IMDRF International Medical Device Regulators Forum

Regulated Product Submission

Daniel Yoon, Health Canada

Patrick Axtell, US Food and Drug Administration

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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.
  - The FDA will announce in September when eSTAR will be required for 510(k)s.
- 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

Progress

- Working group meets monthly and is currently updating N9 with regional updates and discussing where improvements can be made
- Similar changes will be made to N13
- Once updates are finalized, changes will be implemented into eSTAR
  - Currently programmed with FDA and HC submission requirements
- HC and FDA plan to announce a pilot by the end of this calendar year to test the joint use of eSTAR

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)
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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
Notified Bodies	Dawn Thibodeau Elle Helgeman Martin Witte

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Thank you/Questions

Email patrick.axtell@fda.hhs.gov
daniel.yoon@hc-sc.gc.ca