Progress of Product Registration Working Group

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Product Registration WG
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Product Registration Working Group

Goal:

1. Share the reviewing experiences between Taiwan and Japan 【分享彼此審查經驗】
2. Develop mutual understanding 【加強相互了解】

Reasonable Pre-Market Review

Achievement of 2014 - 2016

- Comparison of Regulation on Medical Device Product Registration
- Comparison of Review Requirements for Dental Implant and Hemodialyzer
- Case Study for Dental Implant

Members of PR Working Group

Taiwan	
Ms. Nu-Ching Lin	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. Hirokazu Takahashi	Regulatory System Committee, Japan Federation of Medical Devices Associations (JFMDA)
Mr. Makoto Yokote	Asia Subcommittee, Japan Federation of Medical Devices Associations (JFMDA)

Today's Agenda

1. **Medical Device Regulations and Regulatory Update**
2. **Progress of PR WG**
3. **Next Step**

1. Medical Device Regulations and Regulatory Update

Comparison of Medical Device Regulations

	Taiwan	Japan
MD Classification	Class I-III based on risk classification	I – IV based on GHTF risk classification
Generic Name	Based on Regulations for Governing the Management of Medical Device	JMDN based on GMDN
Premarket Approval Process	Class I: over-the-counter registration Class II, III: TFDA review and approve	Class I: Self notification Class II, III with CS*: 3rd Party Certification (incl. QMS Inspection) Others including Class IV: Minister's authorization with PMDA' review/QMS inspection
GCP Inspection	By TFDA before product registration application	By PMDA during approval review
QMS Inspection	By Authorized Auditing Organization (AAO) before product registration application	By 3rd Party or PMDA during approval review and periodically (5 year)
Document Reliability Check	None	Class I, Class II&III with CS: None Others including Class IV: by PMDA
Adverse Event Reporting	designated by announcement of the Ministry of Health and Welfare or other cases deemed applicable by announcement of the Ministry.	Mandate for all class MDs. Report to PMDA.

*CS: Certification Standard

Recent Topics on MDs in Japan

Guidance on selection of specimen for fatigue test regarding application for approval of dental implant

Published on March 23, 2017

1. Flowchart for determination of worst-case model used in fatigue test for dental implant (refers to ISO 14801:2016)

2. Evaluation of worst-case model determination by load value at starting point for plastic deformation
   1) Test Method: JIS T 6005 (ISO14801), JIS Z 2248 (ISO7438)
   2) Determination of load value at starting point for plastic deformation
      i) Visual observation method
      ii) Energy difference method

2. Progress of PR WG

Progress1: Regulatory Q&A (1)

The WG decided to create Q&As for better understanding of regulations and product registration process each side.

1. The WG group collected and compiled questions, from Taiwan to Japan and Japan to Taiwan
2. The regulators of the WG made answers to the questions
3. The Q&As will be published after this conference

Progress1: Regulatory Q&A (2)

List of Questions from Taiwan to Japan

Type	Taiwan to Japan
Regulations	Acceptance of ISO/IEC test report rather than JIS
	Availability of English information
Product Registration	Details of product registration process
	Agents for product registration
	Predicate MD and Brand new MD
	Clinical Trials
	Simplified process for preclinical Test
	List of approved MDs in Japan
	System for real time review status
	Registration fee
	Acceptance of reports in English

Progress1: Regulatory Q&A (3)

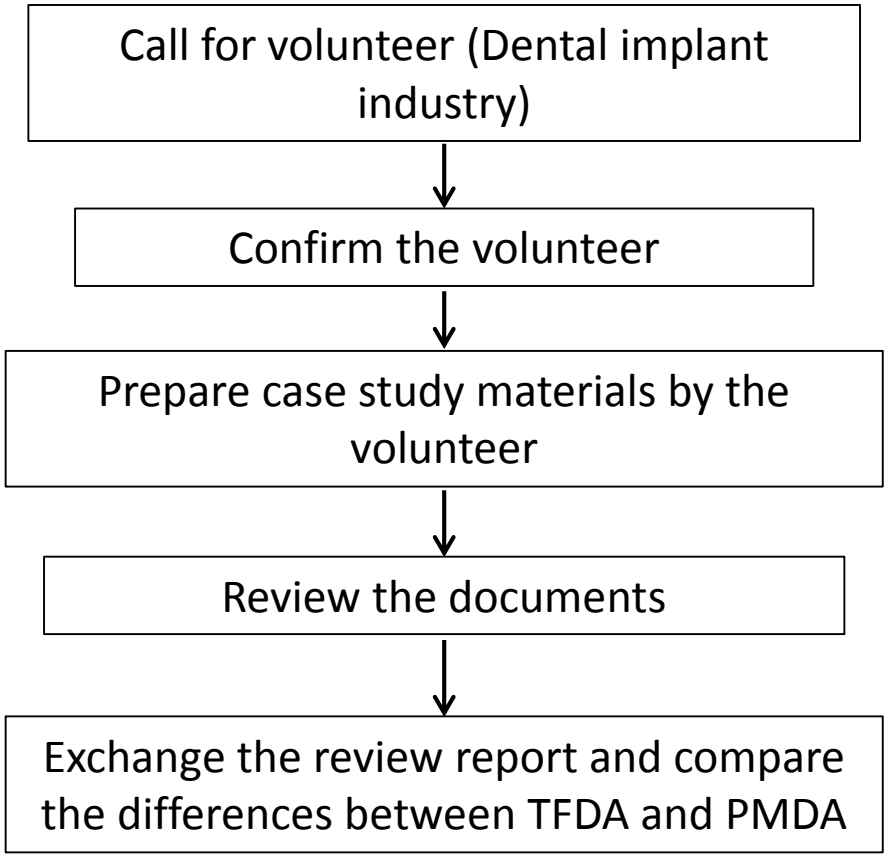
List of Questions from Japan to Taiwan

Type	Japan to Taiwan
Regulations	Regulation for labeling site
Product Registration	FSC for OEM products
	Change of name of manufacturing site
	Change of address of manufacturing site
	How to show the relationship between Marketing Authorization Holder, Manufacture and product
	Points to consider when multiple sites involve in the manufacturing
	Difference in granularity of names on ISO13485 and FSC
	Difference in brand name among regions

Progress2: Conduct of Second Case Study

- For further comparison of technical review between TFDA and PMDA, the WG decided to conduct the second Case Study on Dental Implant focusing on mechanical test.
- The materials for the case study was prepared by Taiwan side.

Workflow

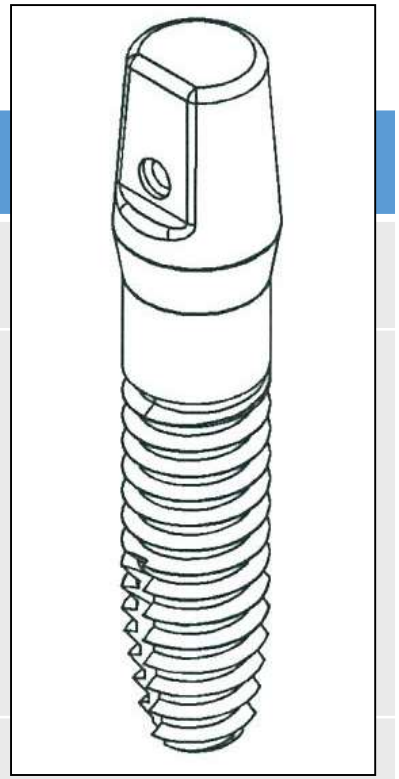


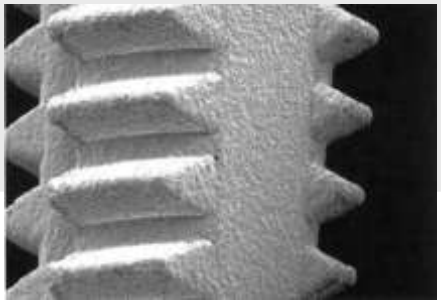
Case Introduction (1/2)

Items	Details
Device Description	1. one-piece implant 2. Indicated for implantation into upper or lower jaw to provide support for prosthetic devices (dental crowns and bridges) to replace missing teeth. 3. Not for immediate loading. 4. Sterilized by vapor steam in accordance with ISO 17665: 2006 5. Shelf Life: 3 years 6. Metal free and suitable for patients who have metallic allergy.

Case Introduction (2/2)

Items	Details
Material	Made of Zirconia
Specification	1. Diameter: 3.6、4.0、5.0 mm 2. Insertion length: 8.0 ~ 14.5 mm 3. Shoulder width: 4.1、4.8、6.0 mm
Surface	Sand-Blasted





Review Comparison (1/3)

Items	Taiwan	Japan
Material and structures	1. Surface processing does influence the fixation of the implant. 2. Details of surface processing method should be clarified. 3. Roughness after the processing also should be defined.	1. Details of sintering and surface processing method should be clarified 2. Roughness after the processing should be defined and compared to the existing device. In the case the roughness is significantly different with the existing device, further explanation or evaluation may be required.

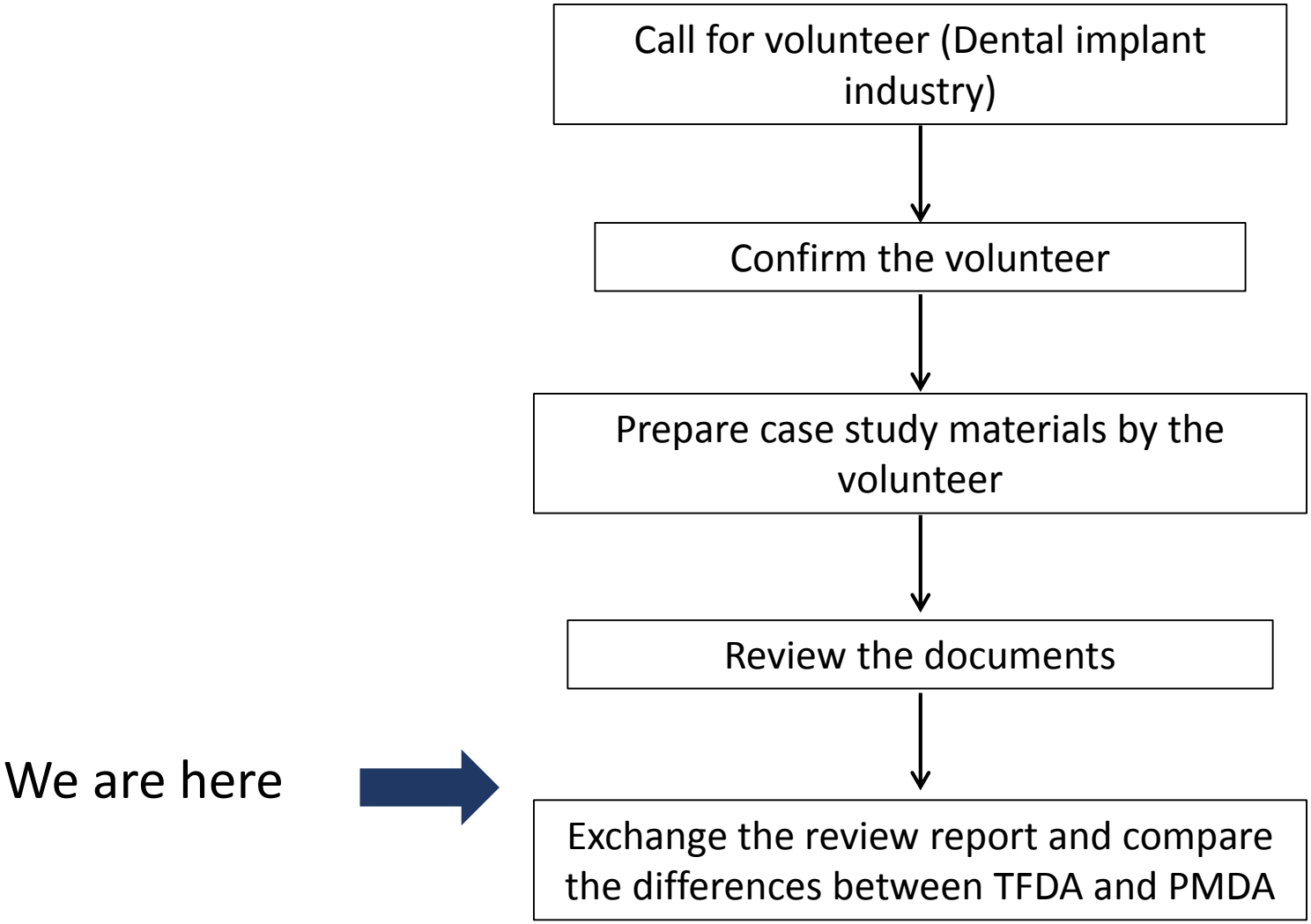
Review Comparison (2/3)

Items	Taiwan	Japan
Physical and chemical properties–For zirconia (Y-ZP) Ceramic Material	**Document:** Grain size、Amount of monoclinic phase & Accelerated aging amount of monoclinic phase、4-point bending & Accelerated aging 4-point bending、Radioactivity、Cyclic fatigue limit stress at 106 cycles. **Results:** According to ISO 13356 standards, test methods and acceptance criteria are mentioned in the report. **Findings:** No findings.	**Overview:** Physical and chemical properties of the device was evaluated in accordance with ISO 13356 and the results meet the acceptance criteria. **Findings:** no significant findings.

Review Comparison (3/3)

Items	Taiwan	Japan
Static & Fatigue test (ISO 14801)	**Document:** Implant-Dynamic Fatigue Test **Results:** Test methods and acceptance criteria are mentioned in the report. And acceptance criteria based on previous generation products. **Findings:** Did not evaluate whether the test sample is the worst case.	**Overview:** Apparently the tests was conducted using the worst case sample but there are no explanation. **Result:** The worst case sample should be stated by the applicant with scientific explanation.

Where we are: Second case study



3. Next Step

Next Step

1. Publication of Case Study 1 and 2
2. Finalization and publication of regulatory Q&As
3. Exchange of challenges during review between TFDA and PMDA/MHLW

多謝!!

Progress1: Publication of First Case Study

Product:

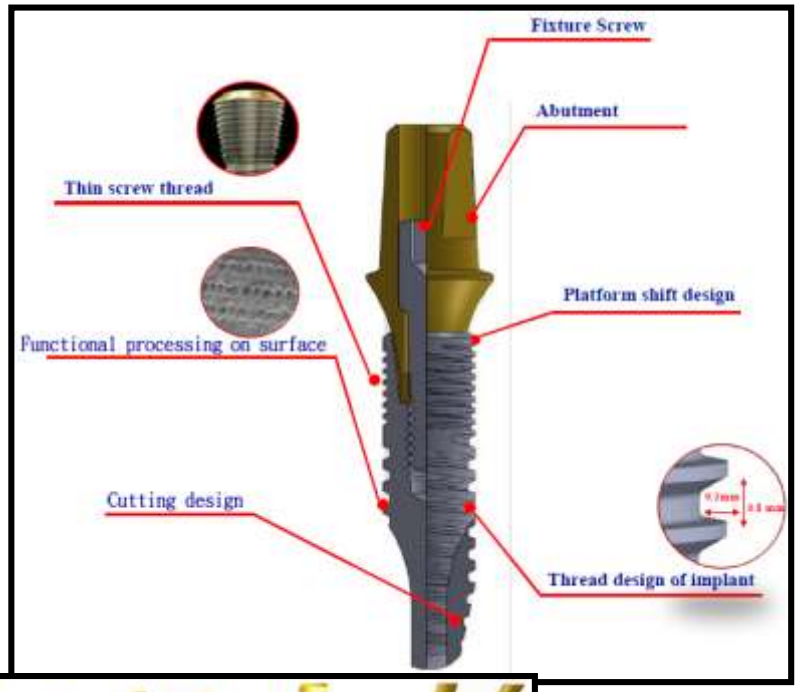
- Fixture Screw with abutment made from processed pure grade IV titanium

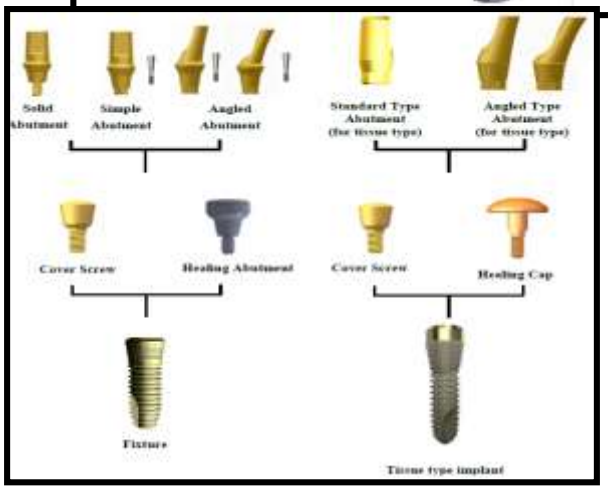
Review Comparison:

- Material and structure
- Biocompatibility tests
- Functional tests

Summary:

- There are no significant differences between TFDA and PMDA. Only few dissimilar findings existed in “Material and Structure” and “Functional tests” sections.





Review Comparison ?

Items	Taiwan	Japan
Shear (lateral) forces	Including the static & fatigue test	
Compatibility (w/ abutment)	Not applicable─one-piece implant	
Corrosion test	Not applicable─Metal free	

Recent Topics on MDs in Japan (1)

New regulation on Reprocessed Single Use Device (SUD)