How Will FDA's CDRH Reorganization Impact Me?

by BONEZONE on May 12, 2020

Ask the Experts is a series of reader questions answered by industry advisors. Send us your questions.

Question: How will FDA's reorganization of the Center for Devices and Radiological Health (CDRH) impact my organization?

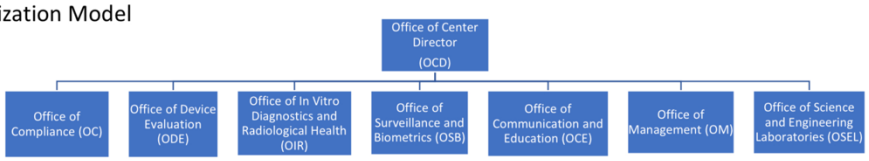
Answered by Monica Burt, Senior Partner, MB&A Consulting: Each of the original seven offices of FDA's CDRH underwent changes to generate efficiencies that will allow FDA to better support and advance CDRH's public health mission and vision. The changes integrated CDRH's premarket and postmarket program functions along product lines, allowing FDA to optimize oversight and decision making by leveraging the knowledge of their functional specialists across the product lifecycle.

Under the reorganization, the following changes were made:

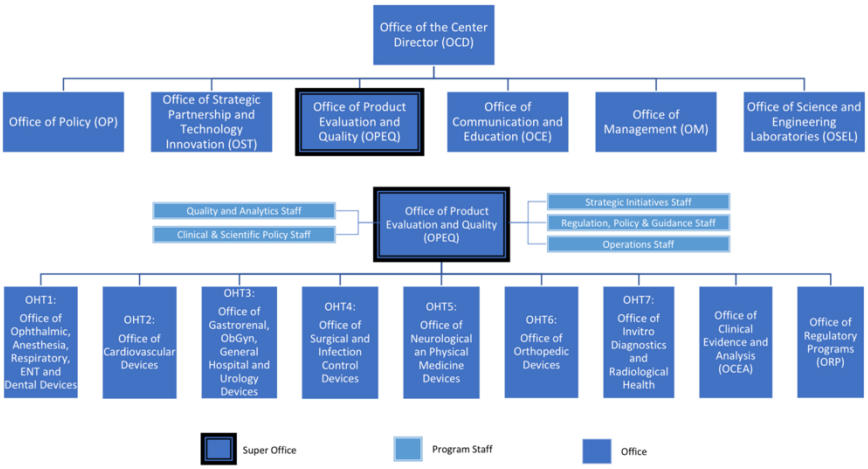
- **Established the Office of Product Evaluation and Quality (OPEQ**) – This combines four previous offices (Office of Compliance, Office of Device Evaluation, Office of Surveillance and Biometrics, and the Office of In Vitro Diagnostics and Radiological Health) into one Super Office focused on a total product lifecycle approach to oversight.
- **Established the Office of Policy (OP**) – This office has two teams: The Guidance, Legislation and Special Projects Team and the Regulatory Documents and Special Projects Team.
- **Established the Office of Strategic Partnership and Technological Innovation (OST)** – This office is a combination of the Science and Strategic Partnerships, Digital Health, Standards, Health Informatics and Innovation teams.
- **Realigned the Office of Management (OM)** – The changes to the OM aligned administrative functions in CDRH to optimize customer service.

- **Streamlined the Office of Communication and Education (OCE)** – Internal and external communications are housed in the newly organized OCE and an Internal Communication Branch was created

Previous CDRH Organization Model



Newly Reorganized CDRH



The previous CDRH organization structure was largely put in place in 1976 when Congress first enacted the Medical Device Amendments. Organized by product lifecycle, the structure was no longer adequate to optimally support complex 21st century devices.

Modern medical devices require an innovative and agile organization that can respond quickly to real-world safety signals and new evolving technologies. FDA believes that the recent organizational and operational transformation will better position the office to fulfill its mission of ensuring that patients and health care providers have continued access to safe, effective and high-quality medical devices.

The previous lack of communication and collaboration between CDRH's premarket and postmarket offices and the broad range of device types seen by specialists generated massive inefficiencies that plagued the office for years. One area where this is particularly evident is in the issuance of Warning Letters.

The issuance of Device Warning Letters, which are used by FDA to alert a manufacturer that it has significantly violated FDA regulations, fell by 90% in the last five years. FDA's timeframe for issuing Warning Letters is 120 days after the physical inspection of a manufacturer. The office cannot issue Warning Letters if they cannot do it in a timely manner, and timely processing of inspection reports is a requirement for issuance of Warning Letters.

FDA's Super Office has been actively clearing the backlog of inspection reports, which means that they will be able to focus on real-time reports and take timely actions when appropriate. Industry should expect to see a rebound in the issuance of Warning Letters in 2020 as the backlog of inspection reports is cleared, CDRH settles into their new Super Office structure and internal communications improve.

Some organizations will feel the impacts of changes more quickly than others, but over time, the changes will be evident to anyone actively engaged in conversations with CDRH. FDA has explicitly stated that any premarket submissions currently under review will remain with the original reviewer.

Remember, the overall goal of the CDRH reorganization was to drive operational efficiencies to better meet public health needs. Now that the reorganization is fully implemented, premarket and postmarket program functions and reviewers are integrated along product lines.

The new structure mobilizes a team approach. It consolidates and integrates aspects of product review, quality, surveillance and enforcement. Premarket, postmarket and compliance no longer sit in siloed offices on opposite sides of a large campus. They are collocated together, working on very specific groups of products and they talk to each other every day.

The reviewer looking at an organization's premarket files sits across from the person working on the same company's postmarket surveillance and the person reviewing inspection reports. These teams will become intimately familiar with all aspects of the organizations in their product categories.

CDRH has a group specifically focused on improving internal agency communication as well, thus industry should expect to see much better communication and collaboration within CDRH.

This improved communication and collaboration will come as a great value to organizations who are operating under healthy comprehensive and compliant Quality Management Systems. It may come as a burden to those who have taken advantage of poor communication and inefficiencies in the past.

The bottom line is, as CDRH improves their processes and infrastructure, industry should double check their own processes to ensure that they are prepared for the fresh and timely level of vigilance and attention from their partners at FDA.

Generally, organizations should continue to communicate with existing known contacts. For general questions about the new CDRH organizational changes, contact the Division of Industry and Consumer Education.

For information on some of the positive outcomes of the OPEQ pilot and to gain more insight into possible changes, check out the article Implementing a Team-Based Approach to Medical Device and Radiological Product Evaluation and Quality.