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FDA's International Harmonization Plan Points To Ongoing Priorities

by Elizabeth Orr

A new draft global harmonization plan from the device center at the US Food and Drug Administration may not contain any surprises, but it does highlight increasing agency engagement with international bodies.

The new *International Harmonization Draft Strategic Plan* from the US Food and Drug Administration shows that the agency may take more action on single-audit programs and increase its interaction with previously neglected regions like Asia and South America, an expert who reviewed the document for Medtech Insight said.

Kim Trautman, who helped set international policy for the Center for Devices and Radiological Health during her 24 years at the FDA, noted that the plan "is really a summary of past work, ongoing work and work for the future that in part has already been a strategic priority for CDRH."

Last year's medical device user fee (MDUFA V) agreement required the FDA to issue the report to ensure further funding for international projects.

Trautman is now managing director and vice president at MEDICept Inc.

While the strategies laid out in the plan are not a surprise, Trautman said, they're important in that they point to ongoing center priorities.

For example, the number of device-related international standards continues to increase, with new documents including product-specific standards, new technology standards like those concerning AI and cybersecurity, and management system standards for quality systems and risk management systems. Funding for international strategies allows CDRH to increase its participation in these ongoing efforts.

The report lists five specific harmonization strategies that CDRH plans to use. These are:

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Strategy 1. Increase engagements in international harmonization, convergence, and reliance efforts.

According to Trautman, this will allow CDRH to devote more resources to the single review process, which will build on the model of the Medical Device Single Audit Program. Single audit or single review programs allow companies to be certified as compliant with regulations in multiple jurisdictions after only one inspection. (Also see "*MDSAP And USMCA: 3 Ways Mexico Can Come Up-To-Speed With The Single-Audit Program Targeted By New Free-Trade Accord*" - Medtech Insight, 28 Jan, 2020.)

Additionally, the center could engage more fully with regulatory groups like the Asia-Pacific Economic Cooperation (APEC) and Global Harmonization Working Party (GHWP) under the plan, which will also "open the door" to participation in the Pan American Health Organization (PAHO).

Twenty-one Asian and Pacific Rim countries belong to APEC, while GHWP has 32 members across the Americas, Asia, Africa and the Middle East. Dozens of countries in the Caribbean and Central and South America belong to PAHO. In the past, CDRH participation in these efforts has been limited due to funds, travel costs, and little CDRH staff assistance in some areas.

Strategy 2. Create mechanism for CDRH to share best practices with trusted partners.

This will help ensure intellectual property and other confidentiality considerations are respected across countries, allowing the single review process to move ahead, Trautman told Medtech Insight.

"This exchange mechanism may also allow CDRH to work internationally on topics that cut across US government agencies, as well as different foreign government agencies," she added. "For example, the topic of cybersecurity or AI is replete with multiple global government agencies 'playing' in the space of how to potentially regulate these new technologies."

Strategy 3. Assess the extent of CDRH implementation of IMDRF technical documents.

When the Global Harmonization Task Force was still active, CDRH was expected to track the implementation of global consortium documents. The International Medical Device Regulators Forum replaced GHTF in 2013 – in part, Trautman said, because the documents were not being used.

"If increased money and resources are being allocated to CDRH, there rightfully is the expectation that CDRH's work in IMDRF will lead to adoption and implementation," Trautman said.

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The strategy will also allow CDRH to move forward with priorities that fit the goal of "global harmonization, convergence and reliance." This is valuable because CDRH goals don't always perfectly align with those of other FDA centers or US government bodies like the Department of Health and Human Services.

"If IMDRF global regulators produce documents that align more closely with CDRH's thinking, then there would be justification to adopt on the basis of this International Plan in order to adopt IMDRF documents," Trautman explained.

Strategy 4. Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision making.

This, Trautman said, further promotes CDRH strategic priorities such as patient engagement and the use of global real-world evidence.

Strategy 5. Participate in outreach activities to encourage harmonization, convergence, and reliance.

Like Strategy 4, this backs up existing CDRH priorities. Additionally, it will make it easier for CDRH to get credit for work that may be overlooked by Congress and outside auditors, Trautman said.

Finally, an appendix to the plan shows what elements the FDA believes may be included in annual assessments – in other words, Trautman said, "the areas CDRH wants to utilize these MDUFMA V expanded moneys for." The table is reproduced below.

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