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FDA and Industry: Outside the Regulatory Box

September 25th, 2:15 - 3:45 pm

The MedTech Conference
Philadelphia
September 24-26

Join more than 3000 medtech executives in Philadelphia for the annual MedTech Conference. The medical technology industry continues to evolve at a rapid pace.

New technologies such as digital health and 3D printing, taken with FDA's growing focus on firms' quality culture, require new regulatory approaches. In response, FDA has launched a set of innovative programs that break from conventional medical device review and oversight. These programs offer the promise of streamlined approaches that promote the introduction, improvement and distribution of devices from manufacturers that know and show strong quality practices.

This session will highlight these FDA programs and consider how they might progress from pilots to permanent initiatives, and how FDA will develop new approaches to support innovation and good quality practice.

MODERATOR:

- **Zach Rothstein**, Esq., Associate Vice President, Technology & Regulatory Affairs, AdvaMed
- **Steve Silverman,** Esq., Vice President, Technology & Regulatory Affairs, AdvaMed

SPEAKERS

- **Stephanie Christopher**, MA, Program Director, CfQ & SPI, Medical Device Innovation Consortium (MDIC)
- **Diane Johnson**, Senior Director, North America Regulatory Affairs Policy and Intelligence and Digital Health Policy Lead, Johnson & Johnson Medical Devices
- **Bakul Patel**, MS, MBA, Associate Director for Digital Health, FDA
- **Lauren Silvis**, JD, Chief of Staff, U.S. Food and Drug Administration
- **Francisco Vicenty**, Program Manager, Case for Quality, US FDA/CDRH/Office of Compliance

Click to learn more about the conference agenda. Contact Brenda Summers to get your 10% discount registration code.

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