21 September 2012

IMDRF International Medical Device Regulators Forum

www.imdrf.org

Letter of Invitation to RPS Tool Vendors

The management committee of the newly formed International Medical Device Regulators Forum (IMDRF), composed of the regulatory authorities of Australia, Brazil, Canada, the European Union, Japan and the United States, joined by observers from China, the Russian Federation and the World Health Organization, met recently in Singapore to consider new work items (NWI) that would help achieve its goal of promoting regulatory convergence in the regulation of medical devices. The work of the Forum builds upon the work of the Global Harmonization Task Force (GHTF), which it will now supercede.

One of the five NWIs adopted by the management committee is related to the Regulated Product Submission. The Forum has decided that it should form a working group comprised of regulators and industry to participate in the beta testing of the RPS 2 DSTU[1] standard to confirm that it is fit for purpose for medical device applications.

With this in mind IMDRF is seeking esubmission software tool providers to support such testing. Interested parties would provide IMDRF RPS testing team members free of charge access to and training on functional RPS building and viewing tools. Testing tools would be necessary at the beginning of the HL7 RPS DSTU period, with access and support to continue throughout the duration of the test period.

In return, participating vendors would have early access to the IMDRF RPS test package material as well as attendance at IMDRF RPS test planning teleconferences.

[1] Regulated Product Submission Draft Standard for Test Use

Please contact the undersigned, chair of the IMDRF RPS working group if you are interested in participating in this effort at the IMDRF RPS email account listed below.

Confirmation of your interest in working with IMDRF RPS working group is requested by October 12, 2012.

Sincerely,

Mike Ward

Mike Ward
Chair
IMDRF RPS Working Group
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