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# Increasing access to essential medicines through pre-qualified, quality local sources

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# Overview of presentation

1. **Introduction to PFSCM** and our Quality Assurance Unit
2. **Objectives** of prequalifying vendors
3. **PFSCM's prequalification** process and tools
4. **Target countries** and status update
5. **Grading** of wholesalers and rational
6. **Major challenges** facing suppliers / vendors in Africa
7. **Working with vendors** to uplift their standards
8. **Areas of collaboration** among partners





# Introduction to PFSCM

**PFSCM solves complex supply chain challenges** by leveraging our expertise with local, regional, and international logistics stakeholders, ensuring that quality health products are accessible in low- and middle-income countries.

## Our specialized services include:



**Planning** for product demand



**Storing** products in compliant warehouses



**Sourcing** and procuring products



**Tracking** the location of products in the supply chain



**Moving** products internationally and locally

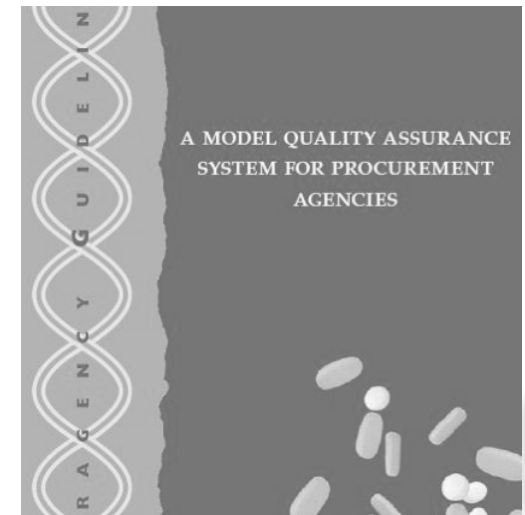


**Quality** at the core of everything we do



# Introduction to PFSCM's Quality Assurance Unit

- PFSCM has a robust Quality Management System (QMS), recently achieved certification to **ISO 9001:2015 standard**
- Quality Assurance (QA) is **part of QMS unit**
- PFSCM QA was part of a team that developed **WHO Model for Quality Assurance (MQAS) system** for procurement agencies





# QA functions

- Implement **sampling/testing criteria** and facilitate product testing
- Maintain **item master**
- Liaise with our procurement team on **vendor selection**
- Undertake **documentation reviews** (e.g. product dossier reviews, regulatory compliance)
- **Prequalify vendors, manufacturers, and wholesalers** for compliance to WHO cGMP / MQAS / GDP
- Lead **incident management meetings** for product non-compliance / client complaints





# Prequalification objectives for local suppliers to PFSCM

- **Ensure suppliers meet** our quality standards for our procurement needs
- **Reduce the risk** of being supplied with counterfeit / suspected counterfeit products
- **Reduce lead time** between the supplier and our clients
- **Comply to** in-country regulatory requirements for product market approval
- **Avoid** the long, cumbersome importation process
- **Meet the increased need** by clients to have products sourced in country
- **Comply to** WHO MQAS as a procurement agency
- **Respond to the changing dynamic:** No longer enough to know product is manufactured in a WHO / SRA facility; need to know how it is stored nearest possible to the patient





# Prequalification process and tools (modules for audit)

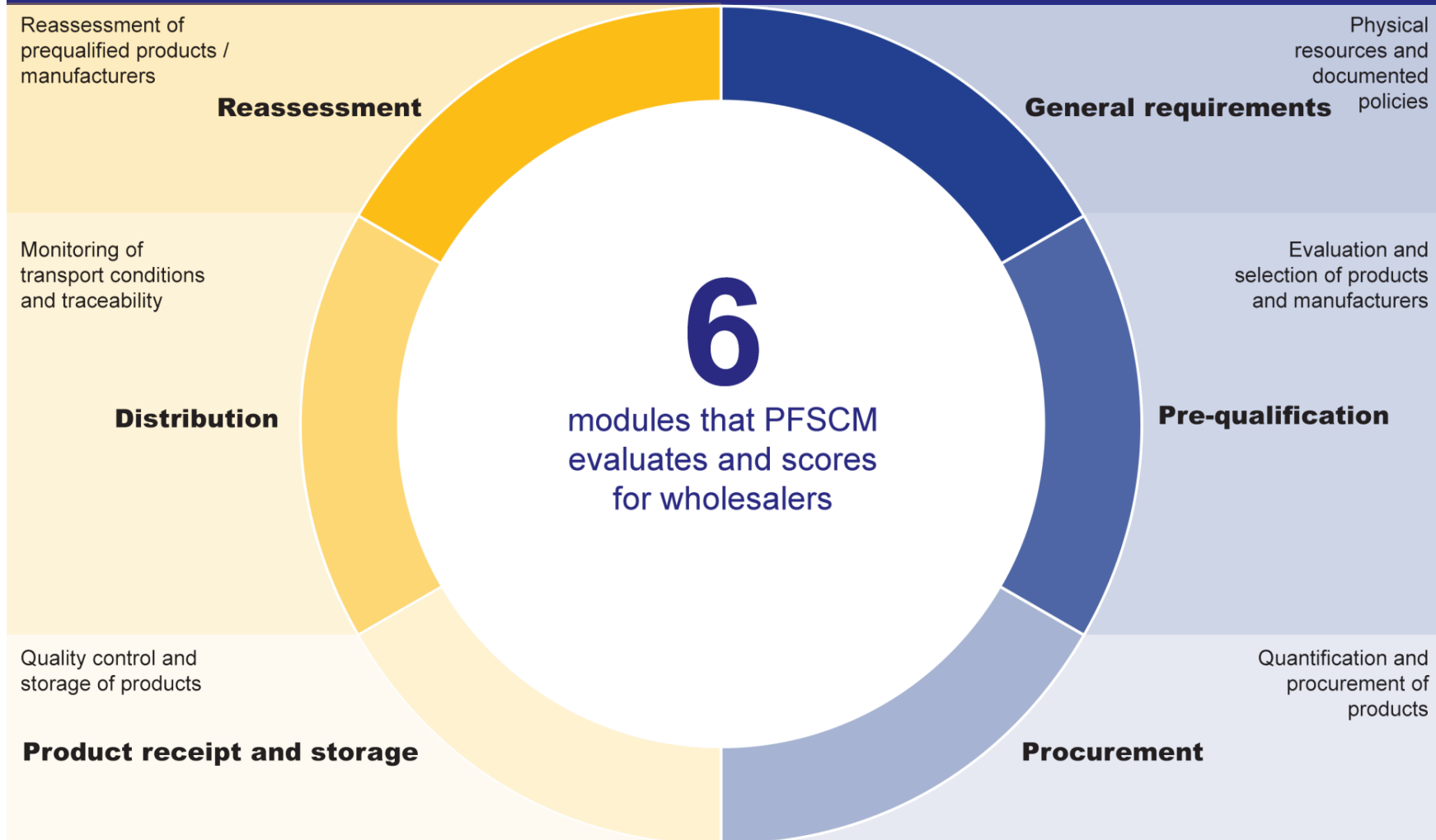
- **Procurement Unit identifies** potential supplier for audit
- **Audit conducted** by Procurement rep, QA manager, or QA consultant
- **Done in compliance** with our SOPs for prequalification of manufacturers and wholesalers based on WHO cGMP / MQAS / GDP guidelines
- **Use of internally developed audit tools** in line with WHO cGMP / WHO MQAS / GDP guidelines





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# Six modules that PFSCM evaluates and scores for wholesalers



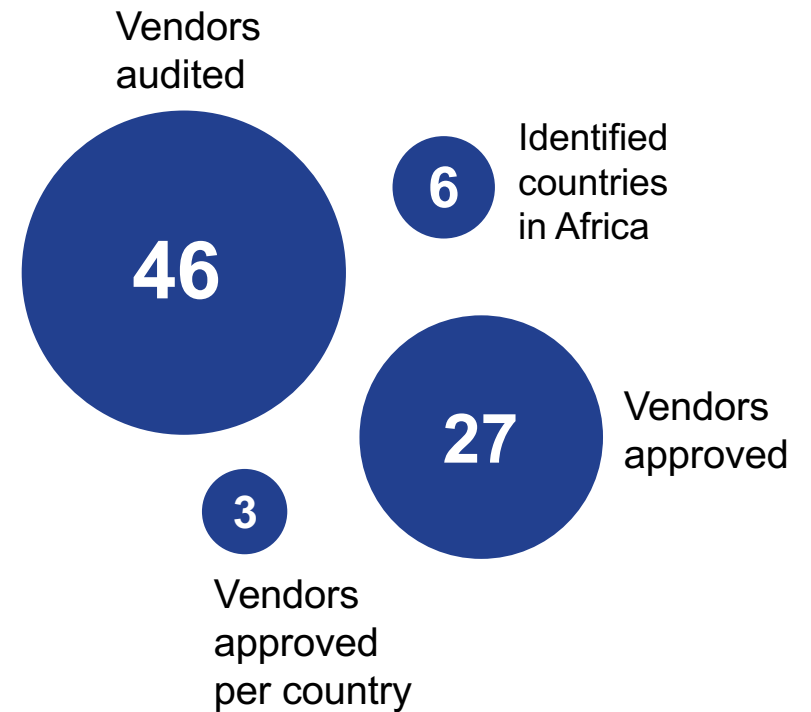


# Target countries and status update

## Target for end of 2017



## Progress in November 2017



# PFSCM grading of wholesalers



**100-90%**

General requirements, prequalification and reassessment, procurement, receipt, storage and distribution  
Pass on QC criteria using ISO 17025, WHO-PQ, or USFDA-approved labs



**100-80%**

General requirements, prequalification and reassessment, procurement, receipt, storage and distribution.  
Pass on QC criteria using ISO 17025, WHO-PQ, or USFDA-approved labs



**100-80%**

General requirements, procurement, receipt, storage and distribution  
< 80% on prequalification and reassessment and / or fail on QC criteria



**100-50%, non-pharma, only for 1 year**

General requirements, receipt, storage and distribution  
< 50% prequalification and reassessment and / or fail on QC criteria



**< 80% and <50% on all requirements for pharmaceutical and non-pharma wholesalers, respectively**



# Major challenges for wholesalers in Africa to meet WHO MQAS / GDP standards

- **Lack of awareness** of WHO MQAS / GDP standards
- **Lack of specific expertise** / skills on QA
- **Absence of regulations** or lack of enforcement by local regulators
- **Lack of Quality Management Systems (QMS)** in their operations
- **Lack of resources** to invest in modern infrastructure / warehouses
- **Prioritization of price over quality** — clients and owners





# How PFSCM is working with wholesalers to upgrade quality standards

- Through our prequalification audits, vendors are introduced and sensitized to **WHO MQAS / GDP standards**
- **Sharing of audit reports** with all vendors audited, which they can use as a benchmark
- Establishment of a **bridging mechanism for non-pharma vendors** — Grade D wholesalers
- Exploring a mechanism to engage vendors to **move to a higher grade**, particularly from Grade C to Grade B



# Areas of collaboration among partners

- Development of **harmonized tools** for prequalification of suppliers, particularly wholesalers
- **Sharing of audit reports** to avoid multiple audits to same suppliers—one network system
- Establishment of a **database of audited suppliers** in Africa
- Establishment of a **fund to help African vendors**, particularly wholesalers, to upgrade their quality standards
- Working with national medicines regulatory authorities to **implement WHO MQAS**
- Establishment of a **pool of QA experts** who can help wholesalers provide the technical expertise





# Thank you! Questions?

For more information, please contact:

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