Update on WHO work

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World Health Organization
Kyoto, 15 – 17 September 2015
What's new since March 2015

• Prequalification of IVDs:
  – Dossier, inspections, changes, PMS
• Ebola-related work
• Regulatory strengthening
Prequalification of IVDs

• Streamlined PQ since mid-2014:
  – Emerging Mx need guidance and assistance
  – QMS implementation is the most difficult part
  – Unmet needs, especially for HCV

• Capacity building mechanism to strengthen NRAs
  – Joint assessments
  – Collaborative procedure
  – NRA and manufacturers training

• Programme framework expansion to PoC/near to PoC HPV IVDs

• QA partnership with USG (USAID and CDC): common assessment mechanism informing UN, Pepfar and partner organizations' procurement
• PQDx in active implementation phase since 2010: submissions quality is increasing
• However, still urgent need for guidance
• PQDx developing 13 guidance documents
  – Reference documents
  – Stability studies
  – 3 Sample dossiers
  – IFU
  – Quality control principles
  
  Closest to publication for public comments

• Excellent support to WHO PQ on development of these by regulators and from standards bodies
# MDSAP / PQDx inspections alignment

<table>
<thead>
<tr>
<th>Alignment with MDSAP</th>
<th>Status (August 2015)</th>
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<tbody>
<tr>
<td>Inspection Cycle</td>
<td>Initial (stage 1 and 2)</td>
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<tr>
<td></td>
<td>Surveillance (replaced by annual report)</td>
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<td>Special (follow up, changes / complaints)</td>
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|                                      | Re-inspection                                                                      | **✓**
|                                      | **No**                                                                              |
|                                      | **✓**                                                                               |
|                                      | **✓**                                                                               |
| Inspection time calculation          | MDSAP/_AU-F0008.1 (unlocked version)                                               | **✓**
| 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                                            |
|                                      | Adapted activity based report implemented (reviewed evidence, trail, persons involved & evaluation / conclusion) | **✓**
|                                      | **Training ongoing**                                                                |
PQDx changes notification and assessment

• Current guidance on reporting of changes in place since June 2014

• Result has been variable compliance and significant work load for PQDx

• PQ currently revising guidance
  – Improve clarity to ensure consistency and transparency in decision making process

• Lack of substantive international guidance on this topic (changes/variations) makes it difficult for manufacturers
  – Need for international harmonization
PQDx post-market surveillance

• Launch of WHO guidance on post-market surveillance for in vitro diagnostics
  http://www.who.int/diagnostics_laboratory/postmarket/en/

• Continuation of WHO complaint handling procedure through standardized IVD complaint form
  – 7 new complaints in 2015
  – most of the complaints that we have received are for RoW regulatory versions but are of relevance to the stringently regulated products

• Expect to see improvement in vigilance reporting from Mx and end users
Ebola-related efforts

- The response to the Ebola outbreak is now heading into enhanced surveillance activities to identify all remaining cases.
- EUAL assessment of IVDs:
  - 24 applications for IVDs; 4 products listed, one more shortly.
Survey on regulation of medical devices: categories

- Market surveillance
- Inspection/QMS
- Enforcement
- FSCA Monitoring

- Reliance
- Conformity assessment
- Advertising
- Clinical investigation controls

- Legal Framework (regulation, guideline)
- National Regulatory Authority (NRA)
- Definition of a Medical Device
- Registries of establishment and devices
- Labelling
- Risk Classification
- Adverse Event Reporting
- Import controls
To the extent that regulations and guidelines are made available and accessible, comporting with principles of good regulatory practice, these data represent a global overview of medical device regulation, not implementation.
Global trends: regulatory frameworks

- Regulate: 103
- Medical device definition: 80
- Reliance: 52
- Import controls: 61
- Register medical devices: 62
- Register establishment: 48
- Adverse event reporting: 59
Global assessment tools: input for harmonized tool
Harmonized tool: Phase 1 and 2

National Regulatory System (NRS)

Inspection & Enforcement (INE)

Laboratory access and Testing (LAT)

Clinical Trial’s Oversight (CTO)

Licensing premises (LIC)

Vigilance (VGL)

Registration & marketing authorization (RMA)

Market surveillance and Control (PMC)

NRA Lot release (LTR)

PHASE 1

PHASE 2

1. Minimal Capacity
2. Stable Formal System Approach
3. Maturity level (ISO 9004)
4. BEST IN CLASS PERFORMANCE
5. NO FORMAL APPROACH

Elements to be considered under relevant functions

Maturity level (ISO 9004)

Minimal Capacity

Stable Formal System Approach

BEST IN CLASS PERFORMANCE

NO FORMAL APPROACH
Planning for the WHO International Consultation on Regulatory Systems Strengthening (RSS), 2014-2015

Harmonization of medicines, IVDs, medical devices, blood, traditional medicines & vaccines tools

Working Groups sessions

- Working Group 1 – Policy. Terminology
- Working Group 2 – Methodology/Process
- Working Group 3 – Functions/Indicators

Meeting with expert for revision of the NRA assessment tool for medical devices 1-2 October

- 2nd International Consultation Geneva 1-3 Dec

1st Web Policy consultation
2nd WEB Policy Consultation
2nd version harmonized tool
Phase 1

October 2014
January 2015
October 2015
December 2015
Thank you