IMDRF Regulated Products Submission (RPS) WG Update

Nancy Shadeed
Health Canada
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