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FDA And 3D Printing — What Will The Regulatory Regime Become?

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The US Food and Drug Administration (FDA) already has had its regulatory eye on 3D printing for some time. The Agency already has evaluated and authorized for marketing more than 100 devices that are produced on 3D printers, including knee replacements and other implants personalized for a patient's unique anatomy. It also has approved the first drug product made on a 3D printer. These medical products have come to the market using FDA's traditional premarket review structures and controls, but FDA is looking down the road. FDA now must be ready and plan for the coming explosion of new "3D printing" technologies that will change how and where medical products are manufactured.

To this end, earlier this month, FDA Commissioner Scott Gottlieb issued a statement ([here](#)) outlining where FDA may be taking regulation of 3D printing in the future. Some key points of interest from the statement are:

- As with "digital health" medical devices, FDA acknowledges the need to establish a more comprehensive regulatory pathway that can keep pace with technological advances, in this case with new manufacturing advances. As with the "digital health" space, this move may signal FDA's desire to create premarket review structures, approaches and policies which ensure product integrity and quality but ease the regulatory burden and time necessary to bring new technologies to the market and medical community.
- This regulatory effort will focus not only on traditional manufacturers making medical products with 3D printing technology at traditional production facilities, but it also will focus on non-traditional manufacturers, making products in hospital operating rooms or university laboratories. What regulatory controls will be placed on medical and academic institutions making medical products on-site as opposed to sourcing them from traditional manufacturers? What regulatory controls will be placed on the purveyors of 3D printing equipment supplied to such medical and academic institutions? FDA is working to establish a regulatory framework for how it can apply existing laws for device manufacturing to non-traditional manufacturers.
- The FDA will also further assess regulatory issues related to bioprinting of biological, cellular and tissue-based products. The Agency will evaluate whether additional clarification and guidance are necessary.

At the same time as Commissioner Gottlieb's statement, FDA issued its finalized version ([here](#)) of the draft May 2016 guidance on medical device additive manufacturing (3D printing).

The final guidance, "Technical Considerations for Additive Manufactured Medical Devices", does not appear to deviate from the draft version substantially and provides manufacturers with the Agency's current thinking on manufacturing 3D-printed devices and on technical considerations to characterize and validate such devices. For example, the final guidance explains FDA's thinking on segmentation by addressing the level of acceptable image quality and the ability to recreate the same models from those images. The final guidance also clarifies FDA's expectation for removing manufacturing material residue in additive manufacturing processes. In addition, the final guidance also includes new considerations for handling complex design files and cybersecurity considerations for patient-matched devices.

FDA also emphasizes that the final guidance will not be applicable to all 3D-printed devices, given that the

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industry is quickly evolving which will likely drive the Agency's recommendations to evolve too.

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