Post Market surveillance of Prequalified manufacturers

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Post market surveillance

Quality assurance:

Prequalification of manufacturers

Pre shipment product testing – lot wise

Temperature monitoring – data loggers

Post Market Surveillance – In country activity, last mile assurance

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Feed back from in –country testing

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Draft guidelines under development and review

SOPs to follow for implementation

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Post marketing Surveillance – Elements involved :

- Public procurement and private distribution
- Logistics
- Storage
- Distribution
- Dispensing
- Storage by user

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Scope

- PMS system targeting lot testing of products manufactured according to WHO/UNFPA product specification by prequalified manufacturers.

Objective

- Evaluation of the conformity status of products manufactured by prequalified manufacturers to WHO/UNFPA specifications at user level.

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PMS plan: Risk based approach

- Communication and involvement of stakeholders
- Identification of countries
- Identification of manufacturers and products
- Identification of levels at supply chain
- Development of Sampling plan

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PMS plan: Risk based approach

- Collection and transport of samples to accredited laboratories
- Testing of samples
- Analysis and interpretation of results
- Initiation of follow up actions
- Monitoring and QA of PMS programme

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Identification of countries:

- Supply chain structure
- Infrastructure
- Volume of products handled
- Previous incidents

Supply chain level :

- Infrastructure
- Communication and co ordination

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Identification of manufacturers and products:

- PQ status
- Quality levels as assessed by process averages
- Communication and participation
- Availability of products
- Objective to cover all the type of products in phased manner

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Development of sampling plan:

- Based on respective product technical specifications and the level of Supply chain at which PMS is conducted
- Sampling plan as per Annex B or prequalification testing
- At downstream supply chain – Sampling plans based on the criticality of parameter, applicable AQLs and ISO 2859 – Part 1

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Collection and transport of samples to Accredited laboratories:

- Random samples
- Identification of lots from which samples to be drawn
- Collection of samples, reserve samples
- Identification and labelling
- Documentation of sampling activities
- Secure transport of samples to identified laboratories

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Testing of samples by Accredited laboratories:

- Methods as specified by product technical specifications and applicable ISO standards
- Documentation and review of results

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Analysis and interpretation of results:

- Conformance/ nonconformance – parameter wise
- Comparison of results with pre shipment testing results
- Out comes
- Identification of deviations, if any

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Initiation of follow up actions:

- Communication with stakeholders and investigations - root cause analysis of deviations

- Manufacturing related
- Transportation related
- Storage and handling related
- Testing related

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Initiation of follow up actions:

- Corrective and preventive actions
- Verification of effectiveness
- Analysis of impact on related batches
- Field safety corrective actions and communications
- Communication to stakeholders

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Monitoring and QA of PMS programme:

- Starting with a Pilot programme
- Planning periodicity of the programme
- Implementation of follow up programmes
- Oncourse and follow up actions and improvements
- Assessment of outcomes in terms of measurable quality indicator parameters.

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Thank you