IMDRF RPS ToC WG Update

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Update

- Work done via teleconference since Sept, but the lion's share was produced at the face to face in Brasilia Feb 5-7 (thank-you Anvisa!)
- Generated final draft of the nIVD MA ToC for piloting and a pilot plan for piloting (provided earlier this month)
- Working towards final MA ToCs for November 2013 MC meeting

nIVD MA ToC - Chapters

The ToC is divided into 7 different chapters

- Chapter 1 – Regional Administrative
- Chapter 2 – Submission Context
- Chapter 3 – Non-Clinical Evidence
- Chapter 4 – Clinical Evidence
- Chapter 5 – Labelling and Promotional Material
- Chapter 6A – QMS Procedures
- Chapter 6B – QMS Device Specific Information

nIVD MA ToC - Heading Characteristics

- **Heading Level** – levels are assigned in the document. Along with the location this defines the hierarchy of the ToC
- **Heading Class –** Headings are classified as either IMDRF or Regional.
  - **IMDRF headings** are used by most regulators and are therefore considered an IMDRF heading. Content of IMDRF heading contain common elements and may contain regional elements in addition to the common elements.
    - **Regional Focus –** content needs to be considered with the specific region in mind and will likely need to be adapted for that region (e.g. regional approval numbers or regulatory history, regional variation in approved or requested intended use/indications for use etc.)
  - **Regional headings** are those that contain no common elements. In this case the heading name is consistent amongst IMDRF members, but the content will be specific and different for each region. Headings are also classified as Regional if they are required by only one jurisdiction.

nIVD MA ToC - Content

Example 1

- Heading: General Submission Summary
- IMDRF Heading – Common (left) and Regional (right)Content

a) Statement of the device name, its general purpose, and a high-level summary of key supporting evidence b) Summary of submission, informing the type of submission (new, amendment, change of existing application, renewal…). c) If amendment/supplement, the reason of the amendment/supplement; d) If change to existing approval, description of the change requested (e.g., changes in design, performance, indications, etc) e) Any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission)	**Anvisa:** If renewal, amendment or change, identification of the registration/notification number given by Anvisa for the device or family of devices and the number of the original application must be informed. **EU** If renewal, amendment or change, identification of the CE certification given to the product (family) of the currently approved products must be detailed. **HC** If amendment or new submission based on currently licenced device(s), the Canadian Medical Device Licence Number(s) should be provided along with the description of the change requested.

nIVD MA ToC - Content

Example 2

- Heading: User Fees
- Regional Heading – Regional Heading used by USFDA, Anvisa, EU – there is no common content under this heading, although the heading term “User Fees” is harmonized.

USFDA PMA and Traditional 510(k)

a) FDA User Fee Form
https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=

Anvisa

a) Receipt of the User Fee payment. Information about User Fee available at:
http://s.anvisa.gov.br/wps/s/r/n8

EU

a) Signed quote and agreement for dossier review /audits

nIVD MA ToC - Content

Example 3

- Heading: Reference and Comparison to Similar and/or Previous Generations of the Device
- IMDRF, RF Heading – IMDRF, Regional Focus (RF) heading – this is flagged as RF because the applicant will need to consider the region and may need to adapt the common content for that region (even though the common requirements are the same, they will need to adapt for the regional context)

a) Indications of similar devices (available on local and international market) and/or previous generation of the devices (if existent) considered as provision of background information. b) For similar devices, description of why they were selected. c) A key specification comparison table between the references (similar and/or previous generation) considered and the device.	**HC** If the application is an amendment to a licenced device or is based on a modification of a licensed device, a description of the modifications is required (e.g., changes in design, performance, indications, etc). Comparisons can be used to support the safety and effectiveness of the modification only if made to a currently licensed device in Canada. If this method is used, ensure the Canadian medical device licence of the comparator is stated.

Pilot Plan

- 2 phase plan
- Both phases will involve industry creating submission using the ToC and Regulators evaluating the product
- Historical submissions to be used and restructured
- Phase 1 – Preliminary evaluation of a single submission for a single jurisdiction by a single manufacturer (volunteers to be sought from those currently involved in other IMDRF work)
- Phase 2 – Involve more industry and a variety of different device risk classes and jurisdictions.
- Phase 1 to run Apr-May; Phase 2 Jun-Sep

Pilot Plan

- Feedback to be collected includes:

Manufacturers	Regulators
• Total Effort Involved in the Testing Process (adapting current systems to this structure) • Expected Benefits • Expected Drawbacks • Comments on Layout of Table of Contents • Assessment of the Duplication of Information • Comments on the Clarity of Vocabulary • Clarity of Optional or Regional Requirements • Difficulties and Potential Solutions • Comparison With Previous Submission • Comments about Regional Variations (adapting base to region) • Other Comments	• Total Effort Involved in the Test (how different it is from what we are doing now? Effort to adapt current practices/process) • Expected Effect on Future Effort • Comments about the Layout • Implications for Evaluations • Ease of Locating Information • Manufacturer Understood Requirements (or Further Guidance Recommended) • Scope to Reduce Cross Jurisdictional Differences (Little Return For Additional Headings) • Comparison With Previous Submissions • Other Comments

Next Steps

- Conduct the Pilot Phase 1 (Apr – May)
- Assess feedback (Jun)
- Finalize the IVD ToC for Phase 2 (Jun)
- Conduct Pilot Phase 2 (Jul – Sep)
- Finalize ToCs for Nov IMDRF MC Meeting