IMDRF International Medical Device Regulators Forum

IMDRF Table of Contents Pilot

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IMDRF RPS ToC

- The IMDRF RPS ToC WG has been working to establish common and regional headings for use in medical device submissions
- Although the primary focus is headings and structure, content is also necessary to communicate meaning of headings
  - scope limited to what goes where when required (i.e. comprehensive set of elements) and no specific guidance on WHEN it is required

Keywords on Headings

Keyword Type	Example Values	Comments
Species	Rabbit Pig	The type of animal used in testing
Component	Component 1 Component 2 Component 3 Component-All	The component of the device
Model	Model #1234 Model #5678	The model number or distinct device number
Material	Silicone Titanium	The type of material tested
Type of Test	Precision Reproducibility Linearity Normal Range/Cutoff Accuracy Specimen matrix	Keywords should be added to files to indicate the type of testing covered in the file

Background

- There are two main documents that work together to communicate to industry (and eventually tool-vendors)

  1. Table of Contents
  2. Classification Matrix

- There are IVD and nIVD versions of both

nIVD MA ToC

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 – Headings

- 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 – used by most regulators and are therefore considered an IMDRF heading. Content contains common elements and may contain regional 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, etc.)
  - Regional Headings – contain no common elements. Heading name is consistent amongst IMDRF members but content will be specific and different for each region

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 US FDA, ANVISA, EU – no common content although the heading “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
  - RF because applicant must consider the region and may need to adapt common content for that region
  - Although common requirements are the same, applicant must adapt for the regional context

nIVD MA ToC – Content

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.

Classification Matrix

- Document classifying each heading for each submission type of each jurisdiction
- This will define the heading requirement for a given submission type (i.e. required, not required, optional, conditionally required, etc.)
- Distributed with the ToC for Phase 2

Example of Classification Matrix

		CIV New	
		Classification	Condition
CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION			
CH6B.1	Chapter ToC	R	
CH6B.2	Quality management system information	NR	
CH6B.3	Management responsibilities information	NR	
CH6B.4	Resource management information	NR	
CH6B.5	Product realization information	NR	
CH6B.6	Device Specific Quality Plan	R	
CH6B.6.1	Design and development information	NR	
CH6B.6.2	Purchasing information	NR	
CH6B.6.3	Production and service controls information	R	
CH6B.6.4	Control of monitoring and measuring devices information	NR	
CH6B.7	QMS measurement, analysis and improvement information	NR	

ToC Pilot

- Pilot initiated October 1, 2015
- Australia, Brazil, Canada, China, European Union, USA are participating regulators
- Open to manufacturers of certain submission types requesting market authorizations to two or more regions

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.

ToC Pilot

- 24 participation requests received, 13 accepted, 1 accepted submission withdrawn
- Submissions received to-date by region:
  - Australia – 1
  - Brazil – 7
  - Canada – 2
  - China – 4
  - EU – 1
  - USA – 2

Feedback from Pilot

- Generally positive feedback has been received from both manufacturers and regulators.
- To-day's sessions will discuss this in greater detail.

Thank you