



How is 3D Printing Revolutionizing the Medical Device Industry?

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Moderated by **Janet Rozovics Gottlieb**, Executive Director,
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What is Additive Manufacture?

additive manufacturing (AM), *n*—process of joining materials to make **parts** from 3D model data, usually **layer** upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies.

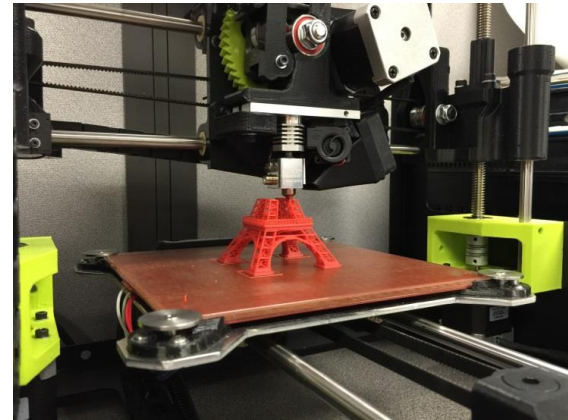
Subtractive Manufacture

“Traditional manufacturing methods”
material is removed from a solid block
Including: Milling, Casting, Turning,
Drilling or Shaping

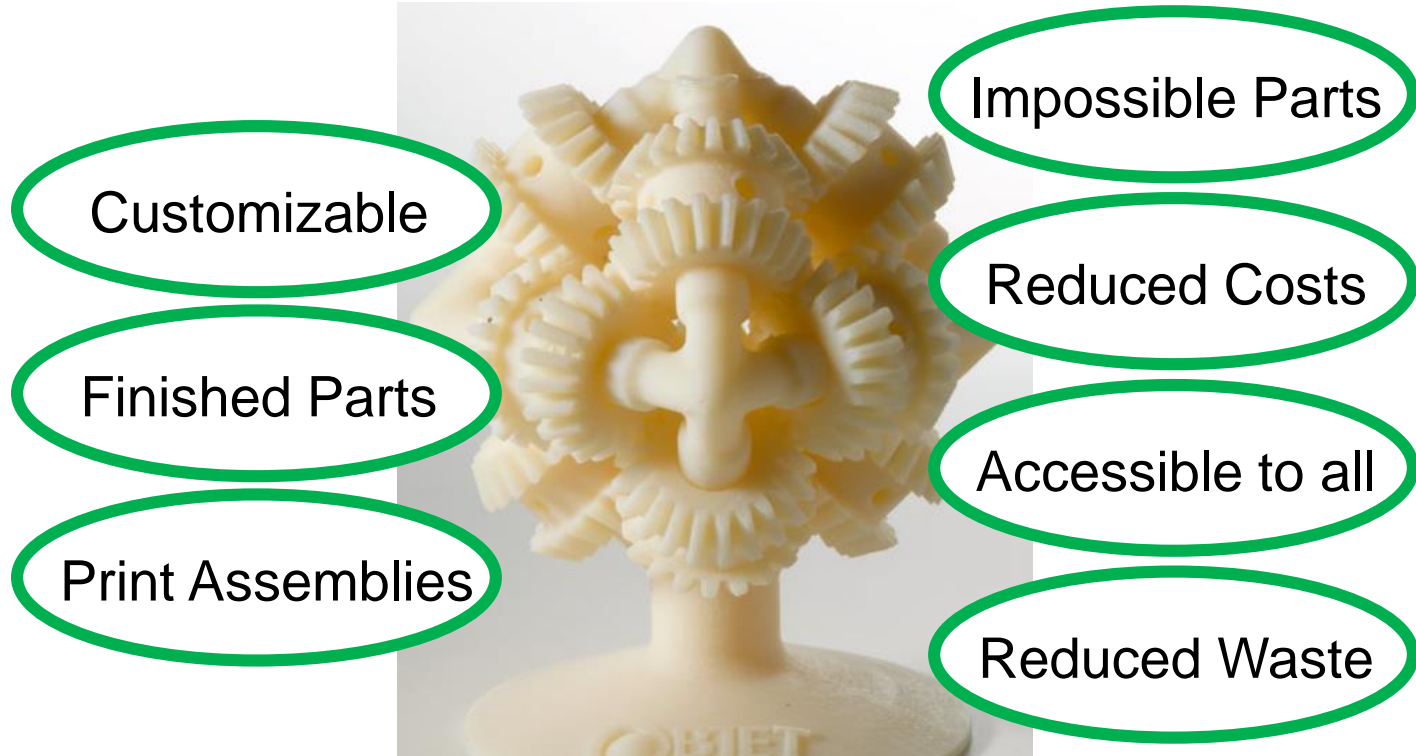


Additive Manufacture

The desired shape is acquired by
successive addition of material layer by
layer.



Why is Everybody so Excited?



Customizable

Finished Parts

Print Assemblies

Impossible Parts

Reduced Costs

Accessible to all

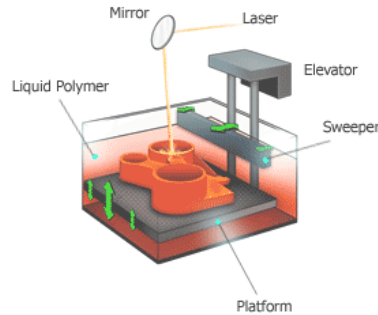
Reduced Waste

Imagination is the limit!

Why Isn't Every Part 3D Printed?



Types of Additive Manufacturing



ISO and ASTM Identified 7 Categories

- Material Extrusion
- Vat Photopolymerization
- Material Jetting
- Binder Jetting
- Powder Bed Fusion
- Directed Energy Deposition
- Sheet lamination



<https://www.3dnatives.com/en/additive-manufacturing-aerospace-growing-061220184/>



<https://3dprintingindustry.com/news/3d-printing-buildings-summary-additive-manufacturing-construction-97342/>



<https://3dprintingindustry.com/news/3d-printing-automotive-industry-3-132584/>



<http://www.lasercutworks.com/show/3d-printed-footwear-under-armour-trainers/>



Aerospace

Design optimized to
save weight

<https://www.3dnatives.com/en/additive-manufacturing-aerospace-growing-061220184/>



Construction

Printed on site with reduced
labor requirements

<https://3dprintingindustry.com/news/3d-printing-buildings-summary-additive-manufacturing-construction-97312/>



Automotive

Complex low volume
part printed on
demand

<https://3dprintingindustry.com/news/3d-printing-automotive-industry-3-132584/>

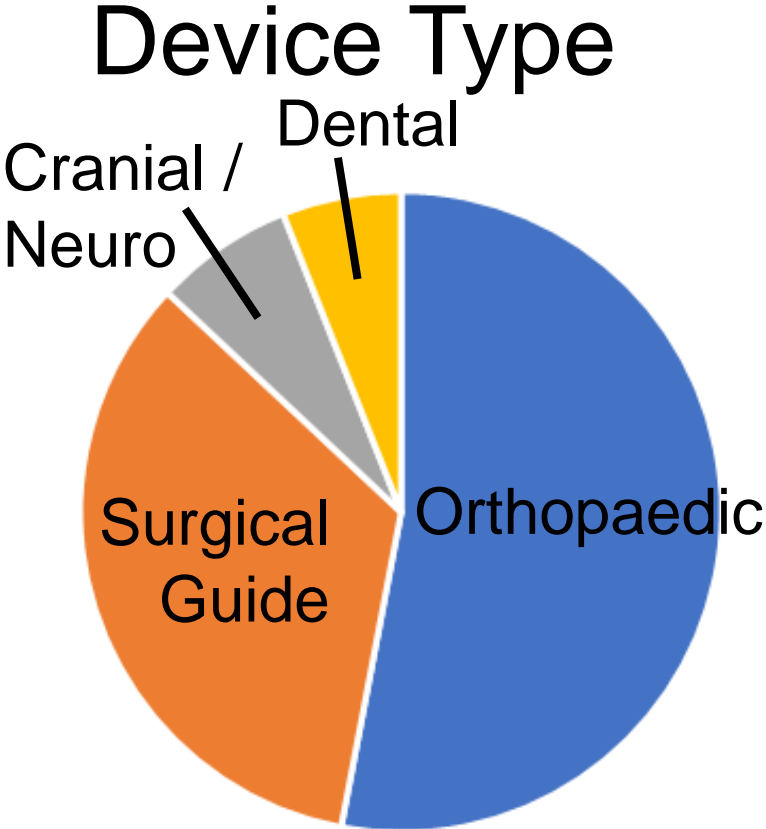


Training Shoes

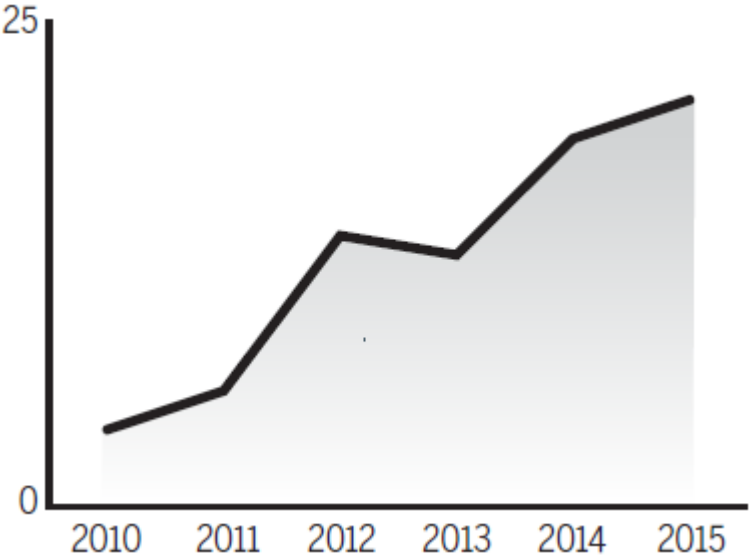
Custom shoes printed
in store

<http://www.lasercutworks.com/show/3d-printed-footwear-under-armour-trainers/>

Devices Cleared 2011 to 2015



Number of 510(k)s



Ricles, L.M., Coburn, J.C., Di Prima, M. and Oh, S.S., 2018. Regulating 3D-printed medical products. *Science translational medicine*, 10(461), p.eaan6521.

Additive Manufacturing Paradigms

LOCALIZATION



Local
Manufacture



Traditional
Factory

Additive Manufacturing Paradigms

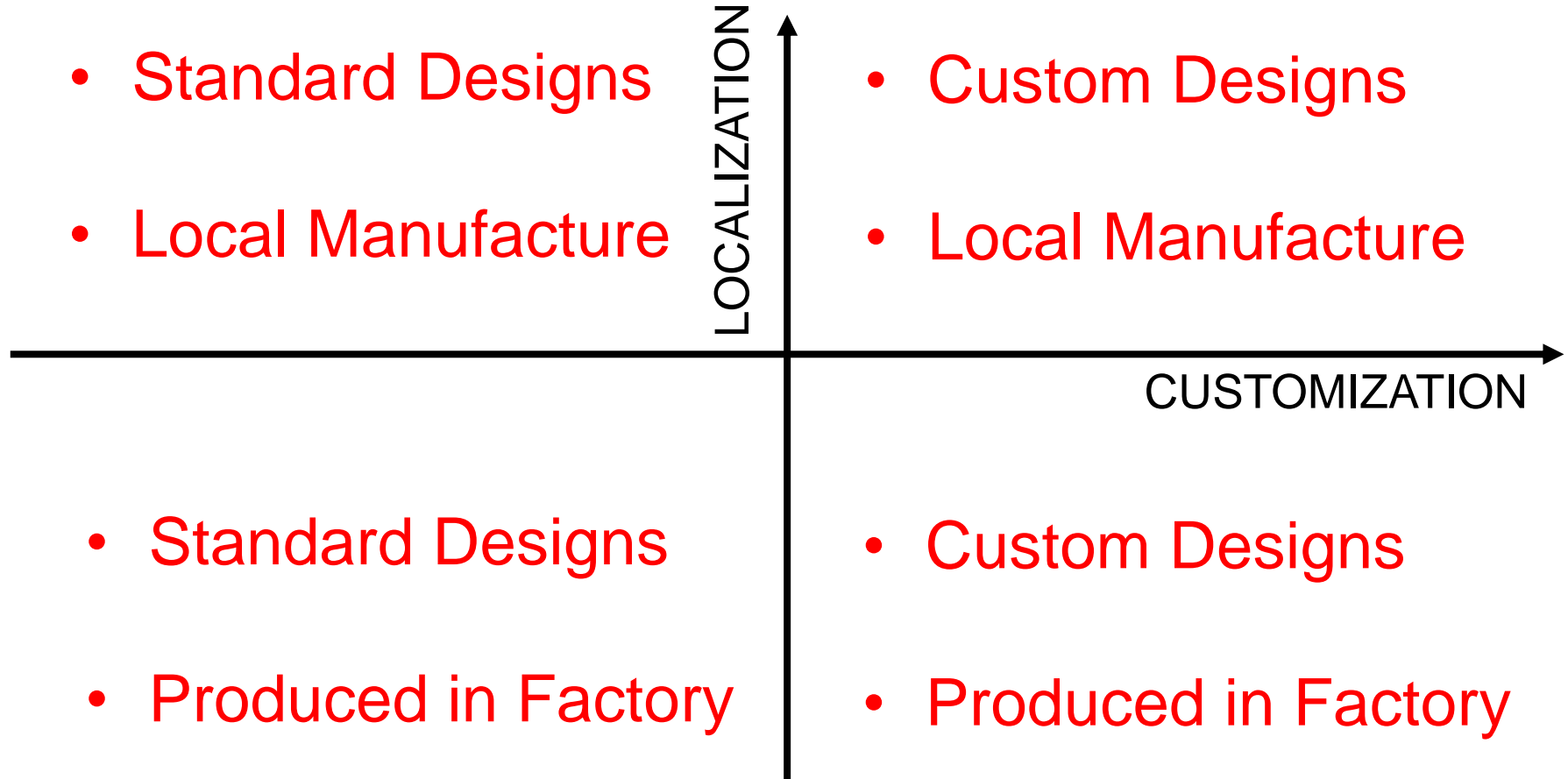


Mass
Production

CUSTOMIZATION

Custom
Design

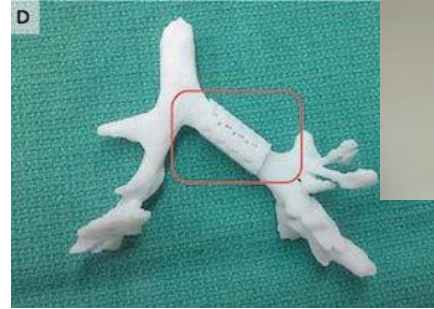
Additive Manufacturing Paradigms



Additive Manufacturing Paradigms



LOCALIZATION



CUSTOMIZATION



Additive Manufacturing Paradigms




LOCALIZATION



CUSTOMIZATION





HOW IS 3D PRINTING REVOLUTIONIZING THE MEDICAL DEVICE INDUSTRY?

Mark C. Levy, Esquire
Partner
Eckert Seamans Cherin & Mellott, LLC

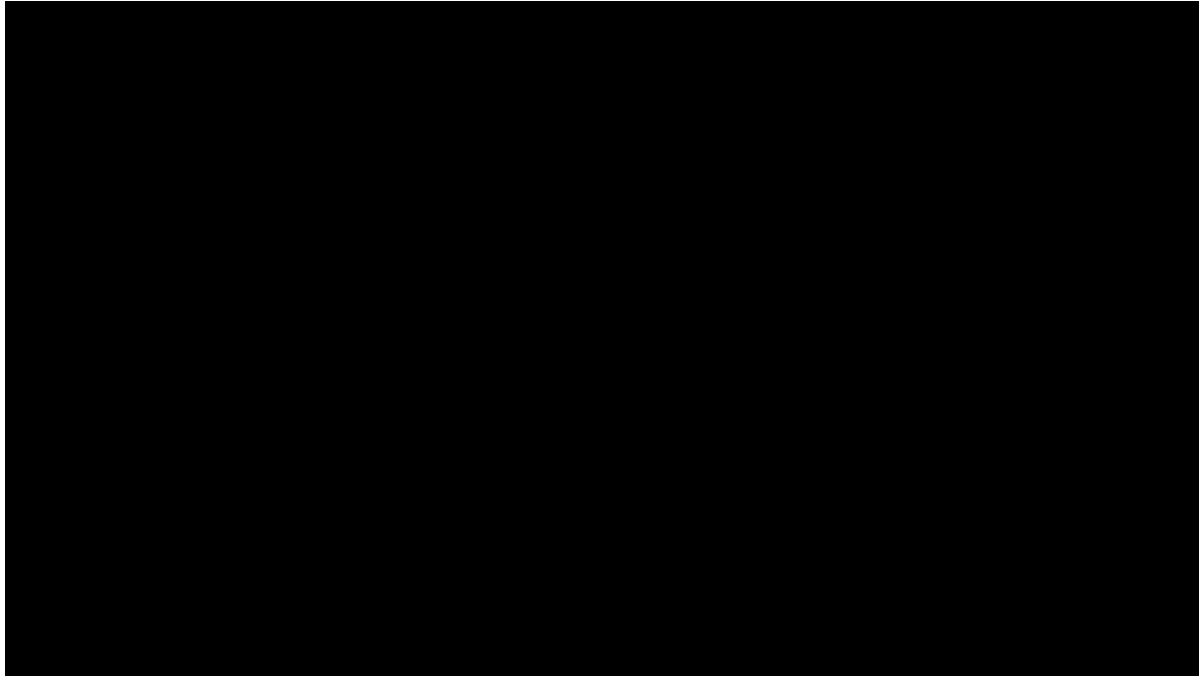
Medical Devices: FDA Regulation in the Era of Technology and Innovation
June 6, 2019



FDA's Evolving Role in 3D Printing

- “Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing.”
 - Public Workshop—October 8-9, 2014
 - Device manufacturers, AM companies, and academia
 - Five themes: materials, design, printing characteristics, physical and mechanical assessment of final devices, and biological considerations of final devices such as cleaning and sterility

FDA's Evolving Role in 3D Printing



FDA's Evolving Role in 3D Printing

Feedback from Workshop served as a basis for:

- “Technical Considerations for Additive Manufactured Medical Devices”
 - Guidance Issued December 5, 2017
 - (draft---May 10, 2016)

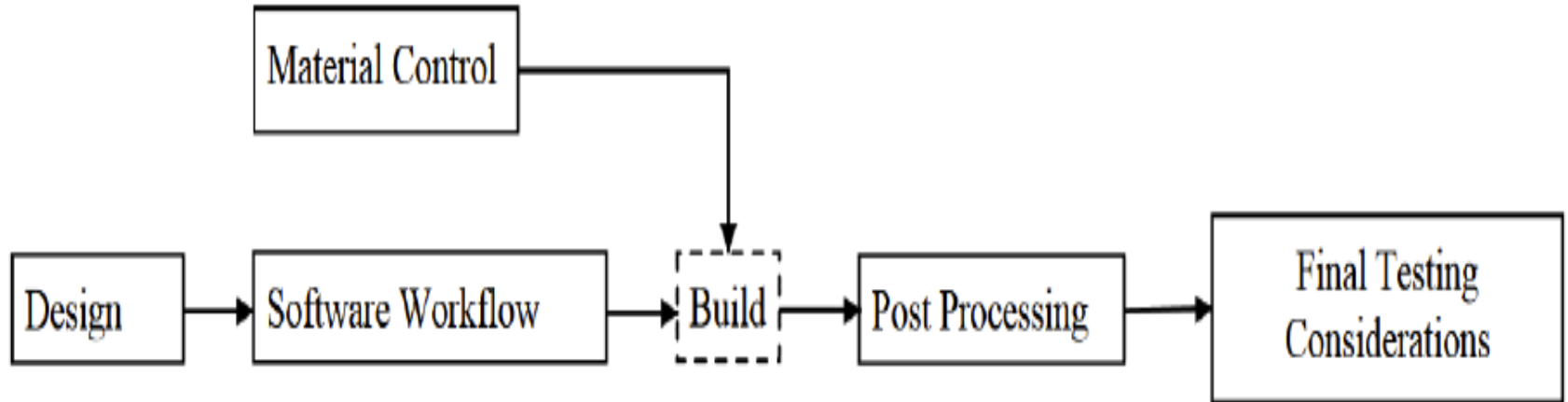
FDA's Evolving Role in 3D Printing

- Leap Frog Guidance—FDA's "initial thinking" re: "emerging technology"
- Does not address "Point of Care" device manufacturing
- Does not address biological, cellular, or tissue-based products
- Focus on technical aspects of AM
- Encourages use of Pre-Submission process

FDA's Evolving Role in 3D Printing

- “The effects of the different steps in the AM process can be seen in final device testing; however, determining the root cause of failures from manufacturing defects can be very difficult without a clear understanding of each step.”

FDA's Evolving Role in 3D Printing



FDA's Evolving Role in 3D Printing

- Device Design
- Patient-Matched Device Design
 - Effects of Imaging
 - Anatomical matching via software
 - Necessity for data integrity, cybersecurity and protected health information

FDA's Evolving Role in 3D Printing

- Build volume
- Support material
- Slicing
- Build paths
- Validation of software

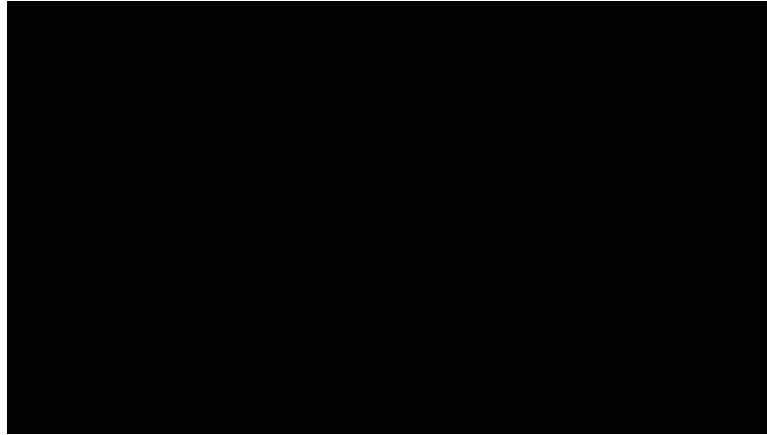
FDA's Evolving Role in 3D Printing

- Material controls
 - Starting material
 - Material reuse
- Post-processing
 - Heat treatment
 - Final machining, etc.
 - Process Validation and Acceptance

FDA's Evolving Role in 3D Printing

- “Technical Considerations for Additive Manufactured Medical Devices”
 - Webinar—1/10/18
 - <https://www.youtube.com/embed/ZbyU5c7IDOs>

FDA's Evolving Role in 3D Printing



FDA's Evolving Role in 3D Printing

- Warning Letter

- Oxford Performance Materials, Inc.
 - 1/5/17
 - Cranial and maxillofacial implants
 - Failure to validate cleaning and sterilization
 - Failure to control recycled materials
 - Failure to maintain receipt, storage and handling procedures
 - Failure to control environmental conditions
 - Failure to document equipment maintenance –lack of documented cleaning records

FDA's Evolving Role in 3D Printing

- Warning Letter

- Kelnyiam Global, Inc.
 - 5/10/17
 - Patient-specific cranial and maxillofacial implants
 - Failure to maintain design change procedures and approvals
 - Failure to evaluate complaints
 - Failure to validate process with verifiable results
 - Failure to establish procedures for incoming product

FDA's Evolving Role in 3D Printing

- Warning Letter

- Failure to have management review of QS system
- Failure to have corrective and preventive actions procedures, e.g., training

Health Canada

- Guidance – “Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing”
 - Effective 4/30/19
 - Pre-market Class 3 and 4 devices
 - Design, manufacturing, material control, device testing and labeling
 - Distinguishes patient-specific devices after criticism of first draft



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