IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION
Chair

Regulated Product Submission (Canada / USA)

Daniel Yoon

Acting Manager, International Programs

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European Commission

European Union

IMDRF International Medical Device Regulators Forum

Regulated Product Submission

Co-chairs:

Patrick Axtell, US Food and Drug Administration

Daniel Yoon, Health Canada

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Background

- RPS Table of Contents (ToC) is intended to provide a harmonized format for submitting medical device market authorization applications
  - Latest version was published in 2019
- RPS extension was approved in 2021 to update the ToC documents to be current
- The goal is to translate the updated ToC documents into a new type of dynamic template for building submissions

eSTAR

- eSTAR is a dynamic pdf template that guides applicants through the process of preparing medical device submissions
- Currently used by the US FDA for 510(k) and De Novo submissions.
- eSTAR will ensure all the required documents are included in the submission and placed in the appropriate structure before it is sent to the regulator
  - Ensures consistency and reduces processing delays
- Health Canada and the US FDA launched a joint pilot in January 2023 with 9 participants

N9 and N13 updates

- Minor refinements
  - Made content current for all jurisdictions
  - Minor improvements in harmonization in several subchapters
  - Removed reference to and use of Classification Matrices
  - Updated with MDR and IVDR content and references
  - Moved Essential Principles, Standards information, and Risk Management to Chapter 2 from Chapter 3
  - Simplified Regions column (will now list conforming regions or “IMDRF” for all)
- Larger changes
  - 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 additions/changes to EU, TGA, NMPA, ANVISA regional content

Consultation and next steps

- N9 and N13 updates were approved by the Management Committee in January for public consultation
- Consultation is open until April 15, 2023
- WG will analyze comments and revise the ToCs accordingly after consultation closes
- WG will also begin transferring ToC updates to eSTAR template
  - Currently programmed with FDA and HC submission requirements
- Proposed final documents will be submitted for MC consideration

Membership

Jurisdiction/Affiliation	Representative
Australia	Meryl Clarke Tania Ahmed Simone McGinley Shraddha Swami Leon Weekes
Brazil	Augusto Bencke Geyer Anderson de Almeida Pereira Priscilla Consigliero de Rezende Martins
Canada	Johnny Chou Allison Oldfield Daniel Yoon (co-chair)
China	Shiqing Zhang Yue Min
European Union	Maria Chiara Orlandi (EC) Mario Gabrielli-Cossellu (EC) Rainer Edelhäuser (Germany)
Japan	Madoka Murakami (MHLW) Yuzuru Okazaki (PMDA) So Hifumi (PMDA) Hideharu Komiya (PMDA)
Singapore	Agnes Goh Koh Chee Gake
South Korea	Young-mee Kwon Yunju Lee Yi Le Ahn (Rebecca)
United Kingdom	Jillan Hussein
United States	Patrick Axtell (co-chair) Kenneth Cavanaugh
World Health Organization	Helena Ardura-Garcia
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Thank you/Questions

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