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StarFish Medical Analysis: IMDRF seeks participation in regulatory submission pilot program

A single international regulatory submission for medical devices

By Vesna Janic, August 20, 2015

In general, medical device companies that have a complete Design History File or Technical File can complete a submission to the FDA, Health Canada or EU with a little extra work. In some countries medical devices that have a CE mark can be marketed with a simple application. Still, the regulatory process is different and therefore the announcement from the International Medical Device Regulators Forum's (IMDRF) of a pilot program that would evaluate a single international submission format is exciting. It would allow companies to place their products on the market faster and with less regulatory effort.

The FDA Center for Devices and Radiological Health (CDRH), Offices of Device Evaluation (ODE) and In Vitro Diagnostics and Radiation (OIR) announced their participation in the IMDRF Regulated Product Submission Table of Contents Pilot Program on August 19, 2015. The Forum's key goal is to expedite medical device regulatory harmonization and convergence. The program is open for both 510(K) and PMA submissions, with some exclusions. The participants would simultaneously submit to the FDA and another jurisdiction: European Union (EU), Australia, China, or Canada. It should be noted that the scientific review is outside of the scope of the program, so if the submission is accepted each regulator will follow their own scientific review process.

The purpose of the Pilot Program is to provide FDA and IMDRF an opportunity to evaluate the structure of the submission format and receive feedback from industry. The submission will be electronic using IMDRF's Table of Contents (ToC) format. Companies that are interested in participating in the program should contact FDA Pilot staff by email at *Jodi.Anderson@fda.hhs.gov*. It should also be noted that special FDA eCopy requirements must be met. The program runs from Sept 2015 to Sept 2016.

The ToC provides a comprehensive submission structure that can be used as a harmonized international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is very useful even if you are not planning to participate in pilot; chapter 1 is nicely organized as a table that lists common content and regional content for submissions, as applicable. The guidance documents can be found on IMDRF's Web site. It will be interesting to see how successful this pilot will be. Stay tuned until next year…