The Veeda Newsletter

May 2017

FDA to Create Digital Health Unit
With ongoing work on guidance related to software as a medical device, and a new dedicated unit to digital health coming to the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH), the agency is slowly but surely dipping its toe into the rapidly advancing field.

Bakul Patel, associate center director for digital health at FDA, told attendees at MedCon in Cincinnati on Thursday that current work is directed at funneling through about 1,400 comments on draft guidance on software as a medical device released last October, which is also a priority for the International Medical Device Regulators Forum (IMDRF).

Patel noted that FDA is currently working on "what clinical validation looks like for software," adding that the 46-page document will likely be simplified to 20 pages when finalized.
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Biosimilars Forum Seeks More Clarity in FDA Draft Guidance on Biosimilar Interchangeability – The nonprofit industry group Biosimilars Forum is calling on the US Food and Drug Administration (FDA) to clarify that a demonstration of interchangeability represents a distinct requirement for additional data compared to a demonstration of biosimilarity. Read More

India to restart inspections of API mfg facilities in China with huge rise in imports
In order to ensure only quality active pharmaceutical ingredients (API) are imported from countries like China, Government will be restarting inspections of drug manufacturing facilities in China soon.

"In the light of the fact that India has faced repeated scrutiny of its manufacturing facilities in the name of quality medicines, the commerce ministries along with other concerned ministries are serious to set up a permanent audit office in China to conduct inspections on a regular basis in China," says Drug Controller General of India Dr G N Singh. Read More

Upcoming Conferences and Events

Veeda Clinical Research will be participating in the CPHI CHINA Conference on June 20-22, 2017 Shanghai, China.

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