RBM VCWG Meeting

PQT-VC Approach to Post-Market Activities

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WHO Prequalification – Vector Control
Regulatory Lifecycle

Pre-market evaluation:
Conversions and New applications

Post-market activities

Re-evaluation

End of Product Lifecycle:
Withdrawal or Delisting

Updated Guidelines
Post-Market Roles

Everyone plays a part -

– Manufacturers
– End Users
– Procurers
– National Control Programs
– National Regulatory Authorities
– WHO
WHO normative guidance on PMS for IVDs

- One chapter for each stakeholder
  - Manufacturers
  - End-users (& implementing partners)
  - National regulatory authorities
  - National reference laboratories

- Template forms and report
  - IVD complaint report
  - Manufacturer investigation report
  - Field safety corrective action report

- http://www.who.int/diagnostics_laboratory/postmarket/en/