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主旨：「臺日醫療器材品質管理系統合作備忘錄之實施內容」，業經本部於107年12月07日以衛授食字第1071107250號公告，並載於本部食品藥物管理署網頁(網頁:http://www.fda.gov.tw)「公告資訊」，請轉知所屬會員辦理，請查照。

正本：台灣醫療暨生技器材工業同業公會(不含附件)
副本：

台灣醫療暨生技器材工業同業公會
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部長陳時中

2018.11

Question & Answer for Challenges in Product Registration Process for Medical Device in Taiwan and Japan.

Product Registration WG

This Q&A was made for better understanding of regulations and product registration process in Taiwan and Japan.

Taiwan to Japan

Q1.
Are all medical device standards included in JIS harmonized with ISO/IEC? If not, will Japan accept a test report which complied with ISO/IEC but not JIS?

A1.
Some of the JIS standards for medical devices are not harmonized with ISO/IEC, however PMDA accepts a test report complied with ISO/IEC if the applicant shows the applicability.

Q2.
The English information on MHLW or PMDA website is insufficient such as JMDN, product standards, revised regulations update. Will the information on the websites updated real-time?

A2.
The Japanese contents of PMDA website is translated and transferred to the English website in order of priority. Especially, the highest priority information such as safety information is immediately translated and published on the PMDA website.

As for the standard related English information such as Japanese Medical Device Nomenclature (JMDN) or Certification/Approval Standard are uploaded on the standard specific PMDA website below. Please refer to these information as appropriate.

Standard for Medical Devices
http://www.std.pmda.go.jp/stdDB/index_e.html

Q3.

Please provide the product registration processes and documents which shall be submitted for registration of medical devices.

A3.
Please refer to the attached material.
You can find formats for application in the link below (Japanese only)

https://www.pmda.go.jp/review-services/drug-reviews/procedures/0004.html

Q4.
What are the agency for product registration and certification approval of class A to class D medical devices?

A4.
In Japan, medical devices are classified into 4 categories, Class I to IV, based on the GHTF risk based classification. As for the class I devices, any certification or approval for product registration is not needed but submission of self-notification of the product to PMDA is required. As for the Class II and Class III medical devices which meat Japanese Certification Standards can go to the Third Party Certification Process (review and certificate by Registered Certification Body). Other medical devices including Class IV medical devices need to be submitted to PMDA for review and then approved by MHLW.

Foreign manufacturers can directly submit their application to PMDA or Registered Certification Body, but in any case they should designate Marketing Authorization Holder located in Japan.

Please refer to the attached material.

Basic concept for Approval and Certification for Medical Devices
http://www.std.pmda.go.jp/stdDB/index_e.html

List of Registered Certification Body
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/touroku/index.html

Q5.
How to define a predicate and brand new medical device in Japan?

A5.
Brand new medical devices means devices whose structure, method of operation, intended use or effect is apparently different from approved medical device (predicate device) in Japan.

To find the approved medical device in Japan, please refer to Q6.

Q6.
What kinds of medical devices should perform clinical tests in Japan and would Japan accept the clinical research report performed outside of Japan?

A6.
There is no specific list of devices which are required to submit clinical trial data for approval. It depends on the novelty and risk of the device.

Data obtained from foreign clinical trial can be accepted if the trial was conducted with GCP requirement which is essentially equivalent to J-GCP and if there are no such different in medical environment or ethnic variation that affects the outcome of the clinical trial data.

In some case, utilizing the PMDA's consultation for development and conducting risk benefit analysis including post market phase, clinical trials in Japan can be committed if the trial is to evaluate conformity to the Japanese medical environment or whose additional clinical value is relatively small and risk is assumed to be not big.

Q7.
Is there any simplified process in reviewing the preclinical tests in Japan?
For example, if a device made of metal which is widely used in medical device and for a long time, TFDA accepts the COA which complied with international standards, such as ASTM, to instead of biocompatibility evaluations.

A7.
Also in Japan, some of the pre-clinical tests including biocompatibility tests can be omitted if applicant can show the identity of the raw material to the approved medical devices. Please note, even if raw material is the same, in the case manufacturing process is different and it would affect the safety or effectiveness of the device, additional pre-clinical tests may be required.

Q8.
How can we find the medical devices which approved by MHLW? In Taiwan, TFDA provided a database for people to find the approved medical devices in Taiwan.

A8.
PMDA is providing approval/certification information of certain medical devices on the webpage below. Please refer to these information as appropriate.

List of approved new and improved (with clinical data) medical devices
https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0001.html

List of medical devices certified by registered certification bodies (most of them are Class II medical devices)
https://www.pmda.go.jp/files/000210041.pdf (in Japanese)

You can find the labeling of all class IV medical devices in the link below. For other medical devices, manufacturers are encourage to register the labeling of their devices to the same PMDA site. (Japanese Only)
https://www.pmda.go.jp/PmdaSearch/kikiSearch/

Q9.
Is there on line system for industries to find the real-time status of applications?

A9.
If the application is submitted via FD application system, applicant see the real-time status of the review on the MHLW webpage below. (only Japanese)

https://web.fd-shinsei.go.jp/examination/device/index.aspx

Q10.
Where can the industries find the registration fee?

A10.
You can find the user fee in the MHWL webpage as well as PMDA webpage below. (only Japanese)

https://web.fd-shinsei.go.jp/application/list_device2.html

https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html

You can find the English list of the user fee in PMDA Annual report but please note the data will be one year behind.

https://www.pmda.go.jp/english/about-pmda/annual-reports/0001.html

Q11.
Should the submitted documents be written in Japanese or does Japan accept the English documents? Ex.: Preclinical test reports

A11.
Application Form and STED should be written in Japanese but test data report including pre-clinical test and clinical test can be submitted in English.

Japan to Taiwan

Q1.

When trying to register OEM (original equipment manufacturer) products, it is required by TFDA to submit the Export Certificate (which corresponds to the Free Sales Certificate in Taiwan) stating relationship between outsourcing company (Marketing Authorization Holder: MAH) and commissioned company (manufacturer) with the names of those companies.

However, the Export Certificate format which Japanese MHLW issues doesn't have a field to state it.

Does TFDA accept additional documents which shows such relationship?

A1.

According to Article 7 of Regulation for Registration of Medical Devices, if an imported medical device is commissioned to be manufactured, the FSC (the Export Certificate) are allowed to be issued by respective highest health competent authority of the country either of the outsourcing company and commissioned company.

Practically, the name and address of the outsourcing and commissioned company can be stated in the FSC (the Export Certificate) which Japanese MHLW issues. Besides, the relationships can be demonstrated by the contract for manufacturing signed by the two companies.

*As for OEM products, the name and address of MAH and manufacturers can be stated in the Export Certificate issued by Japanese MHLW.

Q2.

When the name of manufacturing site changed because of company split-up and submitting for change-name application, documents describing the reason for name change is required by TFDA.
Who should be the responsible writer of such document? Parent company or subsidiary company?

A2.
The statement for changing manufacturer's name should be issued by the parent company.

Q3.

When trying to register products under Regulation for Registration of Medical Devices Article 12,

1) sometimes it's difficult to get the FSC with the product brand name from FDA or European regulatory agency.

2) sometimes the name of product is differ in the marketed countries even the product is exactly the same.

What is the acceptable way to show the identity when the name is different?

A3.

If a medical device is going to be registered according to article 12 of the Regulation for Registration of Medical Devices, the product's brand name of the FSC (the Export Certificate) issued by MHLW should be the same as the CFG issued by the government of USA and the government of EU members or other competent authorities.

If the brand name is different due to marketing strategy, TFDA would accept it if the Japanese and overseas brand name are stated alongside in the FSC (the Export Certificate) issued by MHLW like below.

Brand name in Japan (Brand name overseas).

* The Japanese and overseas brand name can be stated alongside in the Export Certificate issued by MHLW if the MAH submits the Notification for Exporting Medical Devices to MHLW. Furthermore, the overseas brand name stated in the Export Certificate should be same as the name stated in the Notification for Exporting Medical Devices.

Q4.

What is the regulation in Taiwan about manufacturing sites which is only responsible for putting labels on the products?
In Japan, such manufacturing site doesn't have to be registered as manufacturer. So it is impossible to submit the Japanese certificate of registration of such sites.

A4.
Putting label is a part of manufacturing processes. For imported products, the applicants could list the putting label site in section 3.4 (Manufacturing procedures that require contract manufacturing, including packaging, sterilization, etc.) of the "Quality System Documentation (QSD)" application form.
But it is not required to fill the ISO 13485 or GMP/QSD qualification number in the space for registration number in section 3.4 if the manufacturing site doesn't have the number.

Q5.
In Japan, often MAH responsible for premarket approval is different to the actual manufacturer.
Certificate of approved products issued by MHLW contains information about MAH and the product but not actual manufacturer.
Certificate of registered manufacturer issued by MHLW doesn't contain information about the product.
What kind of document does TFDA accept to show the relationship among MAH, manufacturer and product?

A5.
According to Regulation for Registration of Medical Devices, the FSC (the Export Certificate) shall be included in the submitted documents. To show the relationship, the FSC (the Export Certificate) is required to contain information about the name and address of both MAH and manufacture. The Certificate of approved products and Certificate of registered manufacturer are not necessary.

Q6.

What kind of documents can be accepted by TFDA to prove the location of the manufacturing site is not changed when the address of manufacturer changed because of annexation of cities?

A6.

Firstly, your representing agent in Taiwan needs to apply for a Quality System Documentation (QSD) letter of new address issued by TFDA.

With it and other documents mentioned by Article 28 of Regulation for Registration of Medical Devices, the application file will be completed. Documents for change in address of manufacturing factory including:

1. Application form;
2. Original copy of medical device license;
3. Original copy of statement issued by the manufacturer for changing the address;
4. Original copy of Letter of Authorization issued by the manufacturer;
5. Copy of Quality System Documentation (QSD) letter issued by TFDA;
6. Original copy of certification issued by government and notarized by R.O.C (Taiwan) foreign affairs office in Japan

Q7.

The name of manufacturing site is stated in the Export Certificate issued by MHLW while sometimes the name of division is also stated in the ISO13485 certificate.

In such case, what kind of additional documents does the applicant should prepare to show the identity of these two names?

A7.

If the manufacturer name is different between the FSC (the Export Certificate) and ISO 13485 certificate due to the name of division, TFDA accepts the statement issued by the manufacturer.

Q8.

What are the points to consider when there are multiple manufacturing sites involving in the same process?

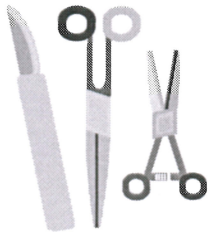
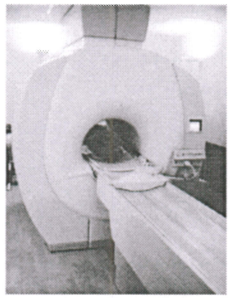
A8.

The actual manufacturer must be responsible for the full quality management system. Generally speaking, if a manufacturing process involves multiple sites, the actual manufacturer is the site which supervises the whole quality system and carries out the final QC and product releasing in most of the time.

In general, if the MAH holds a full quality management system which meets the regulation, Good Manufacturing Practices for Medical Devices, and each contract manufacturer is managed under it, the MAH can be considered a legal manufacturer. The QC of each manufacturing site should be recorded in the QMS of MAH, it's not required for the medical device registration. Only final QC of the finished product is needed for registration. (Note: the assembly, packing and sterilization sites should be noted in section 3.4 (Manufacturing procedures that require contract manufacturing, including packaging, sterilization, etc.) of the "Quality System Documentation (QSD)" application form.)

If you are not sure whether your case meets these requirements, please contact TFDA.

Overview of Medical Device Regulation

Classification (based on GHTF classification rule)	Class I	Class II	Class III	Class IV
	Extremely low risk	Low risk	Medium risk	High risk
Example	X-Ray film 	MRI 	Dialyzer, Artificial bone	Pacemaker, Artificial heart valve
Category	General MDs	Controlled MDs	Specially controlled MDs	
Review regulation	Self-declaration	Third party <u>certification</u>	Minister's <u>approval</u> (PMDA's review)	
Post-market safety vigilance/surveillance	PMDA and MHLW Outcome examination, AE reporting, Researches, etc.			

Scope of regulations on medical device/IVD marketing in Japan under the PMD Act

Product

Minister's Approval for marketing
or Certification by a Registered Certification Body
or Marketing Notification

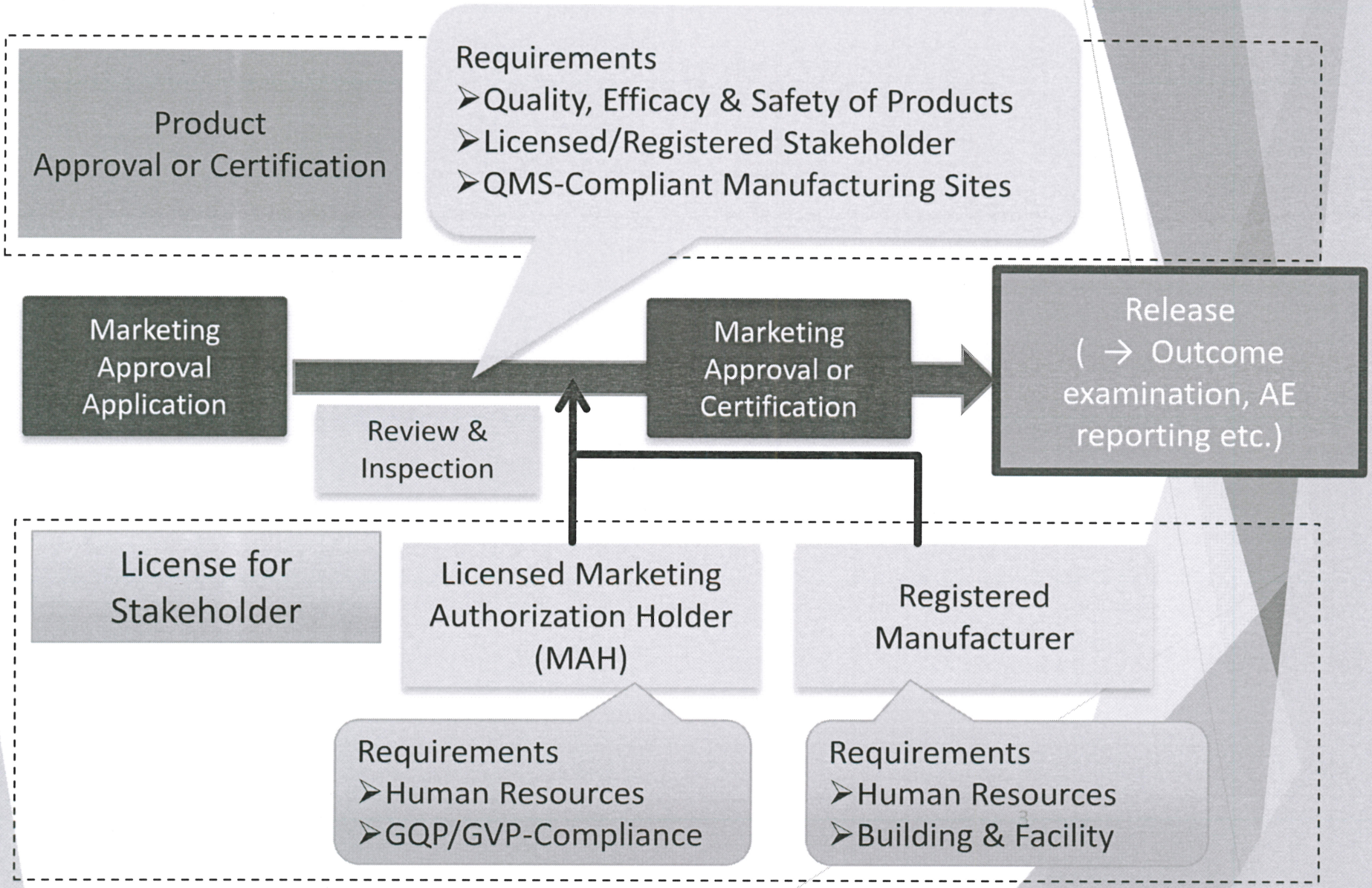
Company

License of Marketing Authorization Holder (MAH)

Plant

Registration as a Manufacturer

Approval/Certification and license system



Regulations and Approval/Certification Process of Medical Devices

- There are two regulatory authorities responsible for regulation of medical devices in Japan, MHLW (Ministry of Health, Labour and Welfare) and PMDA. MHLW is responsible for the administrative actions such as guidance or decision of product approval pursuant to the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices (hereinafter, PMD Act) as well as judgment on whether or not the product is considered as medical devices, while PMDA undertakes application review and post-market safety measures based on the relevant data.

  < PMD Act >

  http://www.japaneselawtranslation.go.jp/law/detail/?id=2766&vm=04&re=02&new=1

- In Japan, medical devices are classified into four classes based on the risk level; Class I (Extremely low risk), Class II (low risk), Class III (medium risk) and Class IV (high risk). In order to market medical devices in Japan, a foreign manufacturer has to obtain approval/certification or submit notification, depending on the classification, pursuant to PMD Act, through a Japanese Marketing Authorization Holder (MAH) or a Japanese manufacturer appointed by such foreign manufacturer. Required procedures for each device classification are shown below.

  Class I devices:
  Notification to PMDA

  Class II devices
  - for those certification standards exist:
    Certification by registered certification body

  - other Class II devices:
    Approval of MHLW

  Class III devices
  - for those certification standards exist:
    Certification by registered certification body

  - other Class III devices:
    Approval of MHLW

  Class IV devices:
  Approval of MHLW

Regardless of the Class of the medical device, the MAH of such device must ensure efficacy, safety and quality thereof based on the evidence before submission.

- For devices that require "Certification by registered certification body", the product must be certified by a Registered Certification Body.

  List of Registered Certification Bodies (available only in Japanese):
  http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/touroku/index.html

- For devices that require "Approval of MHLW", PMDA will verify scientific evidences in the review. Regulatory requirements of individual products are assessed on a case-by-case basis and answered in PMDA's consultations (fees applicable).

  If you seek an opinion from us Japanese regulatory authority regarding necessary regulatory procedures for your product requiring approval of MHLW, we would advise you to make product-specific information available and apply for PMDA's consultations.

  Http://www.pmda.go.jp/english/review-services/consultations/0002.html
  http://www.pmda.go.jp/review-services/f2f-pre/consultations/0003.html
  (only in Japanese)

  Consultation service on R&D or regulatory submission involves consultation fee, but what can be discussed in such consultations may be clarified free of charge in a pre-consultation meeting.

  Consultation fees and other user fees are shown in Table 13 of PMDA's Annual Report. Please note that fees may be changed without notice.
  http://www.pmda.go.jp/files/000221481.pdf

  If you intend to enter into Japanese market, we strongly recommend you to appoint a Japanese MAH and have PMDA's consultation service by the intermediary of such MAH. When you are requesting the free pre-consultation meeting only, accompanying an interpreter instead of the appointed Japanese MAH may be acceptable.

Scope of approval/certification of medical devices and basic rules of evaluation criteria for medical devices are provided in the following web page (available only in Japanese);
http://www.pmda.go.jp/review-services/drug-reviews/about-reviews/devices/0004.html