Two EU notified bodies join international pilot to test common submission format for devices

24 July 2015

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Notified bodies in the EU are being given more time to sign up to a pilot program that is being run by the International Medical Device Regulators Forum to test a common electronic submission format for reviewing device submissions[1].

So far, only two notified bodies have confirmed their participation in the EU arm of the pilot, which will also be run in Australia, Brazil, Canada, China and the US and will commence simultaneously in all jurisdictions in September[2]. The notified bodies had originally been asked by the European Commission to confirm their participation in the pilot by June 20. However, this deadline has now been extended until the end of August/beginning September, Gert Bos, who is coordinating the participation of notified bodies in the EU arm of pilot, told *Scrip Regulatory Affairs*.

The pilot involves testing device submissions against a standard table of contents (ToC) that the IMDRF has prepared as part of its regulated product submission (RPS) project.

The ultimate objective of the pilot is to create a common format that would allow medical device and IVD manufacturers to electronically submit product information to a regulatory agency/notified body for the purpose of gaining market access. The pilot is currently restricted to high-risk devices, and its scope may be extended to other device classes later.

In jurisdictions other than the EU, medical device and IVD manufacturers wanting to participate in the ToC pilot can directly apply to the regulatory agency responsible for reviewing the device submission (eg, to the US Food and Drug Administration or Brazil's ANVISA). In the EU, however, manufacturers can only take part in the pilot through participating notified bodies.

The IMDRF, for its part, issued a formal invitation on July 20 asking all device and IVD manufacturers to sign up to the ToC pilot by August 21[4].

As the IMDRF's invite has only just been issued, "it is too early at this point to confirm how many manufacturers will be participating in this pilot," said Nancy Shadeed, special advisor at Health Canada's international programs division, and chair of IMDRF's working group on the regulated product submission project.

EU notified bodies hesitant?

Commenting on the EU arm of the pilot, Bos said: "It's fair to say that [the] notified bodies have been conservative to endorse the new Table of Content (ToC) format in [the device] dossiers they review". He speculates that the notified bodies' reluctance to join the ToC pilot may be "based on [the lack of] available resources and could well be due to the fact that some of them may be waiting for the results of the first [phase of ToC] trials before getting on board".

However, "I anticipate more [notified bodies] to join [in] at the start of the project, said Bos, who is also acting chair of the coordination group for EU notified bodies (NB-MED) and a member of the EU delegation in the IMDRF's regulated product submission working group. Anecdotal feedback from the notified bodies has been positive, he explained, adding that a couple of more notified bodies have shown interest in the pilot.

Moreover, as this is a pilot phase, the IMDRF expects to deal with only a limited number of applications and manufacturers, and accordingly a limited number of notified bodies, Bos explained. With the passage of time, he expects more EU notified bodies to join the pilot when it gets underway.

Bos explained that notified bodies participating in the pilot would allow medtech manufacturers requesting CE conformity assessment under any of the EU medical device directives to build their technical documentation around the ToC structure. The notified bodies and participating medtech manufacturers would then comment on the ToC structure and make suggestions for improvement.

During the pilot, "the regional guidance on how to use and apply the ToC will be updated and, where neede,d relevant suggestions on the ToC can be forwarded to the ToC group," Bos said. During the pilot phase, all notified bodies – regardless of their participation in the pilot – will be kept informed about the progress of the project. Also, the EU Regulated Product Submission working group "is ready to provide them with all kinds of support," he added.

Other countries carrying out regional pilots in their respective jurisdictions do not have notified bodies or third party assessment bodies, except for some in Australia that are operating under a mutual recognition agreement with the EU. In Australia, the same EU notified bodies might be able to participate," Bos said. At the end of the pilot phase, results from all jurisdictions will be compared and aligned, following which the ToC and guidance will be further improved.

"I look forward to working with a growing team of notified bodies, manufacturers and [regulatory] authorities on this [ToC] trial paving the way for the future assessments of technical documentation in EU," Bos said.

A meeting has been scheduled for late September to bring participants in the pilot fully up to speed with the details of the pilot, and the extent of their contributions to the validation tests, Bos said.

References

1. Request for expression of interest from Notified Bodies to participate in the IMDRF TOC pilot, GROW/I/4/SS/(2015), 15 July 2015,http://ec.europa.eu/DocsRoom/documents/11443/attachments/1/translations/en/renditions/native

2. IMDRF to invite medtech/IVD firms to test common e-submission format, *Scrip Regulatory Affairs*, 13 April 2015

3. EU to test IMDRF regulated product submission for devices, *Scrip Regulatory Affairs*, 22 August 2014

4. Request for expressions of Interest to participate in the IMDRF TOC pilot plan, 20 July 2015, www.imdrf.org/consultations/cons-rps-toc-eoi-150721.asp