Additive Manufacturing: Back on the Radar

Additive Manufacturing (i.e. 3D printing) of Medical Devices. On May 10th, FDA released a much anticipated draft guidance “Technical Considerations for Additive Manufactured Devices” [link] and, on May 3rd, ASTM International held a workshop on “Additive Manufacturing for Medical Applications”. [link]

The Draft FDA guidance is considered a “leap frog” draft guidance, which is intended to serve as a mechanism by which FDA shares initial thoughts regarding an emerging technology that is likely to be of public health importance during the early stages in product development. This guidance focuses on two main topics in regards to additive manufacturing: 1) Device and Manufacturing Considerations, and 2) Device Testing Considerations. Overall, these two topics cover aspects involving the various stages during the additive manufacturing process (i.e. design, software workflow, material control, build, post-processing, and testing), as well as process validation and acceptance activities, and considerations for testing that would impact the information to be included in a regulatory submission. The draft guidance does not cover point-of-care applications or use of additive manufacturing for biologic, cellular, or tissue based products. The FDA’s recommendations may change as information becomes available.

On May 3, 2016, the ASTM Committee F04 on Medical and Surgical Materials and Devices sponsored a workshop on additive manufacturing. The workshop was intended to discuss the use of additive manufacturing in medical devices, regulatory considerations and to provide a forum to consider whether medical device specific standards are needed. The topics covered included the cleaning and sterilization of additive manufactured parts for use in medical devices, powder management in 3D printers, and examples of additive manufacture uses in medical devices. Members of the FDA gave presentations on variability in custom cutting guides for total knee arthroplasty and the effects of build orientation on the fatigue life of laser sintered Ti-6Al-4V. The workshop ended with a review of the work of ASTM Committee F42 on Additive Manufacturing Technologies, including the standardization strategy, published standards and work items, and then a group discussion.

With these two timely events, it is evident that the application of additive manufacturing in medical devices is back in the spotlight and will continue to raise questions as to the benefits and potential risks this technology may pose as it makes an impact in this industry.