Progress of Product Registration Working Group

藥求安全　食在安心

Ta-Jen Wu

Product Registration WG

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衛生福利部食品藥物管理署

Food and Drug Administration,
Ministry of Health and Welfare

http://www.fda.gov.tw/

Members of PR Working Group

Taiwan	
Ms. Ting-Yao Wu	Section Chief, Division of Medical Devices & Cosmetics, Food and Drug Administration, Ministry of Health and Welfare
Dr. Ta-Jen Wu	Technical Specialist, Division of Medical Devices & Cosmetics, Food and Drug Administration, Ministry of Health and Welfare
Dr. Han-Son Dawn	Regulation Director, Taiwan Medical and Biotech Industry Association
Mr. Tzu-Wei Li	Industrial Technology Research Institute

Japan	
Dr. Madoka Murakami	Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA)
Mr. Daisuka Koga	Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA)
Mr. Hirokazu Takahashi	Regulatory System Committee, Japan Federation of Medical Devices Associations (JFMDA)
Mr. Makoto Yokote	Asia Subcommittee, Japan Federation of Medical Devices Associations (JFMDA)

Overview

1. **Product Registration(PR) WG**
2. Regulations on Product Registration in Taiwan
3. Regulations on Product Registration in Japan
4. Reviewing Comparison between Taiwan and Japan

Product Registration Working Group

- **Goal:**
  1. Share the reviewing experiences between Taiwan and Japan
  2. Mutual understanding

- **Members:**

  Taiwan: Ting-Yao Wu, Ta-Jen Wu, Han-Son Dawn, Tzu-Wei Li

  Japan: Madoka Murakami, Daisuke Koga, Makoto Yokote, Hirokazu Takahashi

Comparison items

- **Proposed items** (in the beginning)

  Taiwan: Dental Implants、Transcutaneous electrical nerve stimulation (TENS)

  Japan: Hemodialyzer、Infusion Pump

- **Comparison items** (concerning the time limit and manpower)

  Dental Implants (Taiwan) & Hemodialyzer (Japan)

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Regulations of Product Registration in Taiwan

- **Pharmaceutical Affairs Act**
  - For the manufacturing and import of medical devices, an application together with fees paid, shall be filed with the central competent health authority for registration and market approval.
- **Regulation for Registration of Medical Device**
  - Revision is announced on Sep., 2014. The STED documents are mandatory for Class III Products.
- **Regulation for Governing the Management of Medical Device**

Risk Based Regulation

GMP/QSD

Class 1

affidavit

On-site registration

GMP/QSD

Class 2

Technical Document

Preclinical testing and QC documents can be waived if with both EU and US marketing approval.

GMP/QSD

Class 3

Technical Document

Preclinical testing, QC documents and Clinical trial reports

3 Classes

Documents required for Registration

QSD: Quality system documentation

■ **More than 1700 regulated medical device items in Taiwan**

Before Marketing a Medical Device Product in Taiwan

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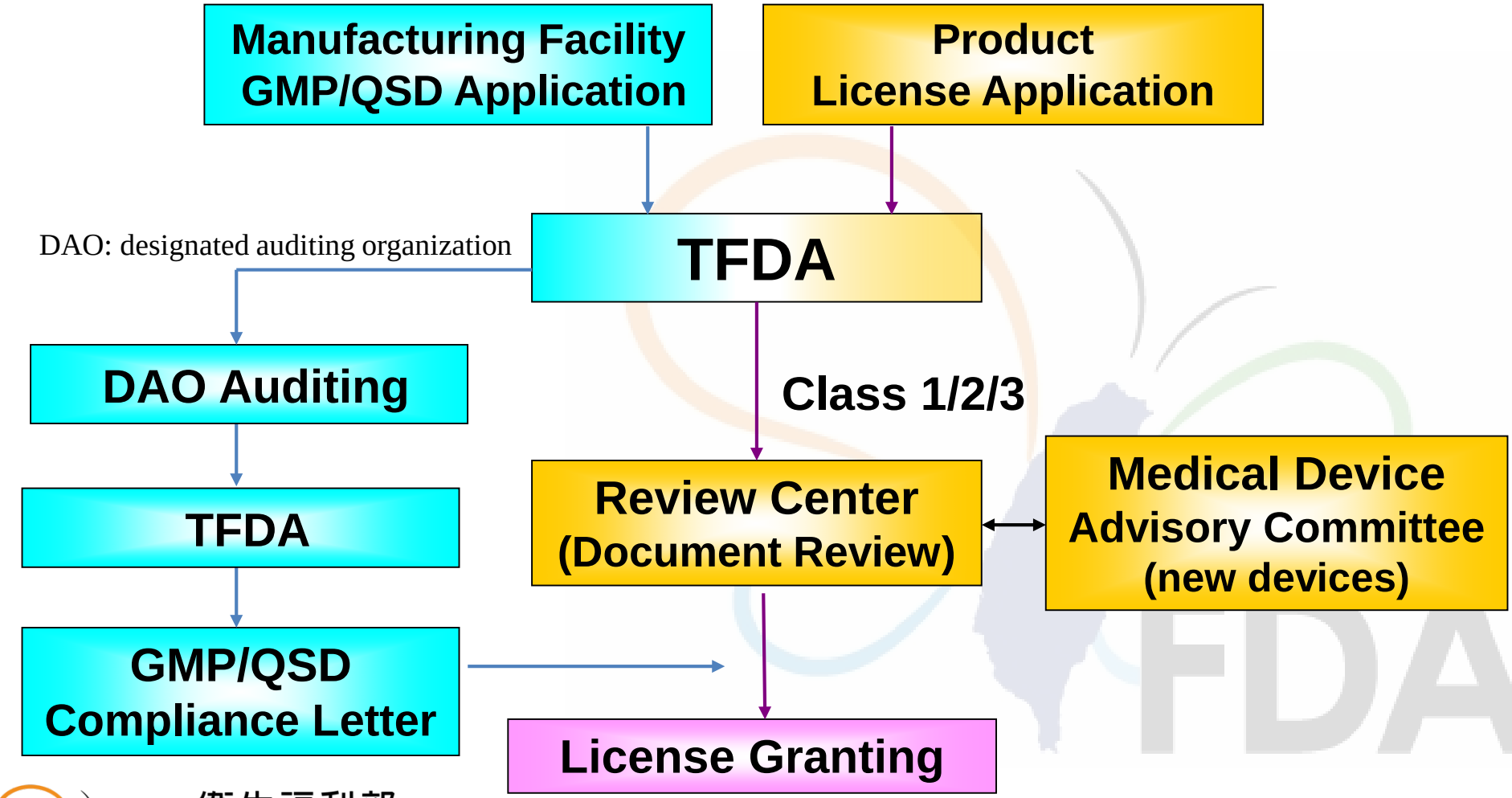

Class I Device Submission

(Over-the-counter registration)

Submission

Registration fee

TFDA

Issue certifications

1. Application form
2. Copy of pharmaceutical distributor/manufacturer license
3. Truth and Accuracy statement (made by applicant)
4. Registration fee

Class II/III Submission

1. **Application form**
2. **Administrative documents:** Copy of pharmaceutical distributor/ manufacturer license, Free-sale certification, Letter of authorization, GMP/QSD certification and etc.
3. **Technical documents:** Construction, Material, Specification, Intended use, Drawing, Preclinical evaluation, QC records and etc.
4. **STED documents** (Only for Class III medical devices since 5 Sep., 2014)
5. **For device with no similar product been registered in Taiwan**: may need scientific theory, research report, safety evaluation and clinical investigation report.

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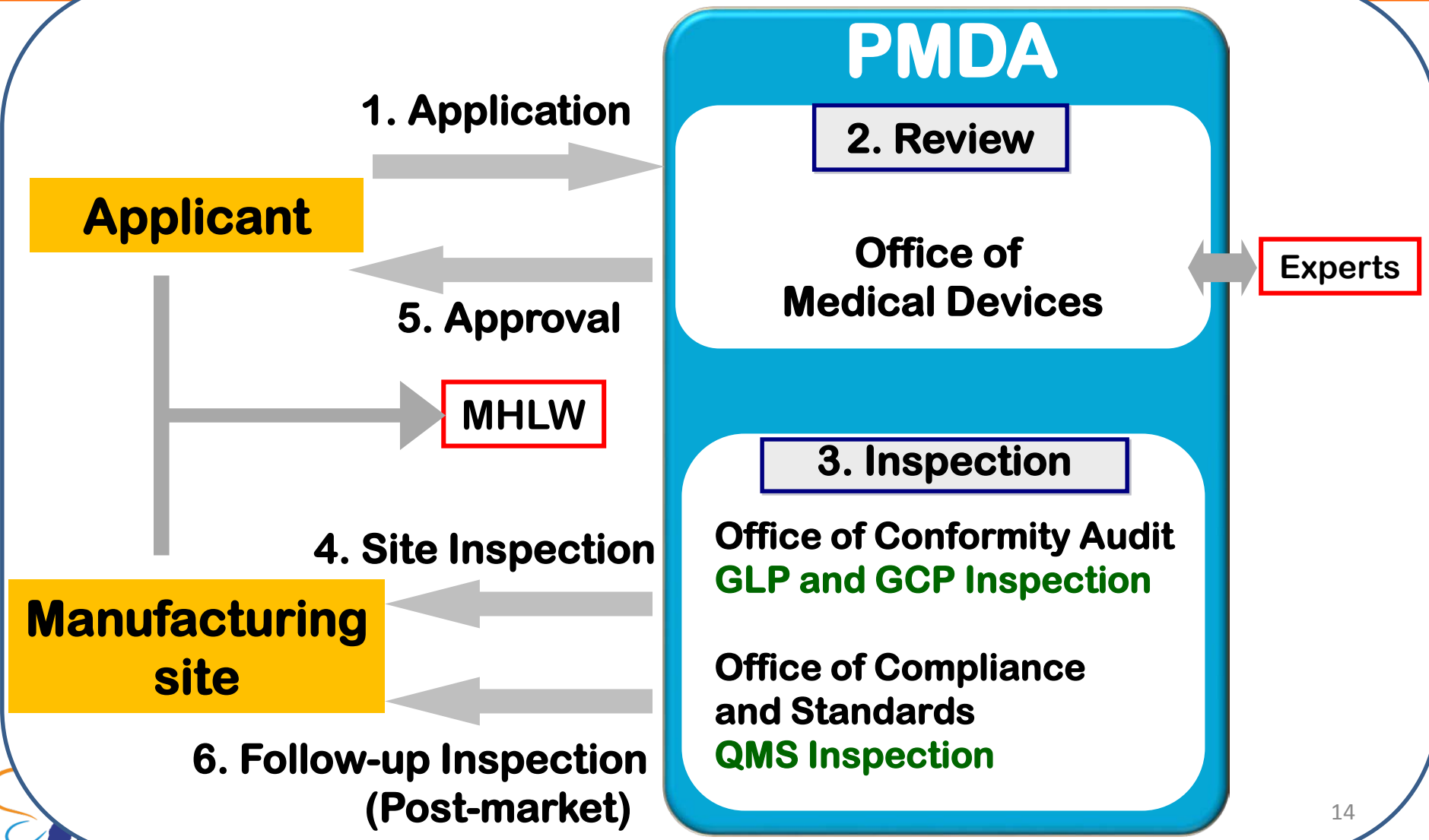
Overview of Classification and Pre-market Regulation for Medical Devices

		Approval		Certification
Reviewed(certificated) by		PMDA		Registered certification bodies
Essential principles		Based on the Pharmaceutical Affairs Law		
Classification	Class I	Self-declaration, no approval/certification required		
	Class II	No certification standards/ unadaptable to any standards		Certification standards adapted
	Class III	Approval standards and Review guidelines	No approval standards or Review guidelines	
	Class IV			
Application dossier		STED & Support data		STED

STED: summary of the technical document
MAH :Marketing Authorization Holder

Overview of review process



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Comparison of Dental Implants

Items	Taiwan	Japan
1. Classification	Class III	Class III
2. Application Documents	Almost the same	
3. STED documents	Almost the same	

Items	Taiwan	Japan
4. Administrative Information	(1) Pharmaceutical Company License or Certificate (2) Affidavit A (3) Certificate to Foreign Government (only for foreign manufacturers) (4) Letter of Authorization (only for foreign manufacturers) (5) Certificate of GMP for domestic or QSD for foreign manufacturers	Documents are not required but information such as name/location of manufacturer, license number for manufacturer, classification of license are required to be written in application document

Items	Taiwan	Japan
5. Requirement of Technical Standard for Approval	The requirements of technical standard are almost the same besides	
	"Compatibility between Fixture and Abutment" and "Static Strength & Shear Bonding Strength" are required for TFDA.	"Compatibility between Fixture and Abutment" is required but "Static Strength & Shear Bonding Strength" are not in Japan. For product using ceramics or polymer, bending test is required.
	Not necessary	"Degradability and Solubility" and "Water Absorbency" are required for MHLW/PMDA.
6. Clinical investigation	Almost the same	

<table>
<tr><th>Items</th><th>Taiwan</th><th>Japan</th></tr>
<tr><td rowspan="2">7. Biological Evaluation of Medical Devices</td><td colspan="2">The Biological Evaluation are almost the same besides</td></tr>
<tr><td>Not necessary</td><td>“使用模擬試験(Stimulation test)" is required for MHLW/PMDA.</td></tr>
<tr><td>8. Others</td><td>For products less than 3.25 mm in diameter or less than 7 mm in length, the intended use shall be limited to "maxillary central/lateral incisors".</td><td>For products out of scope in the chart below, additional evaluation will be required.
<table><tr><th>Size</th><th>One-piece</th><th>Two-piece</th></tr><tr><td>Maximum Diameter</td><td>3.0-6.0mm</td><td>3.0-7.0mm</td></tr><tr><td>Length</td><td>13.5-23.8mm</td><td>6.0-22.0mm</td></tr></table>note: two-piece products less than 3.8mm in diameter and less than 6.25mm in length are excepted from the chart</td></tr>
</table>

Comparison of Hemodialyzer

Items	Taiwan	Japan
1. Classification	Class II	Class III
2. Application Documents	Almost the same	
3. STED documents	(1)STED is mandatory only for Class III Products in TFDA. All technical information/ documents including device description, materials, safety, sterilization, design verification and validation are also required for TFDA. (2)“Essential Principles” and “Risk analysis” are not required for Hemodialyzer.	STED documents are necessary.

Items	Taiwan	Japan
4. Administrative Information	(1) Pharmaceutical Company License or Certificate (2) Affidavit A (3) Certificate to Foreign Government (only for foreign manufacturers) (4) Letter of Authorization (only for foreign manufacturers) (5) Certificate of GMP for domestic or QSD for foreign manufacturers	Documents are not required but information such as name/location of manufacturer, license number for manufacturer, classification of license are required to be written in application document

Items	Taiwan	Japan
5. Requirement of Technical Standard for Approval	Almost the same	
6. Clinical investigation	Almost the same	
7. Biological Evaluation of Medical Devices	The requirements of biological evaluation of Hemodialyzer are almost the same besides	
	"Implantation", "Chronic toxicity", "Carcinogenicity" and "Chemical analysis of potential leachable" tests are required for TFDA.	“Cytotoxicity”, “implantation”, “sensitization”, “pyrogen”, “intracutaneous reaction”, “acute toxicity”, “subacute toxicity”, “genetic toxicity”, “hemocompatibility” are required to be evaluate.

THANK YOU FOR YOUR ATTENTION!!

歡迎至本署網站查詢更多資訊 http://www.fda.gov.tw/