



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
- Industry feedback to be collected over 1 year from participating manufacturers
- 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
- Sub-group continues to explore potential options and their feasibility
- Some jurisdictions are starting to develop their own templates for electronic submissions, moving away from harmonization



Next Steps

- Re-affirm commitment of Working Group to work towards a global solution



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Questions/comments

Thank you!