WHO/UNFPA Prequalification Programme

Joint UNICEF – UNFPA –WHO meeting

Dr. W.D Potter
Remote Inspections Update
Background

- Covid 19 has critically restricted national and international travel
- WHO/UNFPA Prequalification Scheme has been severely affected
  - Prequalification inspections postponed
  - Quality investigations awaiting inspections
- UNFPA has developed guidance on conducting prequalification inspections remotely
- Guidance subjected to detailed review
  - Manufacturers, inspectors, consultants, etc
- Current version issued in September 2020
Outline Procedure

• Updated prequalification scheme published in 54\textsuperscript{th} WHO Expert Committee on Specifications for Pharmaceutical Preparations 202 Annex 9

• UNFPA issue an EOI or periodic request for reassessment for prequalification to manufacturers

• Manufacturer submits documentation:
  • Covering letter
  • Summary of technical documentation (STED) (Appendix 1 of Annex 9)
  • Samples

• UNFPA conducts document review
Outline Procedure – Document Review

• Initial screening of documents
• Assessment of summary of technical documentation by technical experts
• Decision to inspect
• Risk assessment for remote inspection
  • Conducted by UNFPA and inspection team using Check List (Annex 2)
  • Checklist requires probable submission of further documentation
• Decision made on whether to proceed with remote inspection (minimum score of 120 required)
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Score</th>
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<tbody>
<tr>
<td>1  Is the manufacturer’s overall status with respect to change control,</td>
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<td>risk management, process and product compliance to client and</td>
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<td>regulatory requirements acceptable (yes = 20, no = 0)</td>
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<td>2  Is the manufacturing site already prequalified (yes = 20, no = 0)</td>
<td></td>
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<td>3  Assessment of submitted documentation (poor = 0, excellent = 10)</td>
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<td>4  Are the manufacturer’s information technology (IT) facilities judged</td>
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<td>to be acceptable for a remote inspection (poor = 0, excellent = 10)</td>
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<td>5  Assessment of the quality record of the manufacture (poor = 0,</td>
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<td>excellent = 10)</td>
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<td>6  Assessment of the manufacturer’s complaints record (poor = 0,</td>
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<td>excellent = 10)</td>
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<td>7  Have all past CAPAs been resolved (yes = 10, no = 0)</td>
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<td>8  Assessment of the quality of submitted QC data (poor = 0, excellent</td>
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<td>= 10)</td>
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<td>9  Assessment of independent pre-shipment test reports (poor = 0,</td>
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<td>excellent = 10)</td>
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<td>10 Have there been any in-country lot rejections (yes = 0, no = 10)</td>
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<td>11 Have there been any major changes in processes or equipment since</td>
<td></td>
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<tr>
<td>last inspection (yes = 0, no = 10)</td>
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<td>12 Have there been any major changes in senior management since last</td>
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<td>inspection (yes = 0, no = 10)</td>
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<tr>
<td>13 Assessment of the internal audit reports (poor = 0, excellent = 10)</td>
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<td>14 Assessment of minutes and reports of the Management Review Meetings</td>
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<td>(poor = 0, excellent = 10)</td>
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<tr>
<td><strong>Total score</strong></td>
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<tr>
<td><strong>Maximum score</strong></td>
<td><strong>160</strong></td>
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Equipment Requirements for Remote Inspection

• Good internet access – UNFPA Zoom Account
  • Manufacturing site including factory areas
  • Inspectors and UNFPA observers

• Facilities for video conferencing (available in at least two rooms)
  • Zoom breakout room facility will be used to permit parallel sessions

• Facilities for live video feed from factory areas – cameras, smart phones, tablets

• Facilities to view additional documents
  • Scanner
  • Cameras/phones
  • Submission to UNFPA for uploading the Google Drive
Key Stages in Meeting

- Introduction of Key Personnel
  - Attendance list with names and job titles
- UNFPA presentation
  - UNFPA Representative
- Manufacturer’s Presentation
  - Management Team
- Video tour of factory
  - Pre-recorded video
  - Interactive tour by request of the inspectors
- CAPA Review
Key Stages in Meeting (Continued)

• Discussion Meetings
  • Conducted according to pre-circulated schedule
  • Timings and schedule may need to change depending on findings
  • Breakout room facility will be used to permit parallel sessions
  • Further video inspection of plant areas, equipment, processes, laboratories, warehousing, etc will be required
  • Daily opening and closing meetings to review progress and facilitating planning

• Product sampling for prequalification testing
  • Needs to be scheduled in advance
  • Will be witnessed by the inspection team

• Offline UNFPA/inspectors’ meetings

• Closing Meeting
  • Review of closing meeting report and agreement of nonconformities and observations
Practical Experience

• Time zone restrictions reduce duration of meetings
• Video review of factory areas, processes and testing straightforward and effective – tablets might be better than phones for video
• Document review generally effective
  • Access to a scanner to permit sharing of documents critical to success
  • Capability to transfer control of scrolling during live document review to the inspector would improve speed and effectiveness of process
• Occasional problems with clarity of audio
  • Muffled by masks, background noise, location of microphones and room acoustics
• Good Wi-Fi connections throughout all factory areas critical
• Good planning essential for success
Questions & Discussion
Thank you for your attention