4th Joint Conference of Japan and Taiwan

Progress of QMS/QSD WG

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Main Topics

1. QSD/QMS WG activities(2013-2016)
2. Progress of QSD/QMS WG(2015-2016)
3. Monitored audit by TFDA
4. Goal
5. Q&A

2013-2016 Activities

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)

2013-2016 Activities

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)

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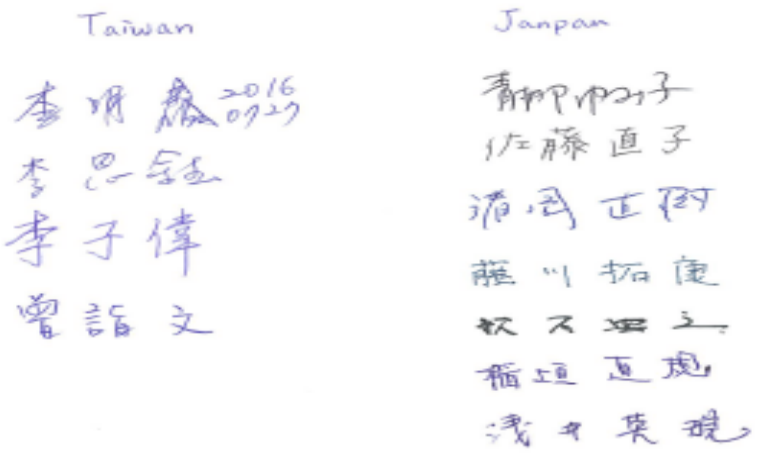
Road map fixed on July 27, 2016

#	Item	Who	Status
Phase I: Letter of Intent and Participation			
1-1	Proivide the information on RCB* system in Taiwan for the purpose of the mutual understanding of how to assess/manage RCB	Taiwan	Closed
1-2	Proivide the information on RCB* system in Japan for the purpose of the mutual understanding of how to assess/manage RCB	Japan	Closed
2-1	Discuss with interested RCBs in Taiwan side	Taiwan	Closed
2-2	Discuss with interested RCBs in Japan side	Japan	Closed
3-1	Interested RCBs in Taiwan designate contact persons.	Taiwan	Closed
3-2	Interested RCBs in Japan designate contact persons.	Japan	Closed
4-1	Interested RCBs in Taiwan provide a Letter of Intent.	Taiwan	Closed
4-2	Interested RCBs in Japan provide a Letter of Intent.	Japan	Closed
5	Review and select interested RCBs	Taiwan/Japan	Closed
Phase II: Confidence Building			
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 4(2a) or 4(2b) should be taken.	TFDA	Open
1(1)-2	(1)One monitored audit for each RCBs seeking to participat after Dec. 2016. (2)Three more sampling monotored audits of RCBs and together with information provided by PMDA on the auditing of the other seven RCBs without monitoered audits.	TFDA	Open
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 4(2a) or 4(2b) should be taken.	Japan RCBs	Open
1(2)-1	According to the results of 4(1), the sampling method is continued so that more RCBs receive monitored audits.	TFDA/Japan RCBs	Open
1(2)-2	According to the results of 4(1), monitored audit should be conducted for every interested RCB step by step.	TFDA/Japan RCBs	Open
1(3)	Both sides discuss/consider Exchange of Letters at the time of the next joint conference. Draft EOL will be provided to MHLW in Sep. 2016.	TFDA/MHLW	Open
2	For PMDA, since one monitored audit in Taiwan has been completed, another monitored audit for PMDA in Japan should be conducted.	TFDA	Open
3	Announce the list of both sides entering Phase III.	TFDA/MHLW	Open
Phase III: Operation			
	Hold a workshop on R.O.C. GMP		



Content of Road map

Phase I : Letter of Intent and Participation

Phase II : Confidence Building

Phase III : Operation

Phase Ⅰ:Letter of Intent and Participation

	Item	Who	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

All of Phase Ⅰ items are already closed!

Phase Ⅱ:Confidence Building

	Item	Who	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 in late Dec.
1(1)-2	(1)One monitored audit for each RCBs seeking to participant after Dec.2016. => Still Open (2)Three more sampling monitored audits for RCBs and Together with information provided by PMDA on the auditing of other RCBs without monitored audits. => Closed	TFDA	Open
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.	(Japan RCBs)	Deleted
1(2)-1	According to the results of 1(1), the sampling method is continued so that more RCBs receive monitored audits.	TFDA/（Japan RCBs）	Deleted

	Item	Who	Status
1(2)-2	According to the results of 1(1), monitored audit should be conducted for every interested RCB step by step.	TFDA/（Japan RCBs）	Open
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/MHLW	Closed on Dec.8th
2	For PMDA, since one monitored audit in Taiwan has been completed, another monitored audit for PMDA in Japan should be conducted.	TFDA	Closed
3	Announce the list of both sides entering Phase Ⅲ	MHLW/ TFDA	Closed on Dec.8th

We are going on to Phase III after December 8th!

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Monitored audit by TFDA

- TFDA and TFDA's Designated Auditing Organizations joined the following 3 audits in Japan as observers for Confidence Building.

- 2016/7/25-26 for SGS Japan
- 2016/8/23-26 for PMDA
- 2016/9/26-27 for TUV Rheinland Japan

Monitored audit for SGS Japan

- 2016/7/25-26 in Tokyo
- 2 auditors for Initial Audit
- Design and Development , Manufacture, Installation and Service of Moist Heat Sterilizer
- Combined Audit for 2 purposes
  - ISO 13485:2003
  - Japanese Ordinance #169

Monitored audit for PMDA

- 2016/8/23-26 in Nagano
- 2 auditors for Routine inspection
- Inspection Product : Catheter
- Audit for Single Purpose
  - Japanese Ordinance #169

Monitored audit for TUV Rheinland Japan

- 2016/9/26-27 in Niigata
- 3 auditors for Survillance Audit
- Design, Development, Manufacturing and Sales of Dental Materials and Related Products
- Combined Audit for multiple purposes
  - ISO 13485:2003
  - JIS 13485:2005
  - 93/42/EEC MDD Annex II
  - ISO 13485:2003 under CMDCAS
  - Japanese Ordinance #169

Results of Monitored audit

- For the preliminary results of monitored audits, Taiwan side is satisfied with the reliability of QMS audits conducted by PMDA and 2 RCBs (SGS Japan and TUV Rheinland Japan).

- The last participant in this working plan, BSI Japan, will be observed in late December.

14

Phase Ⅲ：Operation

	Item	Who	Status
1	Hold a workshop on R.O.C. GMP regulations/Japan QMS regulations annually with the joint conference.	TFDA /MHLW	Open
2	Manufactures may utilize audit reports under this Program as part of the documentation in stead of second level documentation in Taiwan.	TFDA	Open
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, Japan RCBs	Open
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	Open
5	Both sides shall resolve the complaints of both manufactures regarding the implementation of this Program in a timely manner.	TFDA /MHLW	Open
6	Each side shall inform the other side with formal documents when there are significant changes to the organization and related issues.	MHLW/ TFDA	Open

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Phase II Goal and coming Phase III

After Dec, 2016 <= Due date should be fixed tomorrow!

- Sign of EOL（Exchange of letters regarding the mutual exchange of information on Medical device QMS requirements）

EOL will contain below subjects:

- Exchange of audit reports between MHLW/PMDA/RCBs and TFDA.
- Training workshop on annual meetings

Also Taiwan can join various training programs in PMDA Asian training center !

- Perform monitoring audit（if necessary）

As a result of the EOL・・・・

- Exchange of Audit Reports
  - ✓ TFDA intend to require second tier QSD documentation of Japanese manufacturers for QSD registration.
  - ✓ MHLW /PMDA will list Taiwan manufactures at the same risk level with that of U.S.A. and EU, and PMDA will make the most of this list into the reduction of on-site inspection.
  - ✓ Audit reports are necessary to be translated into Japanese/Chinese/English by manufactures.

- Training workshop
  - ✓ Enhance the understanding of Japanese and R.O.C. medical device QMS requirements.

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