Regulated Product Submission

- IMDRF RPS project has two components:
  - Beta testing of standard to make sure it meets business requirements for electronic filing of premarket device applications
  - In parallel, develop common, modular table of contents (ToC) for device applications (IVD and non-IVD)

Regulated Product Submission

- An Health Level 7 (HL7) message standard for electronic submission of product information between companies and regulatory agencies for purpose of gaining market authorisation
- Standard (envelop) independent of submission content (letter)
- Scope: Meant for worldwide use: same model for all product types and all regulatory agencies
- This standard is for use by ICH as Next Major Version of electronic Common Technical Document (eCTD)

IMDRF – Regulated Product Submission (Health Level Seven (HL7))

- Development of RPS being undertaken through HL7, an ANSI accredited Standards Development Organization (SDO)
- Develops standards to improve information sharing and interoperability between health care systems
- Many HL7 standards are also ISO TC-215 standards
- RPS one of several projects under the Regulated Clinical Research Information Management (RCRIM) working group

Regulated Product Submission

- Beta Test Subgroup developed test case scenarios (harmonized and regional) that were considered unique device related business requirements
- Four priority test case scenarios (TCS) were defined and provided to software vendors to create samples to verify that the standard can support the business requirements
- The draft HL 7 RPS standard did not pass during the last HL7 ballot
- The WG will finalise results from the Round 1 TCS and make them public and will further define additional regional TCS for testing

IMDRF – Table of Contents (ToC)

- ToC sub-working group has completed:
- Final ToCs for both non-IVD and IVD devices have been published on the IMDRF website since fall 2014

IMDRF – 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

IMDRF – 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.

IMDRF – nIVD MA ToC – Heading Characteristics

- **IMDRF Headings**
  - **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.

Classification Matrices

- Not all headings in ToCs are required for all submission types and/or jurisdictions
- ToC documents are intended to work together with a separate document created by and for each participating jurisdiction – the classification matrix
- Defines whether, for given submission type, a heading and associated content is required, not required, optional or conditionally required
- Classification matrices are published on regional websites
- With introduction of RPS message standard, publishing/ viewing tools should display what is appropriate for a particular jurisdiction

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	

IMDRF Pilot Plan

- Consulted on a Draft Assembly and Technical Guide to support the IMDRF pilot
- Consulted on an IMDRF ToC folder structure (templates)
- Updated the IMDRF ToC Pilot Plan
- An Expression of Interest Letter was posted

IMDRF Pilot Plan

- Australia, Brazil, Canada, China, EU and United States will be participating in the IMDRF ToC
- Regional pilots are also currently being undertaken by some IMDRF members.

Proposed Timelines

Initiation of pilot	**Sep 2015**
Close of pilot (minimum of 12 months duration)	Sep 2016

Why is the RPS important?

- RPS will allow for unprecedented functionality in terms of the review and management of regulated product information over the entire product life cycle
- Use by regulatory agencies across product lines provides for resource savings and greater efficiencies, including with respect to the training of reviewers
- Expected to increase the efficiency and effectiveness of regulatory processes internationally
- ToC work seen as important step towards goal of common premarket requirements for device applications