Regulated Product Submission Working Group

Co-chairs:

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IMDRF International Medical Device Regulators Forum

Background

- **The RPS Table of Contents (ToC) provides a harmonized format for submitting medical device regulatory submissions**
  - The latest versions were published in 2019 (N9 and N13)

- **A work item extension was approved in 2021 to:**
  - Update the ToC documents
  - Translate the updated ToCs into a new type of dynamic template for building submissions

Updates to the ToC Documents

- **Addition of MFDS (Korea) and MHRA (UK), though regional content additions were limited**
- **Addition of Post-Market Study Plans and Real-World Data subchapters**
- **Consolidated Chapters 6A and 6B into a single Chapter 6 (no redundancy)**
- **Substantial updates to regional content (e.g. EU, TGA, NMPA, ANVISA)**

ToC Document Consultation

- **N9 and N13 updates were approved for public consultation by the Management Committee in January 2023**
  - Public consultation held from February – May 2023
  - 200+ comments received from 10 stakeholders
- **Feedback focused on the following:**
  - Aligning content between N9, N13, and other IMDRF documents
  - Adding/correcting references (e.g. standards, regulations, definitions)
  - Formatting changes
  - Integrating recent updates (e.g. software, cybersecurity, AI/ML)

Next Steps

- **Final versions of N9 and N13 have been submitted for MC consideration**

- **The WG will advance work on an IMDRF dynamic submission template, including:**
  - Leveraging updated ToC requirements
  - Determining governance

Goals of a Dynamic Template

- **Guide the submitter to ensure they provide the necessary information for the submission**
- **Provide a standardized format to make information accessible for the reviewer and submitter**
- **Automate some aspects of the submission preparation process**
- **Collect submission data in a structured format to help automate regional processing**
- **Serve as a comprehensive resource for information needed for submission preparation**

A Note on eSTAR

- **eSTAR is one example of how an IMDRF MC Member has implemented the ToC into a dynamic template**
  - An interactive pdf form that guides applicants through the process of preparing regulatory submissions
  - Currently required by the US FDA for 510(k)s and voluntary for De Novo, PMA, and Pre-Sub US FDA submissions
- **eSTAR ensures all the required documents are included in the submission and placed in the appropriate structure before it is sent to the regulator**
- **Health Canada and the US FDA launched a joint pilot in January 2023 with 9 participants**
  - Joint pilot experience will inform the work of the RPS WG on a dynamic template within IMDRF

RPS Working Group Membership

Jurisdiction/Affiliation	Representatives
Australia	Fiona McCormick Simone McGinley Leon Weekes
Brazil	Augusto Bencke Geyer Anderson de Almeida Pereira Priscilla Consigliero de Rezende Martins
Canada	Daniel Yoon (co-chair) Johnny Chou Allison Oldfield
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European Union	Maria Chiara Orlandi (EC) Mario Gabrielli-Cossellu (EC) Rainer Edelhäuser (Germany)

Jurisdiction/Affiliation	Representatives
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South Korea	Young-mee Kwon Yunju Lee Yi Le Ahn (Rebecca)
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Thank you!

Questions?

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