



IMDRF International Medical
Device Regulators Forum

**Regulated Products Working Group -
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Open Stakeholder Meeting
March 2015**

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Update

- Developed an IMDRF ToC pilot plan
- Drafted Assembly and Technical Guide to support the IMDRF pilot
- Built IMDRF ToC folder structure (templates)



Pilot Plan

- The ToC Working Group has previously conducted pilots for both of the ToC structures, using historical submissions.
- Regional pilots are also currently being undertaken by some IMDRF members.



IMDRF ToC Pilot - Objectives

- The following general objectives are proposed:
 - To evaluate the adaptability of the ToC structure from an industry perspective when applying to more than one jurisdiction (simultaneously or sequentially)
 - To evaluate the proper usage of the ToC headings including the appropriate placement of documents within the headings and submission of complete and relevant content.



IMDRF ToC Pilot - Objectives

- To evaluate the proper usage of the ToC headings including the appropriate placement of documents within the headings and submission of complete and relevant content.
- To establish and ensure ToC pilot technical guidelines are fit for purpose and to the extent possible, harmonized amongst jurisdictions.



Submissions in Scope

The scope of regulatory submissions accepted during the pilot should be:

- real regulatory submissions
- intended for more than one participating jurisdiction over the pilot period
- accepted regionally for regulatory review.



Proposed Timelines

Development of supporting documents	Jan-Jun 2015
Initiation of pilot	Sep 2015
Close of pilot (minimum of 12 months duration)	Sep 2016



Assembly and Technical Guide

- Previous IMDRF pilot did not include specific guidelines regarding the means of building a submission in a pre-RPS implementation.
- This document is intended to supplement the IMDRF ToC Pilot Plan and describe additional harmonized guidelines for the acceptable folder structure and file format(s) for ToC-based submissions.



Assembly and Technical Guide

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Next Steps

- WG Requested that the MC approve the Posting of the Pilot Plan as an informational document
- WG Requested that MC approve the following proposed documents for public consultation:
 - Assembly and Technical Guide to support the IMDRF pilot
 - Built IMDRF ToC folder structure (templates)



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Thank you