IMDRF International Medical Device Regulators Forum

IMDRF Regulated Products Submission (RPS) WG Update

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Updates

- Current Status of Electronic Submission
- Electronic submission environments using the IMDRF Table of Contents

RPS (Electronic Submission Standard)

- Stakeholders continue to voice concerns with the current interim solution of folder structure and pdf.
- Absence of harmonized dynamic template intended for the collection of harmonized content in IMDRF/RPS WG/N9 and IMDRF RPS WG/N13, as well as regionally specific content.
- Some jurisdictions are starting to develop their own templates for electronic submissions, moving away from harmonization

Update of Work on Electronic Submissions

- The US Food and Drug Administration (FDA) has developed a medical device submission assembly tool (eSTAR).
- The FDA is intending to make eSTAR fully harmonized with the TOC structure.
- FDA and Health Canada have recently worked on the eSTAR tool to include the TOC structure for Health Canada's Class III and IV applications.

New Work Item Extension (NWIE) Proposal

- Experiences to date have identified several recommendations to make the documents “fit for purpose” – using the FDA and HC feasibility work already developed; and
- Achieve the desired end goal- electronic preparation of regulatory submissions for product licensing applications between industry and regulatory authorities.

NWIE Proposal

- Specifically, the following enhancements have been identified:

  -Creation of dynamic templates for IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13;

  -Creation of specific electronic content for each regulatory authority, as well as harmonized content for all regulatory authorities; and

  -Minor updates to contents of IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13.

NWIE Proposal

- Opportunities for harmonization
  - Allowing industry to file electronic applications with multiple regulatory authorities using the same method
  - Instead of separate vocabularies and implementation guides for each regulatory authority, one harmonized approach reduces regulatory burden while increasing predictability, transparency, and regulatory cooperation.

NWIE Proposal

- Opportunities for harmonization
  - Creation of a “fit for purpose,” harmonized, electronic approach to regulatory submissions also serves to operationalize higher level IMDRF documents (e.g., IMDRF/GRRP WG/N47: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices).

Next Steps

- Discussion of NWIE at IMDRF MC meeting
- If approved, timeline is expected to take 12-18 months

Questions/comments

Thank you!