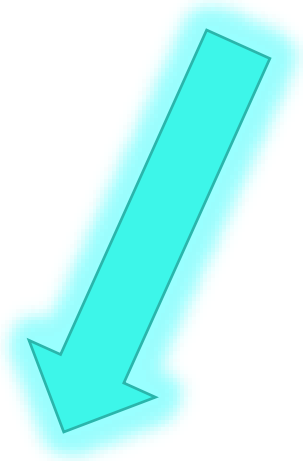
IMDRF International Medical Device Regulators Forum

Regulated Product Submission Working Group

Patrick Axtell, US Food and Drug Administration

Daniel Yoon, Health Canada



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IMDRF 24th Session – Berlin, Germany

About Us

- Initially formed in 2012 at the inaugural IMDRF meeting in Singapore
- RPS Table of Contents (ToC) is intended to provide a harmonized format for submitting medical device market authorization applications
- Work item extension was approved in 2021 to update the ToC documents to be current and translate the updated ToC into eSTAR, 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
- Used by the US FDA for 510(k), De Novo, and Pre-Sub submissions
  - eSTAR required for 510(k)s starting on October 1, 2023
- RPS Table of Contents (ToC) built in to provide a harmonized format for submitting medical device regulatory authorization applications
- eSTAR ensures required documents are included and submission is complete before it is sent to the regulator
  - Provides automation, standardizes structure, reduces processing delays
- Health Canada and the US FDA launched a joint pilot in January 2023 with 9 participants

Membership

Jurisdiction/Affiliation	Representative
Australia	Fiona McCormack Simone McGinley 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	Yuzuru Okazaki So Hifumi Hideharu Komiya Yusuke Tamura
Singapore	Agnes Goh Koh Chee Gake
South Korea	Young-mee Kwon Yunju Lee Yi Le Ahn (Rebecca)
United Kingdom	Eve Hutchinson Rebecca Riches-Duit
United States	Patrick Axtell (co-chair) Kenneth Cavanaugh Lili Duan
World Health Organization	Mark Lanigan
Notified Bodies	Dawn Thibodeau Sharmila Gardner Martin Witte Purvi Patel

Publications

- N9 and N13 are the working group's core documents
  - N9: non-IVD version of ToC
  - N13: IVD version of ToC

- Other documents related to the development of the ToC were published, including
  - N27: Assembly and Technical Guide
  - N19: Common Data Elements for Medical Device Identification

Ongoing work

- Consultation on the updated versions of N9 and N13 took place February – May 2023
  - Over 200 comments were received from 8 stakeholders
  - Requests for improved clarity, terminology changes, minor text changes and additions, layout/organizational changes
- Working group is going through comments
- Afterwards, updated ToCs will be transferred to eSTAR template
  - Currently programmed with FDA and HC submission requirements
  - Adding requirements for other jurisdictions will be explored
- Proposed final documents will be submitted for MC consideration

Opportunities and Challenges

- Some comments highlighted the need for N9 and N13 to align with the documents published by other working groups, such as cybersecurity's N60
  - May require discussions with chairs of applicable working groups
- Learnings from joint HC/FDA eSTAR pilot could help with expanding eSTAR to include other jurisdictions
- Keeping current harmonization (preventing divergence)
- Ensuring eSTAR and N9/N13 documents remain consistent
  - eSTAR is required to have current policies in place
  - N9 and N13 will be updated with policy changes as soon as possible

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Thank you/Questions

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