CONTRIBUTED CONTENT & PRESENTATIONS

FDA'S Draft Guidelines for 3D Printing of Medical Devices

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On May 10, 2016, the FDA issued a document entitled *Technical Considerations for Additive Manufacturing Devices*. Here it is.

The document consists of 25 pages of "draft" guidelines that provide the FDA's "initial thinking on technical considerations specific to medical devices using additive manufacturing." Interested parties are invited to submit comments within 90 days.

The guidelines are organized into two broad areas: (1) design and manufacturing considerations; and (2) device testing considerations. All types of 3D printed medical devices fall within their purview. Biological, cellular, or tissue-based products are not addressed as different regulations are contemplated for them.

In October 2014, the FDA held a public workshop to obtain stakeholder input concerning the 3D printing of medical devices, a technology that the FDA acknowledges easily fabricates complex geometric structures and also has the advantage of facilitating the creation of anatomically-matched devices and surgical instrumentation by using a patient's own medical imaging. These guidelines grew out of the October 2014 workshop and the discussions that subsequently ensued. Topics include guidance for device design, software workflow, material controls, post-processing, testing, cleaning and sterilization, biocompatibility, and labeling considerations.

If you need help processing the FDA's paper or if you want assistance formulating and submitting comments, please let us know.

3D Printing will impact the way we make almost everything. Because the technology will change our clients' businesses, Benesch has formed a 3D Printing Industry Group, a multidisciplinary team led by core members of the firm's Innovations, Information Technology & Intellectual (3iP) Property Group.

For more general information and to learn more (including by viewing more than 20 Benesch-produced videos on 3D printing), click here.

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