
<td>Required</td>
</tr>
<tr>
<td>Distribution Center</td>
<td>Required</td>
</tr>
<tr>
<td>Other sites</td>
<td>Depends</td>
</tr>
</tbody>
</table>

*PMDA determines based on risk assessment*
QMS Application

MAH

- Manufacturing Site (Design Facility)
- Manufacturing Site (Main Assembly Plant)
- Manufacturing Site (Sterilizer)
- Manufacturing Site (Domestic Distribution Center)
Product Families

Generic names of Medical Devices and IVDs are grouped into “Product Families” depending on factors such as characteristics, usage method, risk etc. QMS inspection is conducted per “Product Family”.

<table>
<thead>
<tr>
<th>Stent</th>
<th>Catheter</th>
<th>Non-active instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary stent</td>
<td>Cardiovascular catheter</td>
<td>Single-use surgical knife</td>
</tr>
<tr>
<td>Carotid stent</td>
<td>Pulmonary artery catheter</td>
<td>Esophageal tube</td>
</tr>
<tr>
<td>Drug-eluting stents for femoral artery</td>
<td>Cerebrospinal catheter</td>
<td>Filter for pulmonary functional testing</td>
</tr>
</tbody>
</table>

The relationship between product family and generic name is announced by notification.
QMS Inspection Flow

1. Receive application of QMS inspection
2. Determine on-site or desktop inspection
3. On-site Inspection
   - MAH*
   - Mfg. site A* (Main Assembly)
4. Desktop Inspection
   - Mfg. site B* (Design)
   - Mfg. site C* (Distribution)
5. Conformity assessment
6. Issue compliance certification and inspection report

* example

6 months
# Documents of QMS Inspection

<table>
<thead>
<tr>
<th>No.</th>
<th>Documents</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-1-3</td>
<td>ISO13485 Certification, registered certification body’s Inspection report, etc</td>
<td>Mfg. sites</td>
</tr>
<tr>
<td>1-1-4</td>
<td>Manufacturing process flow</td>
<td>Product</td>
</tr>
<tr>
<td>1-1-5</td>
<td>Mutual relations of QMS between MAH and mfg. sites.</td>
<td>Mfg. sites</td>
</tr>
<tr>
<td>1-2-1</td>
<td>Outline of mfg. site (Number of employees, address, products, etc)</td>
<td>Mfg. sites</td>
</tr>
<tr>
<td>1-2-2</td>
<td>Product list for application</td>
<td>Product family</td>
</tr>
</tbody>
</table>
## Example of MAH On-site Inspection Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>9:30-12:00</td>
<td>1. Opening Meeting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1) Introduction of Inspection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) Overview of Company and Products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. <strong>Management</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>QMS organization, Quality Manual, Quality Policy and Objectives,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Management Review, Internal Audit, Training etc.</td>
</tr>
<tr>
<td></td>
<td>13:00-17:30</td>
<td>3. <strong>Marketing Authorization Holder (MAH)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. <strong>Documentation and Records</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. <strong>Product Documentation</strong> (including Risk Management)</td>
</tr>
<tr>
<td>Day 2</td>
<td>9:30-12:00</td>
<td>6. <strong>Design and Development</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. <strong>Product and Process controls</strong></td>
</tr>
<tr>
<td></td>
<td>13:00-17:30</td>
<td>8. <strong>Purchasing Control</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9. <strong>Customer Related Processes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10. <strong>Corrective and Preventive Actions (CAPA)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11. Team Meeting of Inspectors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12. Confirmation on Findings and Closing Meeting</td>
</tr>
</tbody>
</table>
## Example of Documents for Desktop Inspection

<table>
<thead>
<tr>
<th>No</th>
<th>Documents</th>
<th>Outline of Documents</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-1-1</td>
<td>Layout of all mfg. site building</td>
<td>• Bird’s eye-view photograph or location map of mfg. site</td>
<td>Mfg. sites</td>
</tr>
</tbody>
</table>
| 2-1-2| Floor plan                                        | • Clean room grade  
        • Differential pressure  
        • List or layout of representative manufacturing and test equipment                                      | Mfg. sites  |
| 2-2-1| Organization chart                                | • Responsible persons and departments under QMS                                                                | Mfg. sites  |
| 2-2-2| Quality management system                         | • Quality Manual                                                                                                | Mfg. sites  |
| 2-2-3| List of documents identified with QMS             | • Including name, number, and retention period of QMS documents                                               | Mfg. sites  |
| 2-3-1| Seihin Hyojun Sho                                 | • The document of Seihin Hyojun Sho is all the related documents to the product under QMS.                    | Product     |
| 2-3-3| Validation states of mfg. process                 | • List showing plan about the mfg. process validation.                                                         | Product     |
Timeline after QMS Inspection

Nonconformity is graded from 1 to 6.

**Rank 1 to 3**

- Inspection
- Nonconformity Report within 14 days
- Compliance Cert. & Audit Report about 30 days
- Improvement Report (or Plan*) within 14 days
- Confirmation of the effectiveness

*in case of Rank 1

**Rank 4 to 6**

- Inspection
- Nonconformity Report within 14 days
- Compliance Cert. & Audit Report within 15 days
- Improvement Report
- Confirmation of the effectiveness

Next Inspection

*in case of Rank 4 to 6
QMS Compliance Certification

基準適合証

| 調査を行った品目 | 一般的名称 | | | | | | |
| | | | | | | | |
| 販売名 | | | | | | |
| 承認番号 | | | | | | |

申請者の住所
申請者の氏名

医薬品医療機器等法第23条の2の6第1項の規定により、上記の
に係る同項各号に規定するが、同法第23条の2の5第2項第4号に規定する基準に適合していることを証明する。

年 月 日

独立行政法人医薬品医療機器総合機構理事長 印

有効期間 年 月 日から
年 月 日まで
QMS Compliance Certification

<Certification No.>

QMS Compliance Certification

<MAH name>
<MAH address>

<table>
<thead>
<tr>
<th>Generic Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td></td>
</tr>
<tr>
<td>Marketing Approval Number</td>
<td></td>
</tr>
<tr>
<td>Product Family</td>
<td></td>
</tr>
<tr>
<td>Registered Manufacturing Site (Name, Address, Registered No., Manufacturing Process)</td>
<td></td>
</tr>
</tbody>
</table>

We certify that the manufacturing control and quality control of the above product conforms to the QMS ordinance.

<Issue Date>

Chief Executive,
Pharmaceuticals and Medical Devices Agency

<Term of validity>
Typical Nonconformity

From Nov 1st 2015 to Mar 31st 2016
Researched by Health Labor Sciences Research, Japan
Example of Nonconformity

Japanese QMS Ordinance, Article 65 and 84
(Verification of QMS of Registered Manufacturing Site)

Marketing authorization holder should perform the verification that the manufacturer performs the manufacturing control and quality control based on the Japanese QMS ordinance.

Failure to implement the verification.
Verification of QMS of Registered Manufacturing Site (Article 65)
2. Participation in MDSAP
Japan’s participation in Medical Device Single Audit Program (MDSAP)

• MDSAP is an international initiative to implement a program where auditing organizations can conduct a single audit of a manufacturer of medical devices across the different regulations.

• Japan announced its participation in MDSAP Pilot in June 2015. Australian TGA, Brazilian ANVISA, Health Canada, US FDA and Japanese MHLW have been running MDSAP.
Trial acceptance of MDSAP Audit Reports

- PMDA accepts MDSAP audit reports as a trial.
- The trial period: from June 22, 2016 to December 31, 2016 extended to March 31, 2018
- The MDSAP Audit Report can reduce the manufacturer’s burden in the inspection process, when it is appropriate.
- PMDA basically performs desktop inspection to a site to which the MDSAP audit report is submitted at the timing of QMS inspection application.
## Example of Documents for Desktop Inspection using MDSAP Audit Report

<table>
<thead>
<tr>
<th>No</th>
<th>Documents</th>
<th>Need or not</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-1-3</td>
<td>ISO13485 Certification, registered certification body’s Inspection report, etc</td>
<td>Not</td>
</tr>
<tr>
<td>1-2-1</td>
<td>Outline of manufacturing site</td>
<td>Not</td>
</tr>
<tr>
<td>2-1-1</td>
<td>Layout of manufacturing site building</td>
<td>Not</td>
</tr>
<tr>
<td>2-1-2</td>
<td>Floor plan</td>
<td>Not</td>
</tr>
<tr>
<td>2-2-1</td>
<td>Organization chart</td>
<td>Not</td>
</tr>
<tr>
<td>2-2-2</td>
<td>Quality management system manual</td>
<td>Not</td>
</tr>
<tr>
<td>2-2-3</td>
<td>List of documents identified with QMS</td>
<td>Not</td>
</tr>
<tr>
<td>2-3-3</td>
<td>Validation states of mfg. process</td>
<td>Not</td>
</tr>
<tr>
<td>2-4-4</td>
<td>Quality agreement between MAH and manufacturing sites</td>
<td>Depends</td>
</tr>
</tbody>
</table>
References

• PMDA / QMS
  http://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0002.html
• Documents to be submitted list for QMS inspection
Thank you for your attention!
ISO 13485:2016
QMS Application Strategy

May 11, 2017
ILOODA Co. Ltd.

Seol Yeong-soo
responsible for quality management
Table of Contents

1. ISO 13485:2016 Key Changes
2. Application of Regulatory Requirements QMS
3. Risk Management throughout the Product Realization
4. Re-establishment of the Organization’s Files for Design and Development
5. Re-establishment of Supply Products/Service Management
6. Re-establishment of Complaints Handling Procedure
7. Summary
1. ISO 13485:2016 Key Changes

- Focus on internationalized “regulatory requirements”
- Apply “risk management” throughout the quality system
- A clear need for “design validation and validation activities”
- Improvement of the “supplier management” process
- Improved “feedback process”
- Clear requirements for “software validation”
- Enhanced requirements for “identification and traceability”

* Source: SGS ACADEMY
<table>
<thead>
<tr>
<th>Regulatory Requirements</th>
<th>Risk Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Organizational emphasis on the regulatory requirements for customer safety and performance</td>
<td>◆ Documentation of one or more processes for risk management across the product realization activities</td>
</tr>
<tr>
<td>◆ Requires assessment of the impact on the regulatory requirements in the activities of the manufacturer</td>
<td>◆ Expansion of the quality management system as well as the product realization process (design management) - Introduction of the lifecycle concept</td>
</tr>
<tr>
<td>◆ Communication with and reporting to the regulatory agencies on the applicable regulatory requirements</td>
<td>◆ Review of the results of the design change through risk management</td>
</tr>
<tr>
<td>◆ Evaluation of the impact of the “applicable regulatory requirements” when changing the product design, and reporting it to the approving or regulatory body</td>
<td>◆ Documentation of the assessment of the risk management on the data in the feedback process</td>
</tr>
</tbody>
</table>

**Design Control**

<table>
<thead>
<tr>
<th>Design Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Documentation of the planning and review of the design and development throughout the design process</td>
</tr>
<tr>
<td>◆ The outputs of the design and development should be traceable in the relevant design inputs.</td>
</tr>
<tr>
<td>◆ Documentation of the resources of the design and development process, including the suitability of the participants</td>
</tr>
<tr>
<td>◆ Establishment of a design validation &amp; validation plan, and design transfer</td>
</tr>
<tr>
<td>◆ Usability, clinical and performance evaluation for validation, application of the design history file concept</td>
</tr>
</tbody>
</table>

**Validation**

<table>
<thead>
<tr>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Documentation of the acceptance criteria to be used in the validation, and of the statistical techniques and sample size</td>
</tr>
<tr>
<td>◆ If applicable, ensuring the compatibility of the product with other medical devices</td>
</tr>
<tr>
<td>◆ In the case of software, validate the extent of the potential risk of the process on the product.</td>
</tr>
<tr>
<td>◆ Documentation of the results of the validation, the conclusions, and the additional activities</td>
</tr>
<tr>
<td>◆ Expansion of the software process management requirements: QMS software, process management software, software for monitoring and measuring, etc.</td>
</tr>
</tbody>
</table>

* Source: SGS ACADEMY*
### Supplier Control

- Provision of a documented *"agreement"* between the organization and the supplier, including notification of any major change made.
- Inspection of the purchased product *with regard to its risk based on the evaluation of the supplier*
- Conduct of the purchased-product change through the product realization and the impact of the medical device
- Expansion of the supplier monitoring process

### Feedback Process

- Documentation of systematic ways of collecting feedback
- The data supporting feedback include the production and post-production activities.
- Feedback is applied as an input to the risk management, product realization, and development process.
- Strengthening of the requirements for the handling of segmented and specialized customer complaints
- Adding vigilance reports and a post-management system (PMS)

### Identification & Traceability

- Identification of the status of the product throughout the product realization process
- Documentation of UDI (unique device identification)-applied systems
- Specific requirements, including the traceability records of the implanted devices

### FDA 21 CFR Part 820 Compliant

- Application of additional requirements of FDA, such as design transfer, DMR, and DHF
- Clarification of the applicable provisions of the regulatory authorities’ reporting procedure (MDRs)
- Adding the change notification procedure of the supplier

* Source: SGS ACADEMY*
2. Application of Regulatory Requirements QMS

- ISO 13485:2003
  - Regulatory requirements
  - 9 times

- ISO 13485:2016
  - Regulatory requirements
  - Chapters 4 - 8
  - 37 times

- IMDRF
  (USA, Canada, Australia, Japan, China, Russia, Brazil)

- MDSAP

- Member nations’ individual requirements

Construction of Quality Management System
3. Risk Management throughout the Product Realization

Feedback process
Design change process
ISO 14971
Risk identification
Risk analysis
Risk assessment
Risk control
Supplier selection & evaluation process
Inspection process
Design and development process
Purchase process
Work standard process
HR management process
Complaint assessment process
Manufacturing process
### 4. Re-establishment of the Organization’s Files for Design and Development

<table>
<thead>
<tr>
<th>Requirements</th>
<th>DMR (Device Master Record)</th>
<th>DHF (Design History File)</th>
</tr>
</thead>
</table>
| **7.3.2 Design & development planning** | - Laws and standards by nation  
- Semi-finished specifications  
- Parts specifications  
- Product specifications | - Customer requirements documents  
(marketing requirements, users, user interface, clinical requirements, product requirements)  
- Product concept (design strategy documents)  
- Project plan (plan by department)  
- Risk management plan  
- Design review (selection of sales markets, review of whole schedule, review of responsibility and authority) |
| **7.3.3 Design & development inputs** | - Labeling (product labels, packaging labels)  
- List of processes, devices, and measuring instruments  
- Test and inspection standards  
- Work standards  
- Product drawings (final products, semi-finished products, parts)  
- BOM (bill of material)  
- Parts list  
- User manual, service manual | - Risk analysis report  
- Design review (review of the content conflict, ambiguity, etc., and of the measurability) |
| **7.3.4 Design & development outputs** | | - Design review (review of the output status and design traceability) |

*Source: SGS ACADEMY*
## 4. Re-establishment of the Organization’s Files for Design and Development

<table>
<thead>
<tr>
<th>Requirements</th>
<th>DMR (Device Master Record)</th>
<th>DHF (Design History File)</th>
</tr>
</thead>
</table>
| **7.3.6 Design & development verification** |                            | - Software verification report  
- Hardware verification report  
- Product verification report (external agency)  
- Design review (review of the measurable requirements and outputs, and of the re-implementation due to the problems found during the review) |
| **7.3.7 Design & development validation**  |                            | - Process validation protocol and report  
- Documents to be submitted to the regulatory body  
- Software validation report  
- Final version of the risk management report  
- Product validation report  
- Clinical evaluation report  
- Usability evaluation report  
- Design review (review of the customer requirements and outputs, and of the fulfillment of the legal requirements) |

* Source: SGS ACADEMY*
## 5. Re-establishment of Supply Products/Service Management

<table>
<thead>
<tr>
<th>Step</th>
<th>Process</th>
<th>Objective Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plan</strong></td>
<td>Description of what to be supplied with</td>
<td>Confirmation of the products and services, manuals, and specifications</td>
</tr>
<tr>
<td></td>
<td>Confirmation of technology and process information</td>
<td>Specifications, parts requirements, procedures, and work instructions</td>
</tr>
<tr>
<td></td>
<td>Confirmation of potential suppliers</td>
<td>Potential suppliers’ names and contact information</td>
</tr>
<tr>
<td></td>
<td>Identification of risks associated with products or services</td>
<td>Documentation of the identified risks</td>
</tr>
<tr>
<td></td>
<td>Identification and evaluation of the type and extent of risk management</td>
<td>List of the identified risk results and of the potential risks to be managed</td>
</tr>
<tr>
<td><strong>Selection of potential supplier</strong></td>
<td>Survey of the supplier’s business capability</td>
<td>Code of Conduct, business practices, goodwill, etc.</td>
</tr>
<tr>
<td></td>
<td>Survey of the supplier’s operational capability</td>
<td>Evidences of technology, infrastructure, logistics, quality, and risk management</td>
</tr>
<tr>
<td></td>
<td>Selection of potential supplier</td>
<td>Criteria for the potential supplier documentation and selection, and grounds for the decision</td>
</tr>
<tr>
<td><strong>Evaluation and approval of the supplier</strong></td>
<td>Plan establishment for the evaluation selection criteria</td>
<td>Documented criteria for evaluation and selection</td>
</tr>
<tr>
<td></td>
<td>Improvement of the communication with the potential supplier and of the requirements</td>
<td>The first documented contract</td>
</tr>
<tr>
<td></td>
<td>Evaluation based on the selection criteria</td>
<td>Evidences that meet the criteria for the documentation and records</td>
</tr>
<tr>
<td></td>
<td>Approval of the supplier</td>
<td>Documented decision grounds (including the list of approved suppliers)</td>
</tr>
</tbody>
</table>

* Source: QMS-Guidelines for management of products and services received from suppliers / GHTF Study Group 3 / GHTF/2008-12-11
5. Re-establishment of Supply Products/Service Management

<table>
<thead>
<tr>
<th>Step</th>
<th>Process</th>
<th>Objective Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final decision on management</td>
<td>Establishment of purchase information</td>
<td>Final contract, purchase order, agreement, etc.</td>
</tr>
<tr>
<td></td>
<td>Approval decision and verification activities</td>
<td>Approval procedure, purchase/specification requirements, review/approval records</td>
</tr>
<tr>
<td>Delivery, measurement, monitoring</td>
<td>Product/service warehousing, measurement/monitoring and approval activities</td>
<td>Warehousing records, inspection/test records, approval records</td>
</tr>
<tr>
<td></td>
<td>Data analysis</td>
<td>Recording of the data analysis results</td>
</tr>
<tr>
<td></td>
<td>Identification of problems and corrective action</td>
<td>Recording of the corrective-action results</td>
</tr>
<tr>
<td></td>
<td>Regular re-evaluation of suppliers</td>
<td>Recording of the results of the evaluation of the ability to continuously comply with the requirements</td>
</tr>
<tr>
<td>Feedback and monitoring</td>
<td>Feedback and communication – results of whether to meet the requirements</td>
<td>Letters of the manufacturer and/or supplier</td>
</tr>
<tr>
<td></td>
<td>Corrective and preventive process - CAPA</td>
<td>Documents and records of the corrective and prevention action process</td>
</tr>
</tbody>
</table>

* Source: QMS - Guidelines for the management of the products and services received from the suppliers/ GHTF Study Group 3/ GHTF/2008-12-11
<table>
<thead>
<tr>
<th>Supplier Rating</th>
<th>Initial Evaluation &amp; Selection</th>
<th>Periodic Management Method</th>
<th>Inspection &amp; Acceptance Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key supplier (Risk Class A)</td>
<td>- ISO 13485, CE, cGMP registration review                                                   - Review of the annual supplier performance &amp; conclusion of the quality contract         - Regular analysis of the supplier suitability &amp; of the trend assessment report</td>
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<td>- Review of the external audit agency reports                                               - Review of the monthly corrective-action processing status                                  - Performance of independent testing for the verification of the suitability analysis report</td>
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<td>- Establishing the obligation to change the contract                                          - Review of the monthly pass/fail ratio for the received products &amp; of the monitoring progress - Inspection of the supplied products according to the acceptance &amp; sampling criteria</td>
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<td></td>
<td>- Product/service risk assessment                                                             - Issuance of corrective-action requests against continuous quality problems                - Inspection and acceptance activities performed at the supplier site</td>
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<td></td>
<td>- QMS onsite audit                                                                            - Review of the annual corrective actions taken                                               - Issuance of supplier's product inspection/compliance report or compliance analysis report according to the established acceptance criteria</td>
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<td>Middle-tier supplier (Risk Class B)</td>
<td>- QMS onsite audit                                             - Review of the quarterly corrective actions taken                                           - Inspection and acceptance activities at the supplier’s site</td>
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<td></td>
<td>- Acceptance of self-assessment questionnaire                                                 - Review of the quarterly corrective actions taken                                           - Issuance of supplier's product inspection/compliance report or compliance analysis report according to the established acceptance criteria</td>
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<td></td>
<td>- Review of the internal audit results                                                        - Review of the quarterly corrective actions taken                                           - Inspection and acceptance activities at the supplier’s site</td>
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<tr>
<td>General supplier (Risk Class C)</td>
<td>- Interview of the supplier manager                                                           - Review of the annual pass/fail ratio for the received products, &amp; of the monitoring progress - Considering non-inspection</td>
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<td></td>
<td>- Assessment of the supplier’s financial status                                               - Review of the annual corrective actions taken                                               - Considering non-inspection</td>
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</tbody>
</table>

* Source: SGS ACADEMY
6. Re-establishment of Complaints Handling Procedure

- Receive customer complaints
  - Information documentation
    - Events to be reported to the health authorities
      - Evaluation & survey or not
        - Results and reason
          - Potential events to be reported to the health authorities
            - Health authority reporting procedure
            - YES
            - NO
              - Investigate
                - YES
                - NO
                  - Corrective action
                    - Initial correction or corrective action
                      - YES
                      - NO
                        - Respond to customer complaints
                          - Closing customer complaints
                            - Measure & analyze
                              - Corrective and preventive action/reporting to the higher agencies

*Source: SGS ACADEMY*
7. Summary

- Bolstering of the ability to identify the regulatory requirements by export destination
- SW validation method development & bolstering of the internal human capability
- Reconstruction of the communication system with the customers and regulatory authorities
- A concept change in the verification of the design/development & validation
- A change in the awareness of the importance of the planned implementation of design/development, & of transfer and design change
- Requiring an awareness change in the QMS constructor and operator (company-wide activities)
- The total improvement of the QMS operation method is essential.
  - Need to invest in infrastructure
  - Need to bolster the human capabilities

Introduction of the risk management concept across QMS
Thank you