Introduction to WHO Prequalification of in vitro diagnostics

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Prequalification of IVDs: Aim & Scope

- The aim of PQDx is to promote and facilitate **access** to safe, appropriate and affordable IVDs of good quality
- Focus is placed **on IVDs for priority diseases** and their suitability for use in **resource-limited settings**
- The **scope** of IVDs eligible for PQ continues to expand
- Currently 114 IVDs are prequalified

HIV

Malaria

Hepatitis C

Hepatitis B

HPV

G6PD

Cholera

Syphilis

Tuberculosis NAT

SARS-CoV-2

Blood Glucose meters and test strips

HbA1c POC analysers

Haemoglobin POC

TB LAM

C. trachomatis, N. gonorrhoeae, Trichomonas V

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Prequalification of IVDs: Design

- The PQDx programme is aligned with best international practice for IVDs
- ISO (and EN) standards
- GHTF/IMDRF guidance
- CLSI guidance
- Requirements of national regulatory authorities including FDA, EU, TGA, HC, Japanese Ministry of Health, Labour and Welfare and HSA

WHO specific guidance and requirements: TGS & TSS

Assessment of product version intended for global market

Specific LMIC needs

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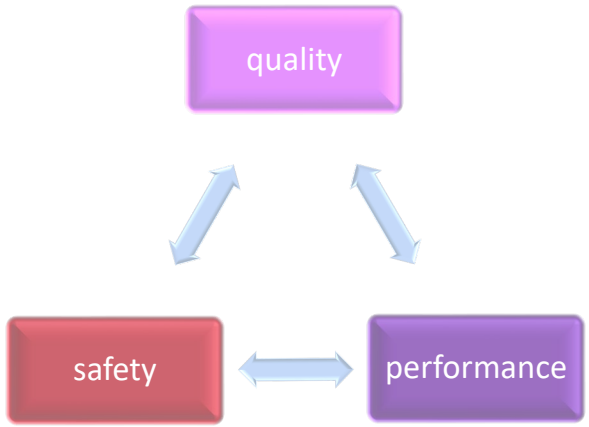
Prequalification of IVDs: Components

- A comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements

- The prequalification assessment process includes three components:



Review of a product dossier

Performance evaluation

Manufacturing site inspection

Labelling review

Full assessment

Abridged assessment

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Review of a product dossier: assessment of manufacturer’s data

- Review performed by technical experts
- Analyzing the relevance of the data in the dossier
- Review of completeness, accuracy and consistency of data over IVD life-cycle

- Are the technical specifications (TSS) met?
- Has the manufacturer considered the use of the product in resource-limited settings?

Requirements for manufacturing site inspection

- Evidence of a fully implemented quality management system (design & development, manufacturing including quality control, storage, distribution) based on ISO 13485
- Demonstrates that the risk management meets ISO 14971 requirements
- Consideration of the robustness of the product for WHO intended settings and users
- Evidence of sufficient capacity to ensure reliable delivery

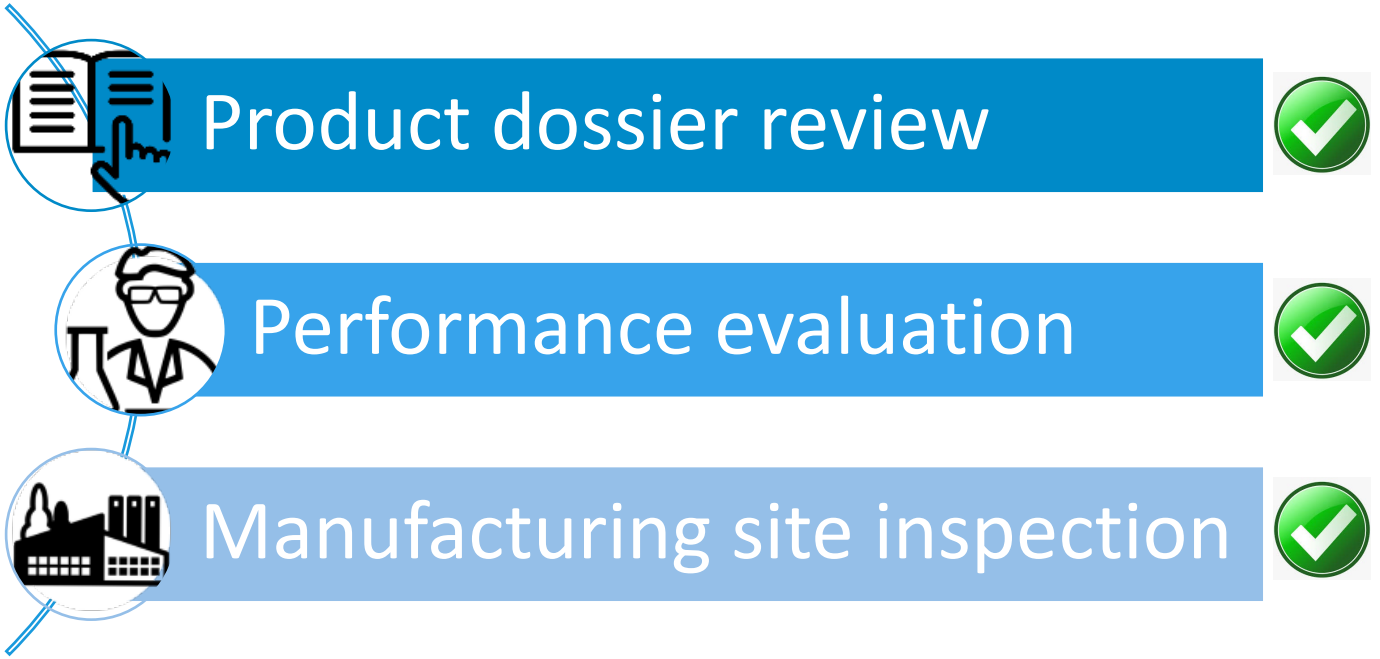
Performance evaluation

- Independent verification of the performance of IVDs submitted for prequalification assessment.
- Assays are challenged with a focus on their use in RLS and in the context of WHO guidelines.
- Conducted in a performance evaluating laboratory (PEL)

Prequalification decision

Final prequalification outcome depends on meeting requirements in all assessment components

- The product is added to the list of WHO prequalified IVDs and public report prepared
- IVD is eligible for WHO and UN procurement & CRP

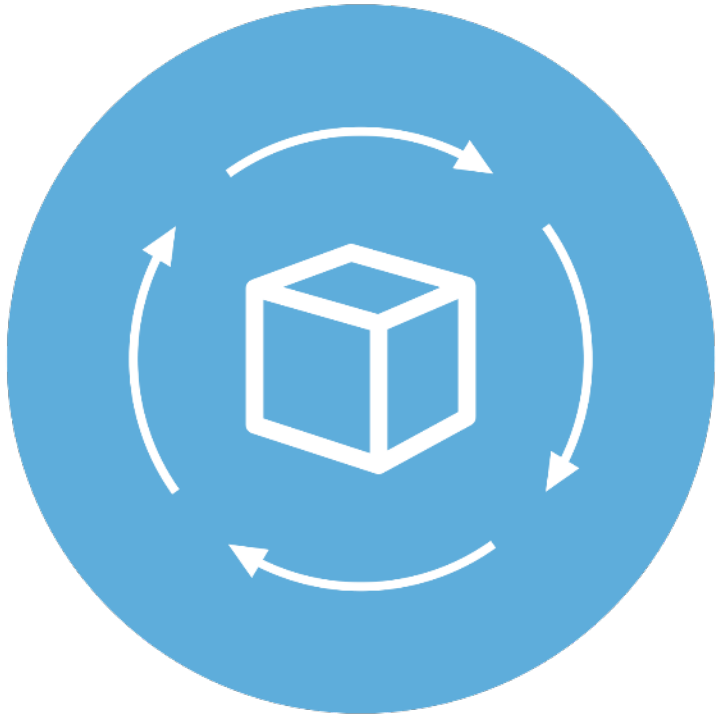


Post-PQ Activities

Ongoing requirements to maintain PQ Listing

The manufacturer must comply with:

- Commitments to PQ
- Annual reporting
  - Sales data, complaints, field safety notices
- Change reporting
- Post market surveillance obligations
- Ongoing compliance with TSS
- Routine site inspections



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Prequalification of IVDs in a nutshell

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Thank you

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