Position Paper
on Question and Answer
for the QMS MOC framework for Medical Device
between Japan and Taiwan

16 October 2020

THE JAPAN-TAIWAN EXCHANGE ASSOCIATION and THE TAIWAN-JAPAN RELATIONS ASSOCIATION concluded Memorandum of cooperation (MOC) on the field of medical device Quality Management System (QMS) requirements in November, 2018. The Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare confirmed mutual position regarding this Question and Answer (Q&A) document on 16 October 2020 as follows:

1. This Q&A document is intended to provide deeper understanding and to promote efficient use of the program based on the MOC for Japan and Taiwan.
2. Further collaboration on this issue may be discussed under the Framework.
3. This document is not intended to create any legally binding obligations.
4. Any differences arising from the interpretation or implementation of this position paper will be resolved through the consultations under the Framework.
5. This position paper may be amended in the future, when it would be confirmed jointly.

This position paper was jointly prepared by

MHLW/PMDA and TFDA,

and will be opened to stakeholders in Japan and Taiwan.

Question & Answer
for the QMS MOC framework for
Medical Device
in Taiwan and Japan

1． Taiwan to Japan

Q1：Valid Documents

What kind of QMS compliance certification and medical device QMS audit reports would be valid for this program?

A1
For this program, QMS compliance certifications and medical device QMS audit reports which are issued by the Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) are acceptable, and the copy of the documents are required at the time of application for QMS audit. Please note that the format and/or descriptions changed by applicants are not acceptable.

Q2：Document translation

Can QMS compliance certifications and medical device QMS audit reports which are issued by TFDA be submitted in Chinese?

A2
QMS compliance certifications translated into Japanese or English should be submitted along with the copy of original certifications written in Chinese. Medical device QMS audit reports can be submitted in Chinese, but if necessary PMDA may ask questions to clarify the contents of the report.

Q3：Submission

In this program, should the QMS compliance certifications and the medical device QMS audit reports which are issued by TFDA be submitted through the applicants (Marketing Authorization Holder or Designated Marketing Authorization Holder)?

A3

Applicants (Marketing Authorization Holders or Designated Marketing Authorization Holders) should submit them as a constitution of the submission documents for QMS compliance audit. Also, it is allowed to submit the documents to Pharmaceuticals and Medical Devices Agency (PMDA) directly from the manufacturer based on the agreement between the applicant and the manufacturer. In this case, the applicant should announce this to PMDA in advance and reception number of the QMS audit application should be described on the cover letter of the documents from the manufacturer.

Q4：Additional query

In the case that both the valid QMS compliance certifications and the medical device QMS audit reports which are issued by TFDA under MOC are submitted as attached files when applying for the QMS audit, could it be expected that there would be no further requirements from PMDA for these files?

A4

If it is confirmed that the subjected products and manufactures (including scope of its activities) subject to the QMS compliance certifications and medical device QMS audit reports issued by TFDA are the same as those of the QMS audit application in Japan, these documents would be generally accepted without additional queries. However, PMDA can issue additional queries if needed, considering the legal compliance.

Q5： Information on QMS audit application in Japan

Where can the information regarding application of QMS audit in Japan be obtained?

A5
Please refer to the website below for information regarding application of QMS audit（including application forms and handling fee）.

Japanese：

https://www.pmda.go.jp/review-services/gmp-qms-gctp/qms/0003.html

English：

https://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0002.html
https://www.pmda.go.jp/files/000227330.pdf
https://www.pmda.go.jp/files/000212616.pdf

2． Japan to Taiwan

Q1：Valid documents (No.1)

What kind of QMS compliance certifications and medical device QMS audit reports would be valid for this program?

A1
For this program, QMS compliance certifications and medical device QMS audit reports which are issued by Pharmaceuticals and Medical Devices Agency (PMDA) and Japan Registered Certified Bodies (RCBs) are acceptable, and the copy of the documents are required at the time of application for QMS audit. Please note that the format and/or descriptions changed by applicants are not acceptable.

Q2：Valid Documents (No.2)

In this program, the combination of QMS compliance certifications and ISO13485 audit report issued by RCBs are acceptable?

A2
No. QMS compliance certifications and the medical device QMS audit reports, not ISO13485 audit report, for applied products should be submitted.

Q3：RCBs to be subjected

Which RCBs in Japan are eligible to this program?

A3
As of Aug 2020, they are TUV Rheinland Japan, BSI Group Japan, SGS Japan, and TUV SUD Japan. Please refer to updated information of RCBs list.

(RCB list webpage : http://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f636825398570804226)

Q4：Document Translation

Can QMS compliance certification and medical device QMS audit reports which are issued by PMDA and RCBs for this program be submitted in Japanese?

A4
QMS compliance certifications and medical device QMS audit reports translated into Chinese or English should be submitted along with the copy of original certifications written in Japanese.

Q5：Information on QMS audit application in Taiwan

Where can the information regarding application for QMS audit application in Taiwan be obtained?

A5
Please refer to the website below for information regarding application for QMS audit（including application forms and user fee）.

Chinese (Traditional):
http://www.fda.gov.tw/TC/site.aspx?sid=2215
English:
http://www.fda.gov.tw/eng/siteContent.aspx?sid=10316