IMDRF RPS UPDATE

March 20, 2013

IMDRF Regulated Product Submission NWI

- Composed of two complementary components:
  - Beta testing of RPS Standard to confirm fit for purpose for medical devices
  - Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD)
- Project takes account of existing work:
  - Beta testing: HL7 RPS WG and ICH
  - ToC: GHTF STED documents
- Seen as important step towards goal of common premarket requirements for device applications

Regulated Product Submission

- Health Level 7 (HL7) message standard for electronic submission of product information between companies and regulatory agencies for purpose of gaining market authorization
- Standard (envelop) independent of submission content (letter)
- Scope: Meant for worldwide use: same model for all product types, all regulatory agencies
- Currently under beta testing by ICH for use as Next Major Version of eCTD

Beta Test Update

Key Activities

- Device Storyboards / Requirements
  - Identify unique medical device business scenarios for pre-market submissions
  - Determine how RPS should enable those processes
- Implementation Guide
  - Define technical details about how all IMDRF regions will use RPS
  - Define Regional differences
- Communicate unique device requirements to HL7
- Testing
  - Test critical RPS functions that will not be covered by ICH testing
  - Work with software vendors to create RPS submissions
  - Verify that the standard can support the requirements

Work Schedule & Status

IMDRF Activity	Planned Completion	Status
Device storyboard / requirement	April 1	In progress
Implementation Guide	April 1	In progress
Test Plan & Test scripts	May 1	In progress
New Device Requirements communicated to HL7	May 1	
Testing @ FDA's White Oak facility	May 21-24	
Initial RPS Ballot content due to HL7	July 14	
Normative HL7 Ballot	Sept 16	
Additional Testing to Inform / plan device implementation	TBD	

IMDRF International Medical Device Regulators Forum

Draft

International Medical Device Regulators Forum

Title: Beta Testing – Regulated Product Submission Implementation Specification

Authoring Group: IMDRF RPS Work Group

Date: February 22, 2013

Phase 2

- Proceed with work required to implement RPS as message standard for electronic medical device applications:
  - Finalize IMDRF IG and controlled vocabularies (including ToCs)
  - Develop and finalized regional IGs and CVs
- Consider interim (longer term?) solutions

Table of Contents (ToC)Update

Achievements

- ToC sub-working group has completed:
  - Final draft of the non-IVD ToC for piloting
  - Accompanying pilot plan
- Both documents to be posted to IMDRF website following March 2013 IMDRF Manegement Committee meeting
- Working towards final ToCs for both non-IVD and IVD 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

- Two 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 (April – May) – Preliminary evaluation of a single submission for a single jurisdiction by a single manufacturer
- Phase 2(June – Sept) - Involve more industry and a variety of different device risk classes and jurisdictions

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

Thank you!
Merci!

Questions?