

FDA Focuses on Digital Health with New Centre of Excellence



Since the start of the COVID-19 pandemic, health systems around the world have seen the surge in digital health. This new trend, however, has brought new challenges, one of which is how these relatively new activities are regulated. Aiming to make digital health tools safer and more accessible, the U.S. Food and Drug Administration (FDA) has launched the Digital Health Center of Excellence (DHCE).

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“Establishing the Digital Health Center of Excellence is part of the FDA’s work to ensure that the most cutting-edge digital health technologies are rapidly developed and reviewed in the U.S.,” said FDA Commissioner Stephen M. Hahn in a press release.

The new initiative is a development of the Digital Health Program in the Center for Devices and Radiological Health (CDRH) and will coordinate the relevant work across the FDA. It is tasked with providing technical advice, advancing best practices and “reimagining digital health device oversight” to help accelerate access to digital health technologies. The specific key goals include: modernisation of the FDA’s policies; expanding the number and expertise of the FDA’s digital health staff; and develop the Digital Health Software Precertification Pilot Program (“Pre-Cert”). Its services are aimed at both internal and external stakeholders, including patients, developers, health care providers, researchers, industry, payers, national and international regulatory bodies, among others.

The DHCE, led by Bakul Patel, former Associate Director for Digital Health at CDRH, will focus on the following functional areas for digital health:

- Digital Health Policy and Technology Support and Training
- Medical Device Cybersecurity
- Artificial Intelligence / Machine Learning
- Regulatory Science Advancement
- Regulatory Review Support and Coordination
- Advanced Manufacturing
- Real World Evidence and Advanced Clinical Studies
- Regulatory Innovation
- Strategic Partnerships

“The establishment of the Digital Health Center of Excellence is part of the planned evolution of the FDA’s digital health program to amplify the digital health work that is already being done and building upon years of work at the agency,” said CDRH Director Dr Jeff Shuren said in a statement. “In the last several years, we have established partnerships internally and externally to coordinate digital health activities and to promote the consistency of regulatory policy while continuing to innovate in our regulatory approaches.”

More information on the DHCE is available [here](#).

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