MEDTECH INSIGHT
CITELINE COMMERCIAL

28 Jan 2021 | **News**

FDA Eyeballs Handful Of Emerging Tech Topics For New Medical Device Development Tools

by Shawn M. Schmitt

Artificial intelligence, machine learning, and virtual and augmented reality are among the themes under consideration for future MDDTs from the US agency.

The US Food and Drug Administration is eyeballing a handful of emerging technology topics as fodder for future Medical Device Development Tools.

The agency's *MDDT program* aims to streamline the approval process for devices with emerging tech via a library of regulatory science tools that have been scientifically validated and qualified.

FDA official Dorn Carranza told *Medtech Insight* "there are many" topics under consideration for new MDDTs, including "in the area of AI/ML, artificial intelligence and machine learning; in the area of advanced VR/AR, medical virtual reality and augmented reality; in the area of cybersecurity; 3D printing; advanced manufacturing.

"All of these are emerging technology areas that are going to need ways – quick ways – to be able to assess those technologies when incorporated in devices," he added.

> ***"A qualified Medical Device Development Tool can help you gain confidence that you are going to be using a method that has been … accepted by the FDA." – Dorn Carranza***

Carranza is associate director for strategic partnerships and innovation in the Office of Science and Engineering Laboratories (OSEL), within the FDA's Center for Devices and Radiological Health.

The agency has put its stamp of approval on eight MDDTs since October 2017:

- Rubric for Applying CVSS to Medical Devices
- BREAST-Q Reconstruction Module
- Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) Questionnaires
- IMAnalytics with MRIxViP1.5T/3.0T And BCLib
- Tissue Mimicking Material (TMM) for Preclinical Acoustic Performance Characterization of High Intensity Therapeutic Ultrasound (HITU) Devices
- OSIRIX CDE Software Module
- Minnesota Living with Heart Failure Questionnaire (MLHFQ)
- Kansas City Cardiomyopathy Questionnaire (KCCQ)

"The goal with these MDDTs is to get ahead of the technology," said Carranza, whose OSEL assesses the safety, performance and efficacy of emerging tech in devices. "Technology development is outpacing the understanding that we have, or anyone has, to be able to assess those technologies."

While any company can use the tools, they're mostly targeted at small manufacturers and start-ups.

"Those are the ones that are using emerging technologies or developing emerging technologies, and they're also the ones that are suffering the most," Carranza said. "The big boys – the Boston Scientifics, the Medtronics – they can do it by themselves."

And, he says, the MDDTs can save smaller firms much needed money and resources.

"If you are developing a novel device, if you are working with an emerging technology, it will

require that you develop your own assessment methods. That's going to take time, money and effort to develop, and then you will still be uncertain whether those methods will be accepted when used in a submission" to the FDA, Carranza said.

But "a qualified Medical Device Development Tool can help you gain confidence that you are going to be using a method that has been qualified by the FDA – accepted by the FDA – when you submit data using that tool," he said.