Current Progress for QMS WG

6th Joint Conference of Japan and Taiwan on Medical Products Regulation

11 Oct, 2018
Szu-Yu LEE
Division of Risk Management

衛生福利部
食品藥物管理署
FDA Food and Drug Administration

Outline

- Activities in 2017
- Progress in 2018
- Goal in 2019
- Future Plan

Activities in 2017

Dec.(2016) -Apr.

- ✓ EoL was modified to MoC format
- ✓ MoC (draft) was confirmed by relevant authorities in Japan

May

- ✓ MoC (draft) was sent to the Association of East Asian Relations by Japan-Taiwan Exchange Association, Taipei Office on May 08
- ✓ MoC(draft) was sent to TFDA on May 12

Jun.-Oct.

- ✓ MoC(draft) was modified by TFDA and relevant authorities
- ✓ MoC(draft) was sent to the Taiwan-Japan Relations Association on Oct. 20

Nov.

- ✓ MoC(draft) was sent to the Japan-Taiwan Exchange Association, Taipei Office by Taiwan-Japan Relations Association on Nov. 02
- ✓ MoC(draft) was agreed most and modified a little by Japan Side and sent back on Nov. 08
- ✓ MoC(draft) was received by TFDA on Nov. 08 and agreed by Taiwan Side on Nov. 22

Dec.

- ✓ QMS workshop for Japanese regulations

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
1(1)-2	One monitored audit for each RCBs seeking to participant after Dec. 2016.	TFDA	Open to Phase Ⅲ
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）	Closed
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）	Closed
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
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	Memorandum of Cooperation (MOC)was proposed and EOL was substituted by MOC.	TFDA/MHLW	Closed
4	Announce the list of both sides entering Phase Ⅲ	JTEA/TJRA/ TFDA	Waiting for signing

Progress in 2018

2018

5/31

- ✓ Final version of MoC(draft) was agreed by Japan Side and Taiwan Side

6/20-21

- ✓ **Monitored audit for TUV SUD PS Japan**
  - ➢ Survillance Audit for Design, Development, Manufacturing and Sales of IVD Reagents

7/31

- ✓ Final version ot MoC(draft) was approved by Executive Yuan in Taiwan

10/10-11

- ✓ 6th Joint Conference of Japan and Taiwan on medical product regulation
- ✓ QMS workshop for Taiwanese regulations on Oct. 11
- ✓ MoC will be signed in Nov.

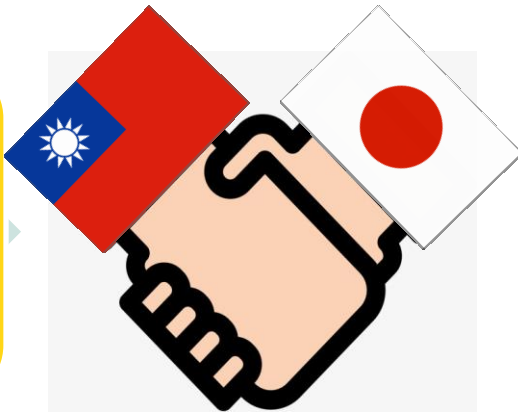
Proposal of Working Plan for 2016

Taiwan
- ✓ TFDA
- ✓ Industrial Technology Research Institute
- ✓ Metal Industries Research & Development Centre
- ✓ Electronics Testing Center
- ✓ Plastics Industry Development Center

Phase Ⅰ: Letter of Intent and Participation

Phase Ⅱ: Confidence Building

Phase Ⅲ: Operation



Japan
- ✓ PMDA
- ✓ TUV Rheinland Japan
- ✓ BSI Group Japan
- ✓ SGS Japan
- ✓ TUV SUD PS Japan

Goal in 2019

In November, 2018

Sign of MOC (Memorandum of Cooperation regarding the mutual exchange of information on Medical device QMS requirements) by JTEA and TJRA

Entering Phase III Since Jan 1, 2019

MOC will contain below subjects:

✓ Utilize audit reports as part of the documentation

✓ Training workshop on annual meetings

✓ Perform monitoring audit (if necessary)

As a result of the MOC · · · ·

Exchange of Audit Reports and Certifications

- ✓ TFDA require none of the quality system procedural documentation except quality manual of Japanese manufacturers for medical device QMS document inspection, except for some procedures of quality system when necessary.
- ✓ MHLW /PMDA put Taiwanese manufacturers into the same risk level with that of United States and European Union, and make the most of the QMS audit reports and the QMS compliance certifications to reduce on-site inspection.
- ✓ Audit reports are necessary to be translated into Japanese/Chinese by manufactures.

Training workshop

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

Phase Ⅲ：Operation

Phase Ⅲ：Operation	Item	Who	Status
1	Hold a workshop on R.O.C. GMP regulations/Japan QMS regulations annually with the joint conference.	MHLW/ TFDA	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 Japan.	PMDA, Japan RCBs	Open
4	Japan/Taiwan will inform each other their inspection schedules of Japanese/Taiwanese manufactures in advance in order to allow PMDA/TFDA to observe inspects/audits performed in a timely manner.	MHLW/ TFDA	Open
5	Both sides shall resolve the complaints of both manufactures regarding the implementation of this Program in a timely manner.	MHLW/ TFDA	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

Future Plan

- ✓ Any new RCBs can seek to participate in MOC after monitored audits.
- ✓ Each item of Phase III will always open till MOC modified or terminated.
- ✓ Members of QMS WG will continuously find new issues to cooperate.

ありがとうございます

Thank you for your attention！

衛生福利部
食品藥物管理署
FDA Food and Drug Administration
http://www.fda.gov.tw/