



IMDRF

International Medical
Device Regulators Forum

IMDRF ToC Pilot

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Pilot Plan

- Pilot intended to evaluate RPS Table of Contents structure with real, live, regulatory submissions sent to multiple regions
- Previous evaluations used historical submissions, which had limitations
 - Limited samples involving more than one region
 - No specific guidelines for building submission pre-RPS



Pilot Plan

- Each region has a classification matrix that sets out specific folder structure
- Manufacturer populates the structure with the relevant information



Pilot Objectives

- Develop and validate documentation supporting the use of the ToC using industry feedback
- Identify potential challenges for industry and develop proposals to address them moving forward
- Provide industry and regulators with experience using ToC in a controlled setting



Pilot Objectives

- Evaluate the proper usage of ToC headings and placement of documents within headings
- Identify additional ToC harmonization opportunities
- Establish and ensure ToC pilot technical guidelines are fit for purpose and harmonized amongst regions to the extent possible



Participants

- Australia, Brazil, Canada, China, Europe, and the United States are participating regions
- Regional pilots are also currently being undertaken by some IMDRF members



Pilot Status

- Pilot initiated October 1, 2015
- Expected to run for 1 year or until all objectives are met
- 22 requests received, 11 accepted
 - 10 nIVD, 1 IVD
- Teleconference convened early February to discuss first impressions
 - Only a few applications received to date
 - Still too early to draw any conclusions



Industry Feedback

- Early feedback focused on technical limitations of ToC
 - Character limit
 - Length of folder names
 - Requiring numerous sub-headers instead of amalgamating under one



Pilot Status

- Pilot and regional information for potential participants now posted on IMDRF website
- Certain regions discussing if scope should be expanded to encourage more submissions



Pilot Status

- Application breakdown by region:
 - Australia: 1
 - Brazil: 10
 - Canada: 4
 - China: 4
 - EU: 3
 - USA: 5



Next Steps

- Increase industry awareness of ToC Pilot and encourage more submissions
- Share pilot application experiences and discuss industry feedback amongst participating regions through regular meetings



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Questions?