Technical support for new PQ applications – overview/outline, eligibility, implementation etc.

Day 2 – Session 5.5

28th November 2023

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Overview and outline:

- **UNFPA workshops with manufacturers, existing and new**
- **October 2014, in Kuala Lumpur, Malaysia**
- **Areas covered: PQ process, Application process, PQ documentation, Dossier reviews, One – to one meeting with UNFPA team and Experts – Q&A, brief reviews of documentation, where clarifications were required to help manufacturers prepare themselves for PQ process**
- **Specific in country project with one manufacturer.**
- **Discussions with manufacturers when explanations on CAPA were warranted**

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Current Scenario:

- **Changes in documentation – STED instead of Product Dossier and Site Master File**
- **Revisions to ISO standards and WHO UNFPA Technical specifications, WHO TRS**
- **Consequent revisions in technical requirements**
- **Continual Updates in the form of Webinars and workshops**

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Current Scenario:

- **Organizational updates in UNFPA**
- **Operational updates in UNFPA SCMU**
- **Notification of significant changes and their review**
- **Complaint analysis – PQed manufacturer wise**
- **Projects such as Data loggers to monitor transport conditions**
- **Post market surveillance of PQed manufacturers**
- **Notice of concern and Notice of suspension**
- **Publication of supporting documents**

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Current Scenario:

- **Corporate changes in manufacturers' operations – Mergers and Acquisitions**
- **New manufacturers**
- **Regional developments and collaborative forums**
- **Developments in technology**

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Technical support - Eligibility:

- **Any manufacturer of male condoms, female condoms or IUDs willing and committed to get Prequalified as per UNFPA PQ process.**
- **Established Quality Management Systems and validated operations**
- **Certified to ISO 13485 by an Internationally accredited notified body**
- **Commitment to provide required resources for preparing to get prequalified.**

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Technical support - Implementation:

- **Gap analysis against the requirements of WHO PQ process and technical specifications.**
- **Explanations and technical inputs**
- **Review of preparedness**
- **Consultation without conflict of interest**

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Thank you