IMDRF International Medical Device Regulators Forum

RPS Work Item: Table of Contents

IMDRF Stakeholder Forum
Washington, D.C.
September 17, 2014

Nancy Shadeed

Health Canada

Update since San Francisco

- IVD and nIVD Table of Contents (ToC) documents (version 1) were endorsed by the MC at the June 30th teleconference
- An additional document entitled “Points to Consider” was also endorsed. This document clarifies how to use the ToC documents
- These documents are available on the IMDRF website.

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 to be made available on each jurisdiction/regulatory authority's 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	

Next Steps

- Classification Matrices will be posted on regional websites
- Each regulator will be free to pilot the new ToCs using real submissions and translate documents as structures will be stable
- Development of training material, Qs and As and exchange of information on implementation plans will be coordinated – survey is currently being undertaken
- Anticipate potential refinement of ToCs within approximately 18 months based on real life experience
- Ongoing discussions regarding the filing of electronic (pre-RPS) versions of ToCs 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 ToC structures for IVD and nIVD applications
- ToCs 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!