5th Joint Conference of Taiwan and Japan

Progress of QMS/QSD-WG and Industry Perspective

1 Dec. 2017

Hitachi High-Tech Science Corporation

Hideki Asai

WG Activities 2013-2016

2013

- Arrangement for the establishment of the framework of the cooperation of the medical products regulation (5 Nov, 2013)
- 1st Japan-Taiwan medical device exchange seminar (10 Dec, 2013)

2014

- Establishment of QSD/QMS WG
- Video-Conferences (14 Jan, 11 Mar, 20 May, 20 Aug, 2014)
- 2nd Japan-Taiwan medical device exchange seminar (10 Jun, 2014)
- 2nd Joint Conference of Japan and Taiwan on medical product regulation (31 Oct-1 Nov, 2014)
- Observation of QMS Inspection in Taiwan (25-27 Nov, 2014)

WG Activities 2013-2016

2015

- Video-Conference (10 Mar, 2015)
- 3rd Joint Conference of Japan and Taiwan on medical product regulation (26-27 Nov, 2015)

2016

- Meeting of QMS/QSD WG in Japan（27 July, 2016）
- Monitored audit（PMDA, SGS, TUV Rheinland, BSI）
- 4th Joint Conference of Japan and Taiwan on medical product regulation (7-8 Dec, 2016)

2017

- **Discussion about agreement and finalization of MoC (Memorandum of Cooperation)**

QMS-WG Road map
(Phase 1 - Letter of Intent and Participation)

No.	Task	Responsibility	Status
1	Provide the Information on RCB system in Japan/Taiwan for the purpose of the mutual understanding of how to assess/manage RCB.	MHLW/ TFDA	Closed
2	Discuss with interested RCBs in Japan/Taiwan.	MHLW/ TFDA	Closed
3	Interested RCBs in Japan/Taiwan designate contact person.	MHLW/ TFDA	Closed
4	Interested RCBs in Japan/Taiwan designate a Letter of Intent.	MHLW/ TFDA	Closed
5	Review and select interested RCBs.	MHLW/ TFDA	Closed

QMS-WG Road map (Phase 2- Confidence Building)

No.	Task	Responsibility	Status
1(1)-1	Conduct sampling monitored audits for some RCBs from Japan to establish confidence on regulatory inspecting/auditing of both parties. The sample number may be 2 to 4 in each side. Then, both sides discuss whether 1(2)-1 or 1(2)-2 should be taken	TFDA	Closed
1(1)-2-(1)	(1)One monitored audit for each RCBs seeking to participant after Dec.2016.	TFDA	-
1(1)-2-(2)	(2)Three more sampling monitored audits for RCBs and Together with information provided by PMDA on the auditing of other RCBs without monitored audits.	TFDA	Closed
1(1)-3	Conduct sampling monitored audits for some RCBs from Taiwan to establish confidence on regulatory inspecting/auditing of both parties. The sample number may be 2 to 4 in each side. Then, both sides discuss whether 1(2)-1 or 1(2)-2 should be taken.	MHLW/ TFDA	Closed

QMS-WG Road map (Phase 2- Confidence Building)

No.	Task	Responsibility	Status
1(2)-1	According to the results of 1(1), the sampling method is continued so that more RCBs receive monitored audits.	MHLW/ TFDA	Closed
1(2)-2	According to the results of 1(1), monitored audit should be conducted for every interested RCB step by step.	TFDA	Open Phase 3
1(3)	Both sides discuss/consider Exchange of Letters (EOL) at the time of the next joint conference(Dec.2016). Draft EOL will be provided to MHLW in Sep. 2016	TFDA	Closed
2	For PMDA, since one monitored audit in Taiwan has been completed, another monitored audit for PMDA in Japan should be conducted.	MHLW/ TFDA	Closed
3	Announce the list of both sides entering Phase Ⅲ	MHLW/ TFDA	Closed

QMS-WG Road map (Phase 3 - Operation)

No.	Task	Responsibility	Status
1	Hold a workshop on R.O.C. GMP regulations/Japan QMS regulations annually with the joint conference.	TFDA/MHLW	
2	Manufactures may utilize audit reports under this Program as part of the documentation in stead of second level documentation in Taiwan.	TFDA	
3	Manufactures may utilize audit reports under this Program as part of the documentation to evaluate the manufacturing sites in the same risk level as US and EU in Taiwan.	PMDA RCBs in JAPAN	
4	Taiwan/Japan will inform each other their inspection schedules of Taiwanese/Japanese manufactures in advance in order to allow TFDA/PMDA to observe inspects/audits performed in a timely manner.	TFDA/MHLW	
5	Both sides shall resolve the complaints of both manufactures regarding the implementation of this Program in a timely manner.	TFDA/MHLW	
6	Each side shall inform the other side with formal documents when there are significant changes to the organization and related issues.	TFDA/MHLW	

Japanese Industry Perspective

- Japanese Industry would like to request;
  - Sign MoC (Memorandum of Corporation) and start Phase 3 tasks as soon as possible.
  - Increase approved Japanese RCBs.
  - Consider acceptance of the certification/report with new Japanese QMS ordinance introducing ISO 13485:2016

- For these tasks Japanese Industry will support as much as possible.

Memorandum of Cooperation

- MoC（Memorandum of Cooperation regarding the mutual exchange of information on Medical device QMS requirements）will be signed in 2017.

It takes 1 year and still waiting.!

- MoC will contain;
  - Utilization of audit reports by MHLW/PMDA/RCBs and TFDA.
  - Training workshop on annual meetings
  - Perform monitoring audit（if necessary）
- After MoC, Phase 3 will start officially.

Increase approved Japanese RCBs.

- **Registered Certification Body in JAPAN (14 RCBs)**
  - TUV SUD Japan Ltd.
  - TUV Rhineland Japan Ltd.
  - BSI Group Japan K.K.
  - DQS Japan Inc.
  - Japan Association for the Advancement of Medical Equipment
  - SGS Japan Inc.
  - Cosmos Corporation Co., Ltd.
  - Japan Quality Assurance Organization (JQA)
  - Nanotec Spindler Inc.
  - Japan Electrical Safety & Environment Technology Laboratories (JET)
  - Fuji Pharma Co., Ltd.
  - DEKRA Certification Japan K.K.
  - Bureau Veritas Japan Co., Ltd.
  - Intertek Certification Japan Ltd.
- **Only 3 RCBs (TUV Rhienland, BSI, SGS) are approved by TFDA and necessary to increase number of approved RCBs.**

Consideration of revised QMS regulation according to ISO 13485:2016

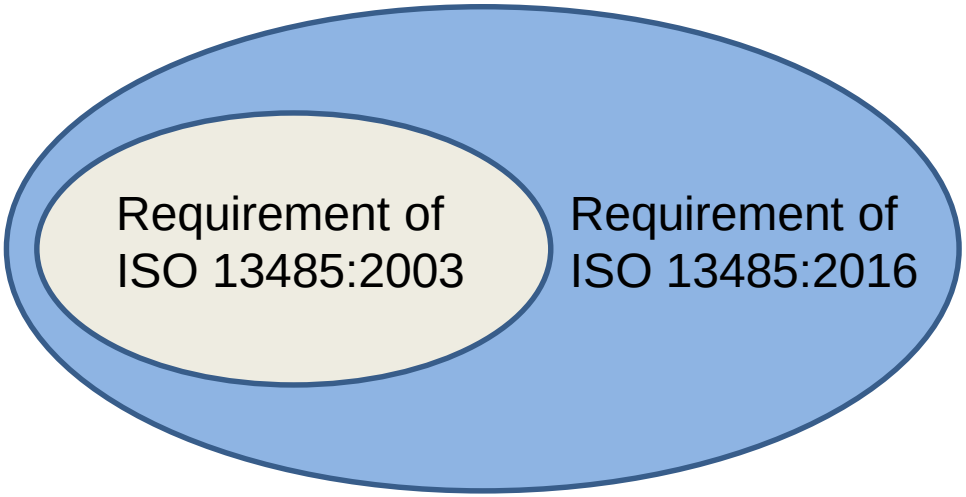
- Future of Japanese QMS ordinance(ISO 13485:2016)
  - It is expected that Japanese QMS ordinance will harmonize with ISO 13485:2016 / Global QMS standard soon. (April-May 2018)
  - Health Labor Science Research Study Group for Medical Device QMS (Chair: Dr Sakurai/PMDA)
    - Start drafting revised QMS ordinance based on ISO 13485:2016.
  - Also JIS Q 13485:201X(=ISO 13485:2016) will be issued soon.

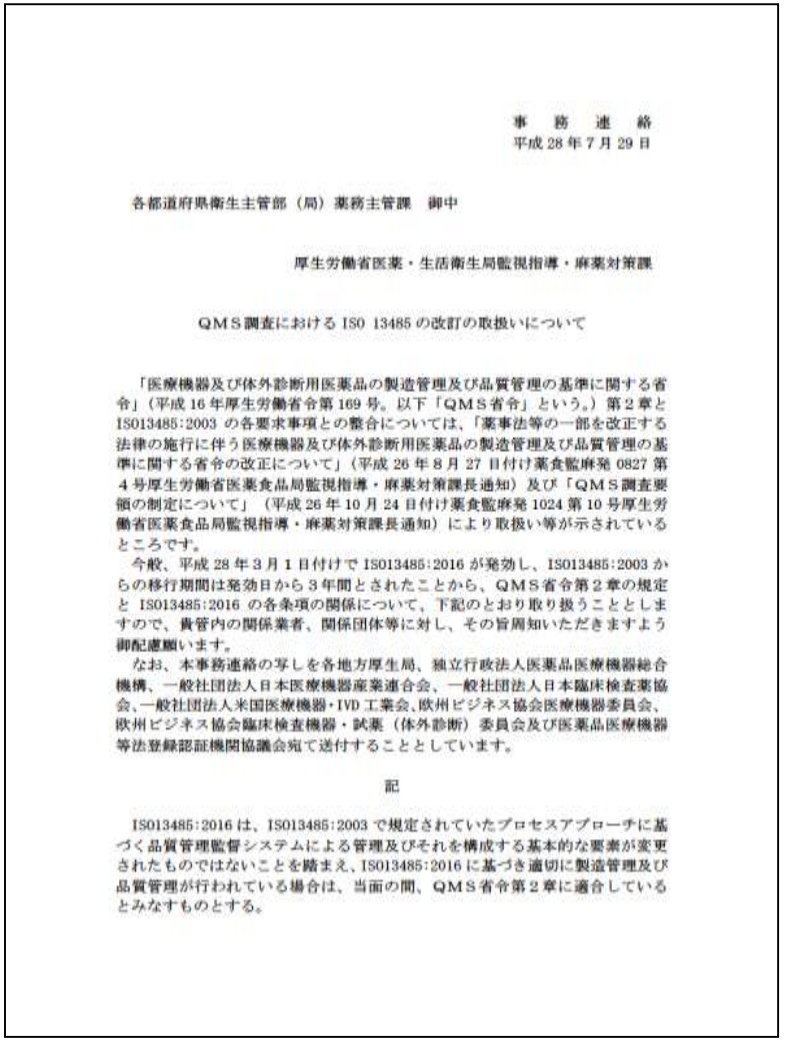
- ISO 13485:2016 had published and both party will introduce ISO 13485:2016 to their regulations and QSD/QMS-WG will discuss this issue.

Utilization of 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)





事　務　連　絡
平成 28 年 7 月 29 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・生活衛生局監視指導・麻薬対策課

QMS 調査における ISO 13485 の改訂の取扱いについて

「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。）第 2 章と ISO13485:2003 の各要求事項との整合については、「薬事法等の一部を改正する法律の施行に伴う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の改正について」（平成 26 年 8 月 27 日付け薬食監麻発 0827 第 4 号厚生労働省医薬食品局監視指導・麻薬対策課長通知）及び「QMS 調査要領の制定について」（平成 26 年 10 月 24 日付け薬食監麻発 1024 第 10 号厚生労働省医薬食品局監視指導・麻薬対策課長通知）により取扱い等が示されているところです。

今般、平成 28 年 3 月 1 日付けで ISO13485:2016 が発効し、ISO13485:2003 からの移行期間は発効日から 3 年間とされたことから、QMS 省令第 2 章の規定と ISO13485:2016 の各条項の関係について、下記のとおり取り扱うこととしますので、貴管内の関係業者、関係団体等に対し、その旨周知いただきますよう御配慮願います。

なお、本事務連絡の写しを各地方厚生局、独立行政法人医薬品医療機器総合機構、一般社団法人日本医療機器産業連合会、一般社団法人日本臨床検査薬協会、一般社団法人米国医療機器・IVD 工業会、欧州ビジネス協会医療機器委員会、欧州ビジネス協会臨床検査機器・試薬（体外診断）委員会及び医薬品医療機器等法登録認証機関協議会宛て送付することとしています。

記

ISO13485:2016 は、ISO13485:2003 で規定されていたプロセスアプローチに基づく品質管理監督システムによる管理及びそれを構成する基本的な要素が変更されたものではないことを踏まえ、ISO13485:2016 に基づき適切に製造管理及び品質管理が行われている場合は、当面の間、QMS 省令第 2 章に適合しているとみなすものとする。

Summary

- In 2017, both party worked for EoC and EoC will be signed soon.
- QSD/QMS-WG task will go into the Operation Phase.
  - Utilization of QSD/QMS audit to minimize documentation.
  - Hold a training workshop to enhance the understanding of Japanese and R.O.C. medical device QMS requirements.

- Japanese Industry expects;
  - Sign MoC and start Phase 3 tasks as soon as possible.
  - Increase approved Japanese RCBs.
  - Consider acceptance of the certification/report with new Japanese QMS ordinance introducing ISO 13485:2016

謝謝

Thank you very much
for your kind attention.

Hideki Asai
hideki.asai.cw@hitachi-hightech.com
Phone: +81-90-5204-4880