Abbreviated WHO prequalification assessment procedure

Industry Briefing on Streamlined WHO Prequalification of Diagnostics Procedure
15/16 May 2014, Geneva

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Categories of products submitted to PQ

- **Scenario 1**
  - Version submitted for PQ has been stringently assessed

- **Scenario 2**
  - Version submitted for PQ has not been stringently assessed but a regulatory version exists that has been

- **Scenario 3**
  - Version submitted to PQ has not been stringently assessed

- Where stringent assessment has been conducted by founding member of GHTF
Scenario 1

- If the regulatory version submitted for WHO PQ has undergone prior stringent regulatory review by a founding member of the GHTF

- Stringent regulatory review recognized as:
  - CE; List A, Annex 2
  - FDA; PMA or BLA
  - Health Canada; Class IV
  - TGA; Class 4
  - Japan; Minister's approval
Scenario 1

An abbreviated PQ assessment procedure will be followed:

1. WHO pre-submission form
2. No dossier requested by WHO
3. Abbreviated WHO site inspection
   - Information package requested to prepare for the inspection, including receipt of previous satisfactory audit report;
   - Shorter duration, fewer inspectors; to verify WHO customer requirements;
   - 1 inspector, 1 technical expert.
4. WHO laboratory evaluation of performance and operational characteristics to inform product selection
Scenario 2

- If the regulatory version submitted for WHO PQ is the rest of world regulatory version but the manufacturer has a "similar" product that has undergone prior stringent regulatory review.

- Stringent regulatory review is recognized as:
  - CE (List A, annex 2), FDA (PMA or BLA), Health Canada (Class IV), TGA (Class 4), Japan (Minister's approval)
Scenario 2

Procedure to be followed:

1. WHO pre-submission form
   - Comparison of key differences between stringent regulatory version and ROW regulatory versions is made:
     - Product description, intended use, test procedure, design, manufacturing site, key suppliers, labelling, instructions of use, quality management system, verification/validation studies, lot release criteria
   - If substantial differences, usual PQ assessment procedure is followed (no abbreviated assessment)
   - If no substantial differences, abbreviated PQ assessment procedure is followed
Scenario 2a

- Usual PQ assessment
  - substantial differences between regulatory versions

1. Dossier requested by WHO

2. Site inspection

3. WHO laboratory evaluation of performance and operational characteristics to inform product selection
Scenario 2b

- Abbreviated PQ assessment
  - no substantial difference between regulatory versions

1. No dossier requested by WHO

2. Abbreviated WHO site inspection
   - Information package requested to prepare for the inspection, including receipt of previous satisfactory audit report;
   - Shorter duration, fewer inspectors; to verify WHO customer requirements;
   - 1 inspector, 1 technical expert.

3. WHO laboratory evaluation of performance and operational characteristics to inform product selection
Scenario 3

- Where no stringently assessed regulatory version exists

- Any regulatory review other than the following:
  - CE; List A, Annex 2
  - FDA; PMA or BLA
  - Health Canada; Class IV
  - TGA; Class 4
  - Japan; Minister's approval
Scenario 3

- Usual PQ assessment procedure will be followed:
  1. Dossier requested by WHO
  2. Site inspection
  3. WHO laboratory evaluation of performance and operational characteristics to inform product selection