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FDA Taps New Office of Device Evaluation Director From Industry

by David Filmore

Device industry veteran John Sheets has been appointed as the new director of FDA's premarket review office for devices. It's the second time this year that CDRH has tapped an industry executive to lead one of its offices.

FDA's Office of Device Evaluation has its first permanent director in almost two years and he comes to the post from the device industry.

John Sheets, who was most recently chief scientific officer at device and biotech firm *Anika Therapeutics Inc.*, officially started as the director of ODE on June 12. The premarket review office has been led on an acting basis since September 2014 by William Maisel, who has also maintained his primary post as CDRH's deputy director for science, and chief scientist. (See (Also see "*'Acting' At CDRH: Two Top Offices Are Now Run By Interim Directors*" - Medtech Insight, 19 Jan, 2015.).)

Maisel will transition back to a primary focus on his top scientist role at CDRH, but he will continue to be responsible for all ODE submission-specific issues, as well as for oversight of ODE guidance, regulation and policy for a 90-day period while Sheets completes financial divestiture of relevant stock holdings, according to FDA spokeswoman Angela Stark. Sheets will also use the transition period "to get to know the staff and organization before assuming full responsibility for ODE," Stark said.

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Sheets, who will have a 90-day transition period to complete necessary stock divestitures, has served as an executive for Anika Therapeutics, Boston Scientific, Johnson & Johnson, and multiple other device firms.

Starks says Sheets has completed an ethics and financial disclosure preclearance.

Sheets has a long career in the device industry. Prior to an approximately one-year stint ending in 2014 at Anika, which makes hyaluronic acid-based technologies for tissue regeneration, pain management and wound healing, he was senior VP for corporate research at Boston Scientific Corp. Earlier in his career he held top R&D and corporate posts at *Bausch & Lomb Inc.*, *Hoya Surgical Optics Inc.*, *Johnson & Johnson* and *Alcon Inc.* Sheets holds a Ph.D. in materials science and engineering.

Since he left Anika in 2014, Sheets has worked as a strategic consultant for several medical device, pharmaceutical and biotech clients. He also served on the board of a start-up company and on two external advisory boards at the University of Florida. He has resigned from all of these posts, FDA confirms.

This is the second time this year that has tapped an industry executive to lead one of its offices. In February, Robin Newman was appointed as director of the device center's Office of Compliance, moving from her position as VP of quality management for Siemens Healthcare Diagnostics Inc. (See *(Also see "FDA Taps Siemens Quality VP To Finally Fill CDRH Compliance Director Job*" - Medtech Insight, 25 Feb, 2016.).)

New leadership of ODE, which is responsible for the premarket review of all devices except for *in vitro* diagnostics, imaging equipment and radiation therapy, comes as the office has already implemented important process upgrades as part of the current MDUFA III user-fee program, and has reported some significant improvements in its review efficiency and throughput. (See (Also see "*FDA Hits User-Fee-Era Record For 'Novel' Devices: A New Normal?*" - Medtech Insight, 14 Jan, 2016.).)

But Sheets also joins as more reforms impacting the review process are in the offing. Congress is currently considering medical innovation reforms that could increase the demands on FDA device reviewers. (See *(Also see "Innovation Bill Scorecard: Device, Diagnostic Provisions In Senate And House*" - Medtech Insight, 8 Apr, 2016.).) And FDA and industry are the middle of

negotiations on a reform proposal for user-fee reauthorization, which will go through Congress next year. (See *(Also see "Resource Gap Remains Between Industry And FDA User-Fee Proposals*" - Medtech Insight, 26 May, 2016.).)

The last permanent director of ODE, before Maisel filled the post on an acting basis, was Christy Foreman, who moved to FDA's tobacco center. (See (Also see "*ODE Chief Foreman Departs Device Center; Maisel Will Fill In*" - Medtech Insight, 19 Aug, 2014.).)

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