



Vendor Scorecard:

1. Prequalification	____/10
2. Quality Control Management	____/9
3. Organization, Management and Quality	
3.1 Organization	____/6
3.2 Quality Management System	____/6
3.3 Documentation	____/19
3.4 Recalled, Rejected or Returned Products	____/7
3.5 Counterfeit Pharmaceutical Products	____/4
3.6 Training	____/3
3.7 Complaints	____/2
3.8 Self-Inspection	____/5
Total	____/52
4. Procurement	____/8
5. Facility and Warehouse Operations	
5.1 Storage	____/24
5.2 Temperature Control	____/8
5.3 Product Recalls	____/6
5.4 Warehouse Operations	____/20
5.5 Pest Control	____/4
5.6 Security	____/6
5.7 Containers and Container Labeling	____/7
Total	____/75
6. Distribution	
6.1 Traceability	____/8
6.2 Expiry	____/2
Total	____/10

**Critical Requirements: Pass \_\_\_\_\_ Fail \_\_\_\_\_**

Prequalification (Section 1)	QC Management (Section 2)	All Other (Sections 3,4,5,6)
Score:	Score:	Score:
Total Points: 10	Total Points: 9	Total Points: 145
%	%	%

**Vendor Category: \_\_\_\_\_**

**1. Prequalification\***

**10 points**

**Prequalification of Manufacturers and Product**

**P/F**

A. Pharmaceuticals supplied by applicant conform to BP, USP, EP or International Pharmacopoeia specifications (unless not available for product)	C	
B. Inspection reports confirm applicant staff or a contracted external inspection group perform pharmaceutical manufacturer on-site inspections that conform to US FDA or WHO cGMP guidelines to validate manufacturing facilities that do not have a valid GMP certificate or recent inspection report issued by a Stringent Regulatory Authority (SRA) as defined by USAID.	C	

**Wt 0-2**

C. SOP for prequalification of pharmaceuticals and manufacturers/suppliers in place and consistent with WHO's "A Model Quality Assurance System for Procurement Agencies," Annex 6, Technical Series 937, 2006	M	1	
D. Applicant provides product specifications to manufacturer or accepts manufacturer specification for medicines not listed in official compendia	M	1	
E. If pharmaceutical site inspections are performed, documentation confirms inspections and re-inspections occur as per stated frequency given in precertification screening application	M	1	
F. Site master files are available for all prequalified manufacturers	M	1	
G. Pharmaceutical product dossiers are available for all procured pharmaceuticals	M	1	
<b>Subtotal:</b>			

Observations:

**Total Score for Section 1: \_\_\_\_\_/10**

\*Prequalification required for International Wholesalers

**2. Quality Control Management**

**9 points**

**Quality Control**

**Wt 0-2**

A. Testing is done according to testing plan or strategy	M	1	
B. Applicant performs random laboratory testing against defined standards with supporting documentation	M	1	
C. Records are available which verify the number of products tested over the past two years and the number of tests where products failed to meet standards	M	1	
D. Laboratory utilized, whether in-house or contracted, complies with the principles of Good Laboratory Principles. Is the GLP certificate available? State authority issuing certificate	M	1	
E. SOP for sample product testing	O	0.5	
<b>Subtotal:</b>			

Observations:

**Total Score for Section 2: \_\_\_\_\_/9**

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### 3. Organization, Management and Quality

52 points

#### 1. Organization

Wt 0-2

A. Company organizational chart defines authority, responsibility and interrelationships of personnel to assure processes for product selection and quality are not compromised. This is also reflected in Quality Manual.	M	1	
B. Written job descriptions for all key personnel (QA/QC, purchasing, storage, distribution and shipping, pharmacist in charge) are available and signed by supervisor and employee	M	1	
C. Number of trained staff appears to be sufficient, such that no one person is overburdened with responsibilities increasing the risk to product quality	O	0.5	
D. Documentation lists full-time and part-time personnel	O	0.5	
<b>Subtotal:</b>			

Observations:

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#### 2. Quality Management System

Wt 0-2

A. Wholesaler has a designated quality manager	M	1	
B. Quality assurance manual is available, includes quality policy statements and is in line with the main principles of US FDA on GMP <sup>1</sup> or WHO guidelines <sup>2</sup>	M	1	
C. Applicant has completed a recommended inspection and certification of compliance with a quality system (such as ISO, national or international guidelines)	M	1	
<b>Subtotal:</b>			

Observations:

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<sup>1</sup> <http://www.fda.gov/cder/dmpg/cgmpregs.htm>

<sup>2</sup> [http://whqilbdoc.who.int.publications/2004/9241546190\\_part1.pdf](http://whqilbdoc.who.int.publications/2004/9241546190_part1.pdf)

**3. Documentation**

**Wt 0-2**

A. Documents are retained for the following activities: Prequalification of manufacturers/suppliers/products, procurement, receipt of products, storage, drug quality testing, disposal of expired/damaged/recalled/substandard drugs, distribution, client complaints, pharmaceutical recalls	M	1	
B. Documents are retained for a period equal to the shelf-life of the products plus one year	M	1	
C. Records of investigations and actions related to products are retained for at least one year after the expiry of the product	M	1	
D. Records of investigations and actions related to temperature-sensitive pharmaceutical products are retained for at least one year after the expiry of the product	M	1	
E. All documents are completed, approved, signed (as required) and dated by (an) appropriately authorized person(s)	M	1	
F. Electronic records are backed up to prevent accidental data loss	M	1	
G. Communication access is available via phone, fax and computer	M	1	
H. SOP for retention of records	O	0.5	
I. Procedures exist for indexing, retrieving, storing, maintaining, disposing of and accessing all applicable documentation	O	0.5	
J. Records are stored in a facility that prevents the modification, damage, deterioration, and/or loss of documentation	O	0.5	
K. Title, nature, and purpose of each document are clearly stated. The contents of each document are clear and unambiguous	O	0.5	
L. Review complaints log for previous year	O	0.5	
		<b>Subtotal:</b>	

Observations:

**4. Recalled, Rejected or Returned Products****Wt 0-2**

A. SOP in place for handling recalled, rejected or returned products	M	1	
B. SOP in place for the destruction of goods	M	1	
C. Records of all returned, rejected and/or destroyed products are kept.	M	1	
D. The recall process is recorded and a final report is issued. Report includes reconciliation between delivered and recovered quantities of product.	O	0.5	
<b>Subtotal:</b>			

Observations:

**5. Counterfeit Pharmaceutical Products****P/F**

A. Counterfeit or suspected counterfeit medicines are segregated immediately from other pharmaceutical products and recorded	C	
B. Upon confirmation of the product being counterfeit a formal decision is taken on the disposal of counterfeit pharmaceutical products and the decision is recorded	C	

**Wt 0-2**

C. Procedures are in place to immediately inform the appropriate national and/or international regulatory bodies	M	1	
D. Such products are clearly labeled to prevent further distribution or sale	M	1	
<b>Subtotal:</b>			

Observations:

**6. Training****Wt 0-2**

A. All personnel involved in distribution activities are trained according to a written training program	M	1	
B. Records of all initial and refresher training are kept and are available		0.5	
<b>Subtotal:</b>			

Observations:

**7. Complaints****P/F**

A. Complaints and information concerning potentially defective or compromised products are carefully reviewed and appropriate follow-up actions are taken, including the recall of the product where appropriate	C		
<b>Wt 0-2</b>			
B. A written procedure is in place for handling complaints	M	1	
<b>Subtotal:</b>			

Observations:

**8. Self-Inspection****Wt 0-2**

A. Self-inspections monitor the implementation of and compliance with the principles of cGMP	M	1	
B. SOP for internal auditing	O	0.5	
C. Self-inspections are conducted by a competent, designated person	O	0.5	
D. Self-inspections are recorded. Reports contain observations and proposals for corrective measures. Corrective actions are taken and recorded.	O	0.5	
<b>Subtotal:</b>			

Observations:

**Total Score for Section 3: \_\_\_\_\_/52****4. Procurement****8 points****Procurement****Wt 0-2**

A. SOP for procurement	M	1	
B. Purchasing system only allows purchase of prequalified products from prequalified manufacturers (verify via demonstration of system)	M	1	
C. Procurement system has the ability to block item codes and authority for this function is properly restricted	M	1	
D. For all manufacturers and products procured, the Certificate of Analysis (COA) corresponding to wholesaler specifications and manufacturer invoice corresponding to batch shown on COA is available	M	1	
<b>Subtotal:</b>			

Observations:

**Total for Section 4: \_\_\_\_\_/8**

## 5. Facility and Warehouse Operations

75 points

### 1. Storage

P/F

A. Storage areas are clean, dry and maintained within acceptable temperature limits (15-25°C or depending on climatic conditions up to 30°C)	C	
B. Special storage conditions required on the label (e.g. temperature, relative humidity) are provided, checked, monitored and recorded	C	

Wt 0-2

C. SOP for storage consistent with WHO 'Good Storage Practices' including:	M	1	
D. SOP for narcotics	M	1	
E. SOP for cold storage	M	1	
F. SOP for rejected products (damaged/returned/expired, etc.)	M	1	
G. SOP for sanitation (cleaning and maintenance)	M	1	
H. SOP for product quarantine	M	1	
I. Pharmaceutical products are stored off the floor and suitably spaced to permit cleaning and inspection. Pallets are kept in a good state of cleanliness and repair.	M	1	
J. Quarantine areas are clearly marked and their access restricted to authorized personnel. Computerized systems used to designate quarantine are allowable, provided they are validated to demonstrate security of access.	M	1	
K. Hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases) are stored with appropriate safety and security measures.	M	1	
L. Narcotic drugs are stored in compliance with international conventions, and national laws and regulations on narcotics.	M	1	
M. Samples of procured product to be tested are stored in accordance with manufacturer labeling.	M	1	
N. Retention samples are maintained for the shelf-life of the product and are stored in accordance with manufacturer labeling.	M	1	
<b>Subtotal:</b>			

Observations:

**2. Temperature Control****Wt 0-2**

A. SOP for temperature mapping	M	1	
B. Temperature control systems specify tolerable limits for time and temperature variations and recording devices are checked and calibrated at regular intervals	M	1	
C. Warehouse has been temperature mapped and an adequate number of monitoring devices are located throughout the facility	M	1	
D. Documentation indicates compliance with temperature and storage conditions for each stored product.	M	1	
<b>Subtotal:</b>			

Observations:

**3. Product Recalls****Wt 0-2**

A. Recalled, returned or rejected products are stored in secure, segregated areas pending appropriate action	M	1	
B. Recalled, returned or rejected products are securely packaged, clearly labeled, and accompanied by appropriate documentation	M	1	
C. Applicable storage conditions are maintained for recalled, returned or rejected products until a decision has been made regarding the product in question	M	1	
<b>Subtotal:</b>			

Observations:

**4. Warehouse Operations****Wt 0-2**

A. SOP for distribution consistent with WHO 'Good Distribution Practices' including:	M	1	
B. SOP for receipt of products	M	1	
C. Pharmaceutical products due to expire first are sold and/or distributed first (FEFO)	M	1	
D. Periodic stock reconciliation is performed by comparing the actual and recorded stocks and discrepancies are investigated.	M	1	
E. Applicant visually inspects a sampling of all batches received for integrity of packages and seals and for uniformity of containers prior to a drug's release for sale (evidence of this activity)	M	1	
F. Inspection of in-stock product expiry dates reveals that all products are within expiry limits (No expired products are available for active distribution)	M	1	
G. Equipment for monitoring is regularly checked and calibrated.	M	1	
H. If wholesaler repackages medicines, it holds a current manufacturing license issued by a Stringent Regulatory Authority	M	1	
I. Labeling of repacked medicines includes the name of the original manufacturer	M	1	
J. Surveillance system to detect and control hazards from damp pallets, damp floors and walls, overhead moisture in storage areas, condensation, and wet unloading and loading conditions	O	0.5	
K. Flow of products through the warehouse is logical, preferably unidirectional	O	0.5	
<b>Subtotal:</b>			

Observations:

**5. Pest Control****Wt 0-2**

SOP for pest control	M	1	
Adequate pest control measures provided by a contracted service are visible	M	1	
<b>Subtotal:</b>			

Observations:

**6. Security****Wt 0-2**

A. SOP for security services	M	1	
B. Storage areas are secure to prevent access by unauthorized persons	M	1	
C. Written procedures are in place to restrict unauthorized access of personnel to pharmaceutical products	O	0.5	
D. Codes of practice and disciplinary procedures are in place to prevent and address the misappropriation or theft of pharmaceutical products	O	0.5	
<b>Subtotal:</b>			

Observations:

**7. Containers and Container Labeling****Wt 0-2**

A. Labels applied to containers are clear, unambiguous, permanently fix to the container and are indelible.	M	1	
B. Shipping containers provide sufficient information to describe the handling and storage conditions and precautions.	M	1	
C. Special transport and/or storage conditions, and international safety symbols are stated on the label	M	1	
D. Written procedures are available for the handling of damaged or broken containers, especially those which hold potentially toxic and hazardous products.	O	0.5	
<b>Subtotal:</b>			

Observations:

**Total for Section 5: \_\_\_\_\_/75**

**6. Distribution**

**10 points**

**1. Traceability**

**Wt 0-2**

A. Records for dispatch include: date of dispatch; name and address of entity responsible for transportation; name, address and status of addressee; description of the products; quantity of products; assigned batch number and expiry date; applicable transport and storage conditions; unique order number; certificate of pharmaceutical product	M	1	
B. Written procedures and records ensure traceability of products including:			
C. Certificate of Analysis corresponding to batch that includes testing against defined standards (BP, USP, International Pharmacopoeia, and EP); if no compendia	M	1	
D. GMP certificate consistent with US FDA cGMP or WHO certification scheme	M	1	
E. Shipping invoice includes: international non-proprietary name, formulation, strength, unit size, pack size, batch number(s), date of manufacture, expiry, price per unit and extended price	M	1	
<b>Subtotal:</b>			

Observations:

**2. Expiry**

**Wt 0-2**

A. Pharmaceutical products are not supplied or received after their expiry date, or so close to the expiry date that this date is likely to occur before the products are used by the consumer	M	1	
<b>Subtotal:</b>			

Observations:

**Total for Section 5: \_\_\_\_\_/10**

**Critical Requirements: Pass \_\_\_\_\_ Fail \_\_\_\_\_**

<b>Prequalification (Section 1)</b>	<b>QC Management (Section 2)</b>	<b>All Other (Sections 3,4,5,6)</b>
<b>Score:</b>	<b>Score:</b>	<b>Score:</b>
<b>Total Points: 10</b>	<b>Total Points: 9</b>	<b>Total Points: 143</b>
<b>%</b>	<b>%</b>	<b>%</b>

Category A: 100 – 90% Prequalification; 100 – 90% QC Management; 100 – 90% All Other  
Category B: 100 – 80% Prequalification; 100 – 80% QC Management; 100 – 80% All Other  
Category C: 80 – 0% Prequalification; 80 – 0% QC Management; 100 – 80% All Other  
Category F: 80 – 0% Prequalification; 80 – 0% QC Management; 80 – 0% All Other

**Vendor Category:** \_\_\_\_\_

Inspectors name(s): \_\_\_\_\_

Signature(s): \_\_\_\_\_

Date: \_\_\_\_\_

Scoring Mechanism:

C - Critical: Potential for direct impact to product quality and/or potential liability to PFSCM  
M – Major: Major departure from recommendations in WHO – A Model Quality Assurance System for Procurement Agencies – 2007  
O – Other: Not “critical” or “major,” but might be considered favorably by PFSCM

Category “A”: Pharmaceutical wholesaler meets 90% or more of the criteria required for the prequalification of manufacturers, quality control management and all other requirements contained within the checklist. An “A” Category enables PFSCM to enlist the pharmaceutical wholesaler for all procurement services and extends the number of years required between facility audits to three years. If reports of quality control issues surface within the three-year audit cycle, PFSCM has the right to conduct audits “with cause.”

Category “B”: Pharmaceutical wholesaler meets 80% or more of the criteria required for the prequalification of manufacturers, quality control management and all other requirements contained within the checklist. A “B” Category restricts PFSCM to purchasing pharmaceutical products which have been approved by a Stringent Regulatory Authority (SRA) and requires the pharmaceutical wholesaler be evaluated every two years.

Category “C”: Pharmaceutical wholesaler does not prequalify manufacturers or conduct quality control management but does meet at least 80% of all other requirements listed on the checklist. A “C” Category restricts PFSCM to purchasing pharmaceuticals products from PFSCM approved vendors. A “C” Category wholesaler will primarily be used for storage and distributions services and will be audited annually to ensure Good Storage and Distribution Practices are upheld.

Category “F”: Pharmaceutical wholesaler which does not prequalify manufacturers, conduct quality control management or meet at least 80% of all other requirements on the checklist will not be recommended as PFSCM pharmaceutical wholesaler. Similarly, if the wholesaler does not pass all critical requirements it will not be recommended.

References:

1. *“A Model Quality Assurance System for Procurement Agencies” – WHO 2007*
2. *“Good Distribution Practices (GDP) for Pharmaceutical Products” – WHO 2005*