6th Joint Conference of Taiwan and Japan on Medical Products Regulation

Progress of Product Registration Working Group

Ta-Jen Wu

TFDA

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Overview

1. Introduction of Product Registration(PR) working group
2. Outcome of PR working group in 2018
   - *Publish the past achievements and Q&A on TFDA and PMDA websites*
   - *Review concerns of Additive Manufactured Medical Devices*
3. Conclusion and future plan

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)

Product Registration Working Group

Goal：

1. Share the reviewing experiences between Taiwan and Japan
2. Develop mutual understanding
3. Reasonable Pre-Market Review to benefit both side industries

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Outcome of PR working group in 2018

- Publish the past achievements and Q&A on TFDA and PMDA websites.

TFDA Website:待填入

PMDA Website:待填入

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Regulatory update of Additive Manufactured Medical Devices in Taiwan

- TFDA announced the「Guideline for Additive Manufactured Medical Devices」on January 12, 2018.
- The purposes of this guideline are to provide reference for manufacturing industries on technical considerations specific to devices using additive manufacturing, to outline recommendations for testing and characterization for devices and to ensure safety and effectiveness of 3D-Printed MD under appropriate regulations.

Review concerns of Additive Manufactured Medical Devices in Taiwan (1/5)

- Additive Manufactured (AM) medical devices, also known as 3D Printed Medical devices, should generally follow the same regulatory requirements and submission expectations as the classification and/or regulation to which a non-AM device.

Review concerns of Additive Manufactured Medical Devices in Taiwan (2/5)

Material

- Starting Material:
  - Detail information should be documented for each starting material used
  - Any processing aids, additives, and cross-linkers used.
- Material Reuse:
  - Describe the material reuse process
  - Document evidence or provide a rationale that material reuse does not adversely affect the final device.

Review concerns of Additive Manufactured Medical Devices in Taiwan (3/5)

Process Validation

- Machine Parameters and Environmental Conditions:
  - Machine parameters should be documented
  - Machine should be qualified for use in its installation location
  - Document each critical manufacturing step in the printed process

Review concerns of Additive Manufactured Medical Devices in Taiwan (4/5)

Process Validation

- Post-Processing:
  - All post-processing steps should be documented
  - Discussion of the effects of post-processing on the materials used and the final device
- Non-destructive evaluation (NDE) and test coupon:
  - to ensure repeatability and consistency within a build cycle and across lots

Review concerns of Additive Manufactured Medical Devices in Taiwan (5/5)

Process Validation

- Removing Material Residues and Sterilization:
  - Validation of the reduction of the manufacturing material residue to levels that do not affect the safety and effectiveness of the device
  - Using final finished devices for assessment

Review concerns of Additive Manufactured Medical Devices in Japan (1/2)

Material

- Material reuse
  - Describing the reuse flow in the manufacturing method column of approval application form
  - Safety assessment of reuse
- Quality management for final products
  - Confirmation of chemical composition

Review concerns of Additive Manufactured Medical Devices in Japan (2/2)

Design

- Worst-case of the device shape
- Modeling precision
- Bone fixing performance (when reproducing the special surface shape by 3D printed)

Japan developed the evaluation guideline for 3D printed medical devices as evaluation index for next-generation.

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Summary

- Review concerns on material of 3D printed medical devices are almost the same.
- After discussion, the review points of process validation/design are similar between TFDA and PMDA.

Future Plan

- Sharing review experiences of cutting-edge technology to enhance both reviewer's capabilities.
- Continuous cooperation on product review to benefit both side industries.

Thank you for your attention!