US Regulatory Landscape for Medical Devices: A Year in Review and a Look Ahead

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From a transition to the global standard for quality management systems (QMS) to the revamping of premarket review pathways in the US, the medical device industry can expect to see at least some regulatory initiatives that 2018 set in motion come to fruition in 2019.

The Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA) has released its list of guidances, indicating which topics will take precedence for 2019 policy clarifications. FDA's new rulemakings agenda is out, as well. In the meantime, 2018 themes indicate the direction these plans are likely headed.

Regulatory harmonization and modernization took center stage this year, speaking to the measures of success in CDRH's three-year policy roadmap from January and its recently updated medical device safety action plan.

An ongoing initiative that underscores the push for both harmonization and modernization relates to the proposed shift away from FDA's QMS regulation toward ISO 13485:2016. A few details on these plans have trickled out in recent months, including a new 5% estimate on the potential overlap between the two approaches to QMS oversight. The gap analysis is reportedly set to be completed by early to mid-2019.

Further, new rulemaking for a 13485:2016 transition is set for fall 2019. "The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements," FDA said. They "will also modernize the regulation." FDA's latest updates on these plans were posted Wednesday, indicating that a transition period "will likely be a few years" and a wide-ranging impact to FDA.

Harmonization

CDRH projects centered on regulatory harmonization that were pursued over the course of 2018 involve the International Medical Device Regulators Forum (IMDRF) and the International Organization for Standardization (ISO), among others.

IMDRF covered a lot of ground this year to finalize eight documents, including six technical documents, a procedural document and an information document. Newly finalized documents on the table of contents (ToC) format for regulated product submissions (RPS), coupled with the RPS beta testing report, are likely to serve as building blocks for an ongoing IMDRF harmonization project, dubbed the medical device single review program (MDSRP) just this year.

Health Canada's adoption of ToC in August and IMDRF's new work item on premarket review processes support the concept of MDSRP. The vision currently involves phased-in implementation, like the Medical Device Single Audit Program (MDSAP), "in the next few years" and a format similar to ToC, CDRH Director Jeff Shuren said at the Medical Device Innovation Consortium annual forum and AdvaMed's MedTech Conference in September.

The optimizing standards for regulatory use final document is intended to yield results heading into 2019, following partnerships with standard development organizations IMDRF formed this year to ensure proper alignment. The new IMDRF-ISO liaison will be testing the combined effort to the development of standards as early as February when

13485:2016 is set to undergo a systematic review, despite recent pushback from the MDSAP consortium. The extent to which upcoming revisions would impact the agency's proposed QMS transition remains to be seen.

Modernization

Regulatory modernization was another major theme during 2018, with the shift being largely underpinned by real-world evidence (RWE), total product lifecycle (TPLC) reviews and least burdensome principles.

This year, CDRH began piloting a new "super office," otherwise known as the Office of Product Evaluation and Quality (OPEQ), for TPLC approach on product evaluation, postmarket surveillance and medical device manufacturing site inspections. Shuren indicated at the FDA/Xavier Medcon in May that OPEQ would enable greater use of epidemiologists involved with RWE to inform decision-making. Another RWE-related project at CDRH involves a new software tool for identifying manufacturing sites to conduct inspections based on real cases.

CDRH set forth a string of proposals in recent months to revamp several of its premarket review pathways as part of the modernization push. The series of proposals began with an April draft guidance on the abbreviated 510(k) pathway, followed by a special 510(k) draft guidance released in September. Both draft guidances seek to increase industry use of summarized or truncated formats via abbreviated or special 510(k) submissions.

Plans to overhaul the traditional 510(k) program were revealed in November, pointing to the proposed expansion of the abbreviated 510(k) program. This was followed by a rule that FDA proposed earlier this month in anticipation of an increase in de novo classification requests. How these plans will manifest during the development of MDSRP remains unclear, though an abbreviated 510(k) program expansion would also support greater use of global standards.

2019 is set to be a transformative year after 2018 set the stage. Whether all the proposals will yield the intended results and become set programs remains to be seen as some proposals in the premarket review space have already raised concerns among industry experts. Other plans around 510(k)s and de novos to watch during 2019 include the new Quality in 510(k) Review Program that CDRH launched in September. Also, a second rule in the de novo space was finalized this month to create efficiencies by clarifying FDA's device classification processes.