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

Regulatory Progress of 3D Printing in Taiwan

Cheng-Wen Lan

Senior Reviewer,

Division of Medical Devices and Cosmetics

2018.10.11

衛 生 福 利 部
食品藥物管理署
FDA Food and Drug Administration

Outlines

- Brief Introduction of 3D Printing
- 《Guideline for Additive Manufactured Medical Devices》
  - Preface, Definitions & Scope
  - Design and Manufacturing Considerations
  - Device Testing Considerations

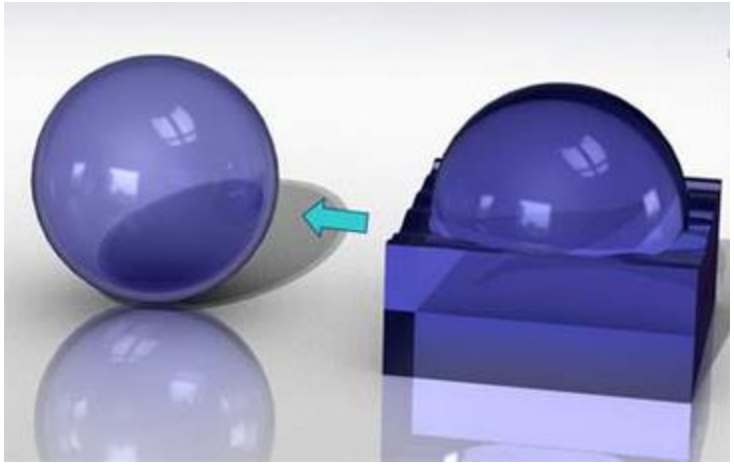
Brief Introduction of 3D Printing

Additive Manufacturing (3D Printing)

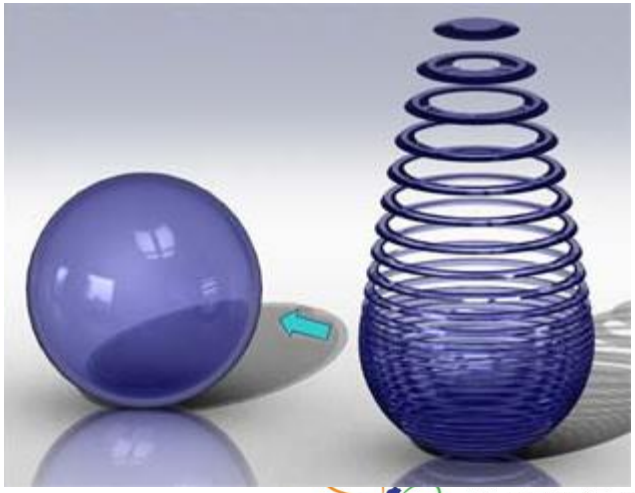
◆ Definition by ASTM ：

Additive manufacturing (AM), also known as 3D printing, refers to a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies.

Subtractive manufacturing



Additive Manufacturing



Ref：http://www.design.lth.se/english/the-department/research-laboratories/3dprintlab/additive-manufacturing/

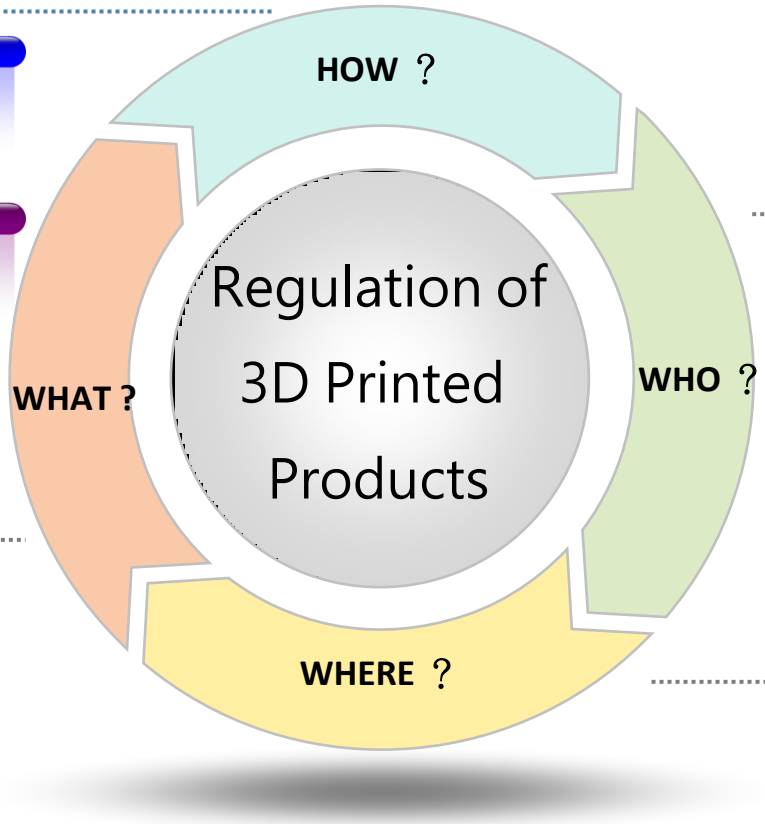
Regulation of 3D Printed Products

Terminology
- ISO/ASTM 52921-13
- ISO/DIS 17296-1
- ASTM F2792-12

Material and Processes
- ASTM F2924-14
- ASTM F3001-14
- ASTM F3049-14
- ASTM F3055-14
- ASTM F3056-14
- ASTM F3091/3091M-12

Testing Methods
- ASTM F2791-13
- ASTM F3122-14
- ISO/ASTM 52921-13

Data Formats
- ISO/DIS 17296-4; 2014
- ISO/ASTM 52921-13



- Printer manufacturer ?
- 3D model designer ?
- Device manufacturer ?
- Surgeon ?

- 3D-printer ?
- Anatomical models ?
- Software ?
- Medical Device ?

- Manufacturing site ?
- Hospital ?

Guideline for 3D Printed Products

- Announced 《Guideline for Additive Manufactured Medical Devices》 on January 12, 2018

- The purpose of this guideline

  --- to provide reference for manufacturing industries on **technical considerations** specific to devices using additive manufacturing (AM)

  --- to outline recommendations for **testing and characterization** for devices

  --- to ensure **safety and effectiveness** of 3D-Printed MD under appropriate regulations

《 *Guideline for Additive Manufactured Medical Devices* 》

-- Preface, Definitions & Scope

Preface

- AM devices should generally follow the **same regulatory requirements and submission expectations** as the classification and/or regulation to which a non-AM device of the same type is subject

Definitions - I

- Medical Software

The processing software in **collection, storage, analysis, display, conversion of information** regarding body conditions, vital signs and medical treatments. The device user entities include hospitals, residential users and long-range healthcare centers. The “Medical Software” administered under the Management of Medical Devices is referred to as a “Medical Device Software”.

Definitions - II

- Build Preparation Software

The software used to **convert the digital design** to a format that can be used to build a device or component through an Additive Manufactured process. This may include multiple software components.

- Design Manipulation Software

The computer program that allows a medical device design to be modified for specific circumstances. This may include multiple software components.

Definitions - III

- Additive Manufactured Machine

A portion of the additive manufacturing pipeline including **hardware, machine control software, required set-up software and peripheral accessories** necessary to complete a build cycle for producing parts*.

(* ISO/ASTM 52900 Additive manufacturing — General principles — Terminology)

Scope

- The AM medical devices mentioned in this guideline refers to the medical devices that are capable of **manufacturing by AM processes** within **pre-established device specifications**, and validating to ensure the consistency of quality that are manufactured under essentially the same conditions.

- This guideline does not address the use or incorporation of **biological, cellular, or tissue-based products** in Additive Manufactured.

Regulation for AM-Processes Associated Devices

- To determine if a AM-processes associated device is a medical device and hence should be administered accordingly, a comprehensive assessment of its functions, usages, operation methods, and working principles is required. The following principles could be beneficial to formulate the assessment:
  - Does the product comply with the definitions of medical device in **Article 13 of Pharmaceutical Affairs Act**?
  - Does the product comply with the specifications listed in **Annex 1 of Regulations for Governing the Management of Medical Devices**?
  - Potential hazards posed to human health
  - Guidance for Medical Software Classification (2015.04.13)

Regulation for AM-Processes Associated Devices

- Examples of regulation for AM-processes associated devices

	Medical Device	NOT Medical Device
Machine	Optical impression systems for CAD/CAM	Machines that are sorely limited to printing process
Software	Surgery planning software	• Teaching software • Build preparation software • Design manipulation software
Material	Materials that are met per Annex I of Regulations for Governing the Management of Medical Device	Raw material stock, manufacturing material for unspecified uses
Final Product	• Dental implants and prosthesis • Orthopedics implants and fixation orthosis • Surgical guide and surgical instrument	3D printed anatomic models

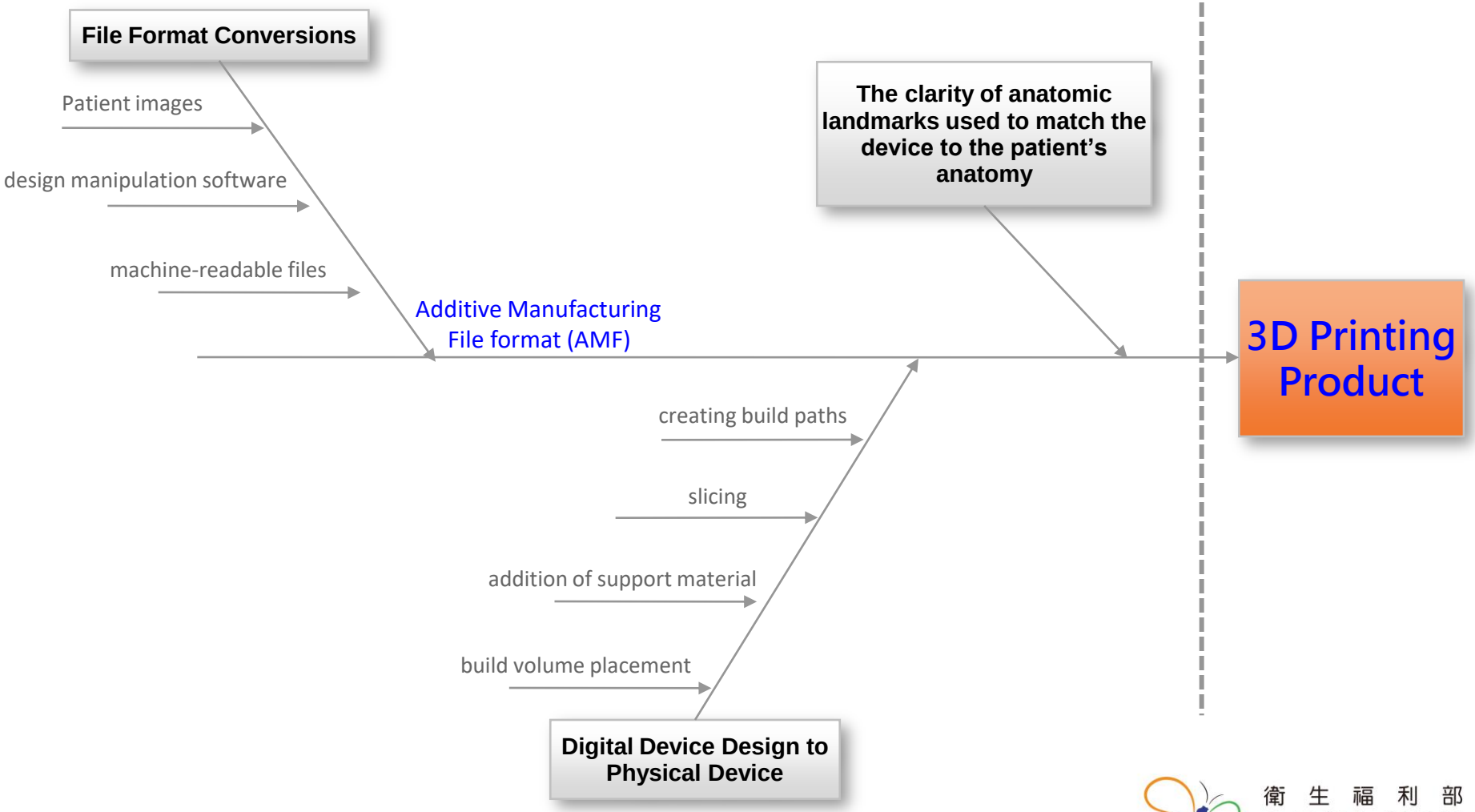
《 *Guideline for Additive Manufactured Medical Devices* 》

-- Design and Manufacturing Considerations

Design and Manufacturing Process Considerations

- Manufacturers must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are **met per Good Manufacture Practice (GMP)**.

Software Workflow



Material Controls

Starting Material

- the detail information should be documented
  -- 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

Process Validation - I

Machine Parameters and Environmental Conditions

- Machine parameters should be documented
- the machine should be qualified for use in its installation location
- document each critical manufacturing step in the printing process

Post-Processing

- All post-processing steps should be documented
- discussion of the effects of post-processing on the materials used and the final device

Process Validation - II

Non-destructive evaluation (NDE) and test coupon

- to ensure repeatability and consistency within a build cycle and across lots

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

《 *Guideline for Additive Manufactured Medical Devices* 》

-- Device Testing Considerations

Device Testing Considerations

- The characterization and testing necessary for a device made through AM may depend on the claimed indication for risk profile, and classification and/or regulation for the device type.
- In general, if the type of characterization or performance testing is needed for a device made using non-AM techniques, the information should also be provided for an AM device of the same device type.

Device Testing Considerations

Device Description

-- identify the range of dimensions

-- describe the type of AM technology used

Dimensional Measurements

-- specify the dimensional tolerances

Physicochemical Properties

-- material chemical and physical properties

-- perform degradation testing while using an absorbable material

Mechanical Testing

-- provide a discussion of how the worst-case devices were selected for each performance test conducted

Sterilization

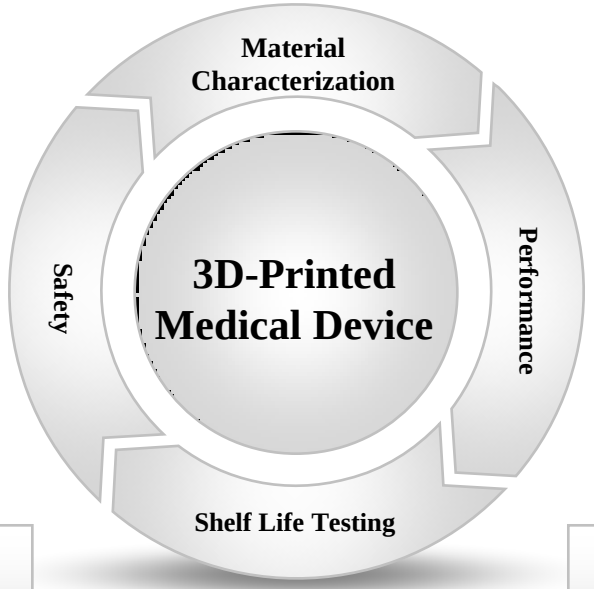
-- under worst-case conditions

Removing Manufacturing Material Residues

-- under worst-case conditions

Biocompatibility

-- evaluate the biocompatibility of the final finished device according to ISO 10993-1



ご清聴ありがとうございました

Thank you for your attention!

FDA