IMDRF International Medical Device Regulators Forum

Update on WHO work

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What's new since September 2014

- Regulatory strengthening
- Prequalification of IVDs:
  - Product dossier
  - Inspections

ToC/RPS

MDSAP

- Ebola-related work

Revised Model Regulatory Framework for medical devices

- 'Regulating medical devices: guiding principles and phasing implementation'
  - definition of a medical device
  - the product cycle of a medical device
  - guiding principles for regulating medical devices: risk based model for market access, conformity assessment, reliance model, vigilance
  - critical elements for regulating medical devices: regulatory system, import controls, distribution channel control
  - phases of regulatory implementation (modular model)

National Regulatory System (NRA) assessment tool

Harmonised NRA-assessment tool for vaccines, medicines, medical devices (including IVDs), blood products and traditional medicines

Outcome of the international consultation January 2015:

- Phase I: common elements for all product streams
- Phase II: specific elements for distinctive product stream

Involving existing models like MDSAP, PIC/s, BEMA

Deciding on indicators for each product stream in the next months

National Regulatory System (NRA) assessment tool: indicators

Modules	Critical	Recomended	Information	Number
NRS	146	29	0	**175**
Marketing Authorization	65	5	1	**71**
Licence	38	11	1	**50**
Post Marketing Surveillance	68	17	1	**86**
Vigilance	34	6	0	**40**
Clinical Trials	46	12	1	**59**
Inspections	45	8	0	**53**
Laboratory	48	2	0	**50**
TOTAL	490	90	4	**584**

Prequalification of IVDs

- Major restructuring and programme reshaping in 2014
- In 2015 on-going work to further improve the programme
- New challenges: post-PQ phase (re-inspections, changes notification/assessment)

ToC / PQDx Product dossier

- Content wise, in general the differences between the TOC and the STED is greater granularity of existing STED requirements.
- WHO has revised its Dossier requirements to incorporate these differences.
- WHO dossier format (numbering) not yet aligned with TOC but the plan is that this will occur after the TOC pilot.
- WHO has a number of specific requirements not required in the TOC, probably the most important ones being submission of information relating to regulatory version, biological safety, and a number of specific QMS related documents.
- WHO has developed 2 classification matrices for Class C and D products, one for use by WHO PQ, the other for use as a guide for Member States developing regulations.
- WHO will not partake in the pilot due to staffing constraints.

MDSAP / PQDx inspections alignment

Alignment with MDSAP	Status	
Inspection Cycle	Initial (stage 1 and 2) Surveillance ? Special ? (follow up, changes / complaints) Re-inspection	√ ? ? √
Inspection time calculation	WHO inspection activities differ	partly
Grading of nonconformities	Level 1 – level 5 (separate for QMS and dossier) **Clarification required (escalation rules)**	√
List of nonconformities	Fully implemented	√
Inspection report	Available report template cannot be used Activity based report was implemented (reviewed evidence, trail, persons involved & evaluation / conclusion) **Training required**	Partly

Ebola-related efforts

- WHO has developed an Emergency Use Assessment and Listing (EUAL) procedure for IVDs, medicines and vaccines (on web for comment, due 27 March) http://www.who.int/medicines/news/public_consult_med_prods/en/
- Assessment based on risk based decision of limited data
  - 3 step process, QMS, dossier and lab (Verification of manufacturers claims of analytical data, and for RDTs, of clinical data)
- 23 applications for IVDs; 2 products now listed
- A head to head study of Ag RDTs tests advancing through the EUAL is being planned and should be completed within 4 to 5 weeks.
- Devices:
  - PPE specifications (TPP)
  - donations

Thank you