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主旨：為更新臺日醫療器材品質管理系統(QMS)問答集(Question and Answer for the QMS MOC framework for Medical Device between Japan and Taiwan)，請惠予協助蒐集所屬會員回饋意見，並於110年9月17日前提供本署，請查照。

說明：

一、因應臺日簽署「臺日醫療器材品質管理系統合作備忘錄」，本署業於109年12月21日發布「Question and Answer for the QMS MOC framework for Medical Device between Japan and Taiwan」，以利臺日雙方準備品質管理系統文件資料在案。

二、為更新旨揭問答集，請貴單位惠予協助蒐集所屬會員自上開合作備忘錄簽署迄今，產品輸日辦理品質管理系統(QMS)文件資料之實務作業疑義或回饋意見。如有相關疑義或意見，請於旨揭期限前提供本署，俾利後續提供日方參考。

三、旨揭問答集已公布於本署網頁(網址：http://www.fda.gov.tw)下之「業務專區>醫療器材>醫療器材製造業者品質管理系統(QMS/QSD)檢查專區>醫療器材(QMS/QSD)相關

公告>公告」，供業者自行下載參考。

正本：中華民國全國工業總會、中華民國全國商業總會、中華民國儀器商業同業公會全國聯合會、中華民國醫療器材商業同業公會全國聯合會、臺中市儀器商業同業公會、臺北市儀器商業同業公會、台南市直轄市醫療器材商業同業公會、臺南市儀器商業同業公會、台灣生物產業發展協會、台灣醫療器材門市發展協會、社團法人中華無菌製劑協會、桃園市進出口商業同業公會、桃園市醫療器材商業同業公會、財團法人生物技術開發中心、財團法人金屬工業研究發展中心、財團法人塑膠工業技術發展中心、財團法人台灣商品檢測驗證中心、財團法人工業技術研究院量測技術發展中心、財團法人醫藥工業技術發展中心、財團法人醫藥品查驗中心、高雄市直轄市醫療器材商業同業公會、高雄市進出口商業同業公會、高雄市儀器商業同業公會、高雄市醫療器材商業同業公會、新北市進出口商業同業公會、新北市醫療器材商業同業公會、新竹市儀器商業同業公會、嘉義市醫療器材商業同業公會、彰化縣醫療器材商業同業公會、臺中市進出口商業同業公會、臺中市醫療器材商業同業公會、臺北市日僑工商會、台北市進出口商業同業公會、臺北市醫療器材商業同業公會、台南市進出口商業同業公會、臺南市醫療器材商業同業公會、臺灣先進科技醫療發展協會、臺灣省進出口商業同業公會、臺灣科學工業園區工業同業公會、台灣顯示器產業聯合總會、臺灣醫療暨生技器材工業同業公會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、中華民國眼鏡發展協會、台灣牙科器材同業交流與公益協會、美國在台協會、歐洲在臺商務協會、美國商會醫療器材委員會、桃園市儀器商業同業公會

副本：

署長 吳秀梅

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(16 October 2020)

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