MEDICAL DEVICES
REGULATORY AFFAIRS
Center of Excellence

IMDRF ToC PILOT
Experience in Three Jurisdictions

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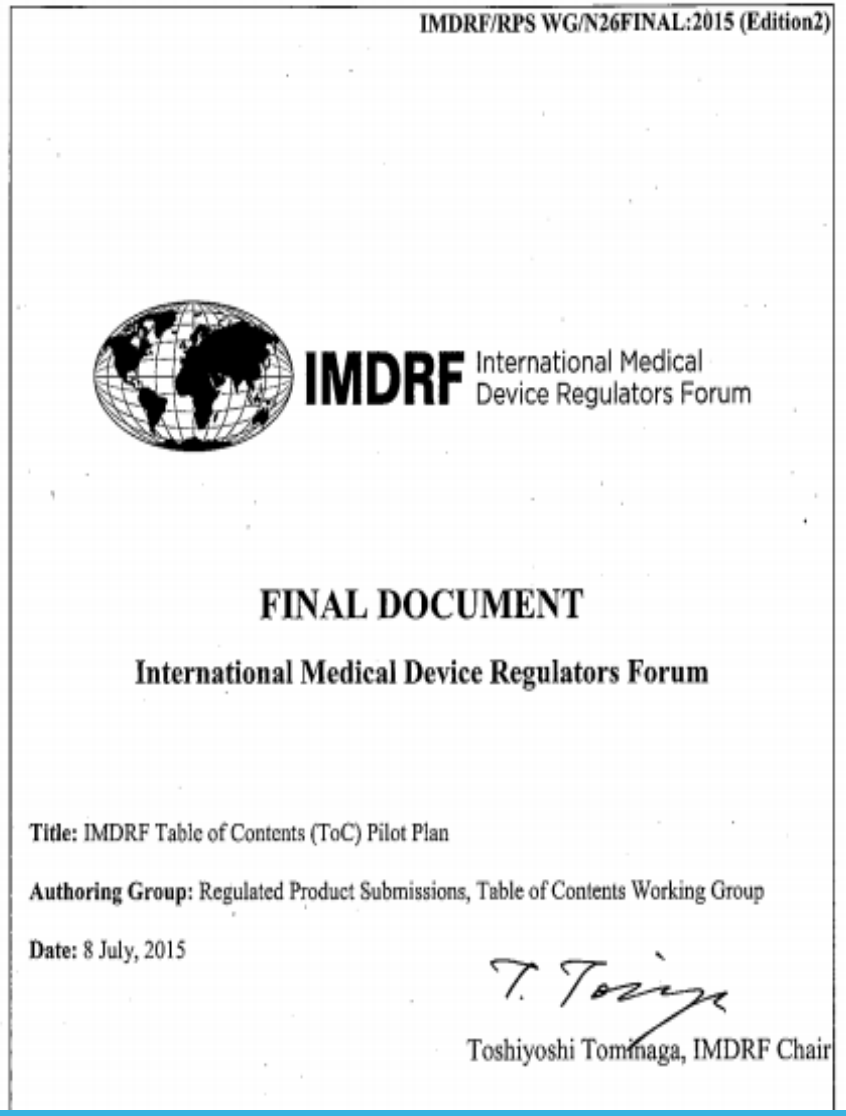
RPS / ToC Pilot Plan

- Establish a comprehensive modular pre-market submissions format for medical devices enabling:
  - Global convergence
  - Stakeholder efficiency gains
- Jurisdictional classification matrices define the required ToC headings & content
- Designed for eventual use in an electronic submission environment
- Distinct ToCs developed for IVD and nonIVD



IMDRF/RPS WG/N26FINAL:2015 (Edition2)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: IMDRF Table of Contents (ToC) Pilot Plan

Authoring Group: Regulated Product Submissions, Table of Contents Working Group

Date: 8 July, 2015

Toshiyoshi Tominaga, IMDRF Chair

IMDRF ToC Pilot

- September 2015 kick -off
  - Projected duration 1 year
- Engage stakeholders to test ToC & shape affiliated guidance through pilot and feedback forums
- Objective: to evaluate the adaptability of the ToC structure from an industry perspective when applying to more than one jurisdiction (simultaneously or sequentially), using real regulatory submissions

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Toshiyoshi Tominaga, IMDRF Chair

IMDRF ToC Pilot Requirements

- Pilot participants must be new and /or amended “real” pre-market applications that would result in regulatory decisions (submissions may be made sequentially or simultaneously to multiple IMDRF jurisdictions)
- Must be the same product; combo products not considered within the scope of the pilot
- Application filed and reviewed regionally
- Regional application submission dates may be staggered within duration of pilot
- E-file: nested folder structure housing pdf files

Suture Product Application

Licensed

In regulatory review

In regulatory review

Benefits

✓	Harmonized structure	→	Leveraging initial dossier across regions can reduce complexity of future dossier preparation and save time
✓	Regional-specific benefits observed	→	China: Anticipated clarity and transparency for future application of ToC templates; pilot allowed for stronger interaction and collaboration with regulators
✓	Clearer & more detailed requirements relative to current regional dossier	→	Facilitates better communication and understanding of requirements across jurisdictions
✓	Flexible format	→	Permits custom headers to capture additional content

Challenges

Highly detailed dossier structure	During initial adoption: ▪ Requires more time to compile ▪ Establishment of new internal procedures, workflows and templates
Impact of regional regulations on standardized dossier format	Efforts required to address different: ▪ Device Classification ▪ Registration Units ▪ Regional interpretations of regulations and guidance documents
Complex folder structure and long file names	Potential technical challenges: ▪ Inter-document hyperlinks ▪ E-file archival ▪ Compatibility with publishing software bound by external requirements

Interactions with Regulators- BRAZIL

- Regulator created instructions for official applicants, and the document was helpful
- ANVISA allowed submission prior to the availability of specific legal documents (e.g., CFG)

Interactions with Regulators- CANADA

- Minimal impact on review process and interactions:
  - Few informal clarifications requested during review
  - Majority were substantive questions pertaining to content
  - Lack of familiarity with content mapping under new format may have contributed to questions

Interactions with Regulators- CHINA

- ToC Classification matrix list developed to align global ToC with regional Chinese requirements. ToC templates are similar to the global example, with modifications based on requirements for each Classification. For example:

	Class II MD	Class III MD	Class II IVD	Class III IVD
New	ToC template 1	ToC template 5	ToC Template 9	ToC Template 13
Extension	ToC template 2	ToC template 6	ToC Template 10	ToC Template 14
Change of Approval Matters	ToC template 3	ToC template 7	ToC Template 11	ToC Template 15
Change of Administrative Matters	ToC template 4	ToC template 8	ToC Template 12	ToC Template 16

- Regulators have spent a significant amount of time working with regulated industry in meetings and workshops to develop current system.

Interactions with Regulators- CHINA

- Benefits: enable use of the general ToC used for other jurisdictional submissions, with modifications relevant for China. Significant time invested to develop first submission is leveraged for use in other submissions.
- Going forward, once ToC templates are implemented, it will provide standardized format for future e-channel submissions, which will be vital for industry to anticipate and plan systems that support CFDA's e-submission systems. These tools have the potential to reduce wait and review time, enhance overall efficiency, and promote transparency.

Summary

- Less complexity in dossier preparation due to more harmonized structure
- Somewhat significant upfront investment – time/cost, but great potential benefit for future
- Clear and detailed requirements per jurisdiction
- Each jurisdiction continues to evaluate the dossier according to local regulation interpretation, which can lead to additional requirements
- Approval times will differ from one jurisdiction to another due to: regional content, local evaluation lead-times

Summary

- Standardized guides and interactive training involving both regulators and industry recommended to clarify requirements and mitigate questions pertaining to the dossier content / format
- Engagement across jurisdictions to increase ToC convergence and to minimize regional-specific content