



**IMDRF**

International Medical  
Device Regulators Forum

# IMDRF Regulated Products Submission (RPS) WG Update

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## Updates

- Implementation options for ToC
- Electronic Submissions Interim Solution



## Next Steps for ToC Guidance

- The ToC may suffer the same fate as STED if we do not take steps to commit to implementation
- Without a commitment from IMDRF MC members on approach, further use of the ToC may be limited
- Industry will not invest if we do not at a minimum indicate that there is broad acceptance of the format across multiple jurisdictions



# Implementation Options

- Jurisdictions should now be moving to accepting submissions in the ToC format and expanding scope of accepted submission types
- Implementation options
  - Jurisdictions move to the ToC as their mandated submission format
  - Jurisdictions should offer the ToC as an option for submissions and work to expand scope to incorporate more market authorization application types in scope



## Implementation Options

- Discussion amongst RAs at IMDRF June Teleconference on implementation plans
- Half of the RAs indicated that they have plans to implement ToC as an option within the next 2 years.
- Health Canada has recently issued a Notice about its decision



## Implementation Options

- Health Canada will accept the ToC as its preferred format beginning April 1, 2019
- Health Canada format will also be accepted but STED format will be discontinued
- Applicants wishing to submit in ToC format before April 1 are encouraged to do so through the regional pilot program
- Guidance documents are expected to be published in the winter



## Implementation Options

- China (CFDA) has plans to utilize the ToC in 2019
- US FDA currently discussing options on utilization for PMAs as an alternate format
- TGA currently accepts the Table of Contents as an option for submissions
- Other RAs currently discussing and looking at the feasibility of adopting the ToC as an option



## Implementation Options

- WG is developing a communication to stakeholders on the ToC
- IMDRF ToC WG has drafted a final Assembly and Technical Guide based on the pilot version
- Main issue pre-RPS remains file path limitations – have been reduced further while maintaining meaning in revised folder templates
- Guide & folders - seeking MC approval at Jan telecon, but would ask for any significant concerns to be raised by **October 31, 2018**





## RPS Electronic Submissions

- RPS WG presented the RPS testing results from Round 2 at MC meeting in Shanghai and is now posted on the website.
- Industry RPS members have started industry outreach through an additional forum on electronic submissions for health products.
- Topics for upcoming discussions include:
  - IMDRF ToC Interim Electronic Format Discussion
  - Discussion of possible vendor forum for medical device submission publishing



## Next Steps

- WG to draft communication with regards to ToC pilot, implementation of ToC for MC consideration.
- MC approval of final Assembly and Technical Guide will be sought at January telecon