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BREAKING: Shuren Steps Down As CDRH Director

by Elizabeth Orr

The US FDA device center head is retiring after 28 years in the federal sector and 15 at the helm of CDRH. Deputy center director Michelle Tarver will step in as acting head.

Jeff Shuren, the longtime director of the Center for Devices and Radiological Health at the US Food and Drug Administration, announced plans to retire in an all-staff email Tuesday afternoon.

Shuren has led CDRH since 2009. During his time at the helm, he has overseen key initiatives including an overhaul of the clinical trials program, the breakthrough devices program, the establishment of the Digital Health Center of Excellence, and the creation of the Office of Product Evaluation and Quality to support the total product life cycle regulatory approach. He was also key in standing up the International Device Regulators Forum and the Medical Device Innovators Consortium. (Also see "*Podcast: A Chat With Jeff Shuren – FDA Device Center Chief Worries About Agency Staffing; Talks MDUFA V, Pandemic, More*" - Medtech Insight, 28 Jun, 2021.)

According to his email, Shuren initially planned to retire in 2020 but chose to stay through the COVID-19 pandemic rather than leave during a crisis.

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“Today, the pandemic is in our rearview mirror, our center is not only back on track, but I think better positioned and stronger than ever before, and our current vision has been achieved,” Shuren wrote. “This was not an easy decision for me to make because CDRH has been my home and you have been, and will continue to be, part of my family. But it is the right decision for our center, and for me. I have my own new worlds still to explore.”

He will officially step down on 28 July, when he will hand the reins to current deputy center director Michelle Tarver. The timing was chosen to allow Tarver full oversight of the upcoming Medical Device User Fee Amendment (MDUFA VI) negotiations. However, Shuren will remain at the FDA for some months to help Tarver transition into the directorate.

In an all-staff email, FDA director Robert Califf described Shuren as “a catalyst for the modernization of medical device regulation and innovator in every sense of the word.”

Shuren's work at CDRH included a strong focus on speeding the path to access for medical devices in the US, which often lagged Europe in device authorizations at the time. In 2023, the center authorized the highest number of innovative devices in its 48-year history.

Trade group AdvaMed expressed its thanks.

“Jeff understood the critical role a regulator plays in the innovation ecosystem, knowing how to balance the ultimate goal of medical device safety and effectiveness with the important goal of spurring innovations that improve and save lives,” said AdvaMed president and CEO Scott Whitaker. “He saw AdvaMed and the medtech industry we represent as partners in addressing patients’ needs, and we hope his leadership serves as a model for all future directors of the CDRH.”

Shuren is the third high-ranking CDRH official to retire in the last year. Office of In Vitro Devices director *Timothy Stenzel* stepped down at the end of 2023, while OPEQ head *William Maisel* announced retirement plans in February.

Tarver Prepares To Take Charge

Incoming acting director Michelle Tarver isn’t a new face at the agency: Shuren’s email notes that she joined CDRH “just a few weeks” before he did in summer 2009. He went on to throw his full support to the new acting director, describing her as “truly wonderful as a person, a colleague, a friend, and a leader.”

Tarver worked in CDRH’s Office of Surveillance and Biometrics and the Office of Device Evaluation before moving into a directorial role. As director of patient science and engagement, she lead patient engagement efforts including the Patient Engagement Advisory Committee.

She has been deputy director of the office of strategic partnerships and technology innovation since July 2023. Her role includes oversight of disaster preparedness and response, digital health, conformity standards development, and transformative products including the new Home as a Health Care Hub initiative.

Tarver holds a bachelor's in biochemistry from Spelman College in Atlanta, a doctor of medicine from The Johns Hopkins University School of Medicine, and a Ph.D. in clinical epidemiology from The Johns Hopkins University Bloomberg School of Public Health. She is an epidemiologist and board-certified ophthalmologist who continues to treat patients.