IMDRF International Medical Device Regulators Forum

IMDRF Regulated Products Submission (RPS) WG Update

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Updates

- ToC regional implementation
- Future of electronic submission environments (RPS)

ToC Implementation

- Health Canada posted draft ToC guidance in April 2019
- Approximately 30% of Health Canada's submissions since April 2019 in the ToC format
- Updates to the ToC to incorporate new EU Regulations
- Other regulators in various stages of implementation

RPS (Electronic Submission Standard)

- Ongoing discussions on how to address common stakeholder challenges with moving towards a standardized method
- Stakeholders continue to voice concerns with the current interim solution of folder structure and pdf
- Some jurisdictions are starting to develop their own templates for electronic submissions, moving away from harmonization

Next Steps

- The US Food and Drug Administration (FDA) has informed the WG that they are developing a medical device submission assembly tool (eSTAR).
- Preliminary discussions are occurring to determine if this tool is compatible with the ToC structure.
- The FDA is intending to make eSTAR fully harmonized with the TOC structure.

Questions/comments

Thank you!