FDA Plans to Expedite Product Reviews by Hiring More Staff

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The FDA hopes to bolster its scientific staff in 2018 — not only to expedite product reviews, but to meet its commitments to industry under the user fee agreements — by implementing a pilot hiring program focused on addressing the approximately 15 percent of positions currently unfilled at CDER and CBER, which total about 1,000 vacancies.

The pilot will first focus on mission-critical positions in medical product review areas supported by the recent reauthorizations of PDUFA and BsUFA — including new efforts in corporate recruitment models, which allow multiple vacancies to be filled with one posting, as well as boosting outreach to professional associations and academia. Additionally, the initiative will revamp the agency's IT infrastructure for human resources.

"We don't just want to hire by brute force," said FDA Principal Deputy Commissioner Rachel Sherman, at a recent agency meeting on hiring and retention. "We want a modern system that will meet our needs not only now but into the future."

The program was first announced by Commissioner Scott Gottlieb this past summer, who called for a systematic review of the FDA's hiring process. Center directors will help oversee the pilot, to align administrative procedures with the agency's scientific staffing objectives (*DID*, July 18).

The agency's workforce has expanded in recent years — with the number of CDER full-time equivalents increasing by 50 percent since 2012 — but the FDA's vacancy numbers are still much higher than other government agencies, which typically post rates between 5 and 7 percent.

As part of the latest reauthorization of the FDA's user fees, the agency "committed to taking a hard look" at its hiring process, to ensure that staff capacity can meet the technical regulatory goals of the next five years, said Steven Berman, an operations research analyst at FDA, during the agency's meeting.

Those goals include faster product reviews and the agency keeping pace with new medical technologies and manufacturing methods. The user fee reauthorization signed this past summer includes provisions for hiring at least 230 additional staff over the next five years (*DID*, Aug. 21).

In January and February 2018, the FDA plans to issue new government hiring certificates, a key step in the recruitment process, for mathematical statisticians, statisticians, pharmacologists, toxicologists and chemists under PDUFA VI and BsUFA II commitments.

Additional certificates for biologists and microbiologists are expected later in the year, according to Melanie Keller, the FDA's acting associate commissioner for scientific and clinical recruitment, and more outreach is planned.

"I think that when our scientific staffers go to some of these conferences, a lot of people come to the table and they are surprised," Keller said. "'FDA is hiring? What do you do at FDA?' And so we really need to get our message out that we are recruiting and we are an employer of choice."

At a congressional hearing last month, Gottlieb said the pilot program dramatically shortens onboarding time and could be rolled out on a wider basis. More detailed results will be made public in the near future, he said (*DID*, Dec. 1).

Currently, the FDA's end-to-end hiring process can take between 150 and 550 days, according to an agency report published in November. Agency staff described the process as substantially complicated, which includes multiple handoffs in the vetting process and unclear responsibilities.

In addition, a survey of hiring managers found that only about a third felt "very satisfied" with the eventual quality of the new hires. The FDA's report said many of the specific skills and competencies the agency is seeking are rare, and competition with private industry can be fierce.

Reagan-Udall to Place Candidates On-Site at FDA

In a move aiming to address the scarcity problem, the Reagan-Udall Foundation aims to spend 2018 developing its own FDA fellowship program to help train a new generation of post-docs in regulatory science.

Currently, the foundation is working to define the curriculum and raise funding before recruiting candidates, who would work on-site at the FDA for two to three years, according to June Wasser, Reagan-Udall's executive director.

"We'll have a joint steering committee to make sure we can identify the right mentors over at FDA for the fellows, and the right research projects," Wasser told *FDAnews*, adding that the foundation will be responsible for overseeing the quality of the program and will employ the fellows.

Candidates would include not only MDs and PhDs, but possibly those with master's degrees in engineering who work on big data projects. The foundation is considering clinical trials methodologists who can work on adaptive study designs and cutting-edge pharmaceutical research.

"There are all these new treatments coming around that don't have regulatory pathways established," such as gene therapies and personalized medicine, Wasser said. And while, in an ideal world, the fellows would go on to become FDA employees, it would not be a requirement.

"A fellow could go off and work in academia or industry after they complete a fellowship, and that would be fine," Wasser said, describing how a more robust regulatory science workforce would be to everyone's benefit.

"The FDA wants to deal with external folks who really understand what they do and understand it well." — Conor Hale

https://www.fdanews.com/articles/184994-fda-plans-to-expedite-product-reviews-by-hiring-more-staff