IMDRF International Medical Device Regulators Forum

RPS Work Item: International Harmonized Structures (formerly Table of Contents)

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Update since Brussels

- Completed assessment of Phase 2 pilot samples and comments received for both IVD and nIVD **International Harmonized Structures** (IHS) – new name
- Conducted public consultation for the IVD IHS
- Held productive meeting in Washington to discuss feedback received and determine necessary actions

Update

- Revised IHS documents based on public comments and feedback from regulators and industry through pilot phase
- Developed a Backgrounder and Lessons Learned/ Q & A document to further clarify how to use the IHS documents
- Updated work plan which foresees development of training materials and maintenance plan

Pilot Feedback

- Pilot process was generally successful
- Main issues associated with use of historical submissions rather than new submissions (limitation of pilot design)
- Identified some areas where more granularity would be beneficial (e.g. software verification/validation)
- Identified areas where further communication clarification would be beneficial

IVD Public Comments

- Good feedback from industry which resulted in many minor/moderate revisions
- Concerns about comprehensiveness of the structure, which includes regional headings
- Education sessions will be necessary to promote understanding on how to use this structure for both IVD and non-IVD applications in a pre-RPS electronic environment
- Classification matrices (which were not published with draft ToCs) will be key in providing clarity

Classification Matrices

- Not all headings in IHSs are required for all submission types and/or jurisdictions
- IHS 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 to be made available with IHS documents on IMDRF website
- 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	

Next Steps

- IVD and nIVD IHS documents (Version 1) and associated explanatory documents to be considered by the MC for endorsement at June 2014 teleconference
- Once endorsed and posted on IMDRF website along with classification matrices, regions will be free to further pilot the new structures using real submissions and translate documents as structures will be stable
- Anticipate potential refinement of IHSs within approximately 18 months based on real life experience
- Ongoing discussions regarding the filing of electronic (pre-RPS) versions of IHS compliant device applications
- Regulators should be consulted on specific implementation plans

Summary

- Piloting, training and elaboration of Qs & As will be important to the successful use of the new IHS structures for IVD and nIVD applications
- IHS developed with aim of supporting RPS compliant applications; classification matrices meant to provide clarity in pre-RPS environment
- Transition rules will vary from regulator to regulator. Consult the relevant regulatory authority for further information

Thank you!