QUAMED
Quality Certification Programme

APPLICATION QUESTIONNAIRE FOR WHOLESALERS TO QUAMED CERTIFICATION PROGRAM (QCP)

All documents and information shared within this application will be treated as confidential by QUAMED.

Please carefully fill this application form and make sure all required attachments are enclosed within your application. For any queries, please contact: info@quamed.org

1. Company details:

Company name:	
Address:	
Postal code:	
Country:	
Phone number:	
Website:	

2. Contact Details:

Contact name:	
Contact position:	
Telephone number:	
Email address:	

3. Overview of the pharmaceutical activities:

What are the main activities of the company?		
How many staff members (expressed in full time equivalent) are employed by your organization?	At headquarters and central warehouse(s)	
	At subsidiaries / branches locations and peripheral warehouses	
Do you outsource some supply chain activities (storage, distribution, transport etc)	☐ Yes ☐ No If yes, please detail below:	

What is the range of products you deal with?	☐ Multi source essential medicines ☐ Innovator (branded) medicines ☐ Medical devices ☐ Chemical reagents ☐ Medical Equipment (X-ray, autoclaves, sonographer, etc.) ☐ Pharmaceutical products from biological source (immunoglobulins, monoclonal antibodies etc) ☐ Medical kits ☐ Other products (please specify below)		
Which GDP/GSP/MQAS standard(s) does your organisation follow?	☐ WHO current Good Storage and Distribution Practices (GSDP) ☐ WHO current Model Quality Assurance System for Procurement Agencies (MQAS) ☐ European current Good Distribution Practice (GDP) ☐ National GDP or other standard (please specify below)		
What was the annual turn-over in United States Dollars in the last three financial years?	Year 1:	Year 2:	Year 3:

4. Current licensing and certification

Are you registered (licensed) by the National Regulatory Authority of your country?	☐ Yes ☐ No If yes: Please detail expiry date if any, registration number below. Please provide license(s) as **Attachment 1a** (If the NRA provides a separate certificate for each warehouse, please make sure to attach all relevant certificates).
Do you have a Good Distribution Practices Certificate?	☐ Yes ☐ No If yes: Please detail expiry date if any, certificate number below Please provide certificate(s) as **Attachment 1b**
Do you have a special authorisation for import of non-registered products?	☐ Yes ☐ No If yes: Please detail expiry date if any, registration number below. Please provide document(s) as **Attachment 1c**
Do you have an authorisation for dealing with controlled substances?	☐ Yes ☐ No If yes: Please detail expiry date if any, registration number below. Please provide document(s) as **Attachment 1d**

Are you certified ISO 9001?	☐ Yes ☐ No If yes: Please detail expiry date, certificate number, latest audit date below Please provide certificate(s) as **Attachment 1e**
Is your company "approved" as wholesaler/distributor by an international organization (please tick the relevant boxes)?	☐ UNICEF Supply Division ☐ UNFPA ☐ Global Drug Facility (GDF) ☐ International Committee of the Red Cross (ICRC) ☐ DG ECHO ☐ USAID / BHA ☐ The Global Fund ☐ Médecins Sans Frontières (MSF) ☐ Others (please specify below) Please provide certificate(s) or document(s) as **Attachment 1f** Please mention your USFDA FEI number (FDA Establishment Identification) if any:
Do you have any other relevant certification?	☐ Yes ☐ No If yes: Please detail below Please provide certificate(s) as **Attachment 1g**
Has(have) your site(s) been inspected by international/local authorities in the last three years?	☐ Yes ☐ No If yes: Please detail below - the name of the authority/body - the standard used as reference (e.g. WHO/EU GDP, national standards, ...) -the frequency of the inspections -the address(es) of the inspected site(s)/warehouse(s). Please provide a proof of the most recent inspection(s) as **Attachment 1h**

5. Description of the pharmaceutical warehouses owned by the organisation:

Central pharmaceutical warehouses	
Number of warehouses	
Physical location(s) of all warehouses (please give detailed address)	
Peripheral pharmaceutical warehouses	
Number of warehouses	

Physical location(s) of all warehouses (please give detailed address)	

6. Type of QUAMED Quality Certification requested (tick one)

☐	**MQAS**	This type of certification deals with auditing the compliance of the client against the current World Health Organisation Model Quality Assurance System for procurement agencies (MQAS)[1] and the Good Storage and Distribution Practices[2]. This type of certification is intended for procurement agencies that have a prequalification programme for their medicinal products, and their manufacturers.
☐	**GSDP**	This type of certification deals with auditing the compliance of the client against the current World Health Organization Good Storage and Distribution Practices (GSDP) [3]. This type of certification is intended for pharmaceutical distributors that do not have a prequalification programme for their medicinal products, and their manufacturers.

7. Audit scope:

Scope of the certification: Do you wish to be audited for all warehouses / activities?	☐ Yes ☐ No (only the HQ warehouses) ☐ Partially (only a selection of warehouses) (please detail below)					
Language(s) in which you prefer to be audited?	☐	English	☐	French	☐	Spanish
Language(s) in which you wish to receive the certificate?	☐	English	☐	French	☐	Spanish
Do you require a remote mock audit to be conducted prior to the audit? (extended remote screening of the strengths and weaknesses of the quality management system)	☐ Yes ☐ No					

8. Assessment of preparedness for the QUAMED certification programme (QCP)

Do you have a quality manual?	☐ Yes ☐ No If yes: Please detail below Please provide the quality manual as **Attachment 2**

[1] https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex3.pdf
[2] https://www.who.int/publications/m/item/trs-1025-annex-7-gdp-medical-products
[3] https://www.who.int/publications/m/item/trs-1025-annex-7-gdp-medical-products

Do you have an independent quality department?	☐ Yes ☐ No If yes: Please detail below Please provide - the organisation chart as **Attachment 3a** - the job description of the quality manager (or equivalent) as **Attachment 3b**
Do you have a quality self-inspection system (equivalent to quality internal audit programme)?	☐ Yes ☐ No If yes: Please detail below Please provide - the self-inspection (internal quality audit) SOP as **Attachment 4a** - the latest self-inspection report as **Attachment 4b**
Do you have a product prequalification programme (equivalent to preselection programme) which aims to ensure the quality of the products to be purchased.?	☐ Yes ☐ No If yes: Please detail below Please provide - the product prequalification SOP(s) as **Attachment 5a** - the SOP(s) describing how to qualify suppliers (manufacturers and wholesalers), including GMP audits, within the prequalification programme as **Attachment 5b**
Do you have a SOP describing the steps and verification processes required when a product enters the warehouse (reception)?	☐ Yes ☐ No If yes: Please detail below Please provide the product reception SOP(s) as **Attachment 6**
Do you have a temperature monitoring SOP?	☐ Yes ☐ No If yes: Please detail below Please provide - the temperature monitoring SOP(s) as **Attachment 7a** - temperature mapping study report of one of the central warehouses as **Attachment 7b**
Do you have a SOP to manage returned products (products distributed but returned to the warehouse)?	☐ Yes ☐ No If yes: Please detail below Please provide the management of returned products SOP(s) as **Attachment 8**
Do you have a SOP to manage product recalls?	☐ Yes ☐ No If yes: Please detail below Please provide the product recall SOP as **Attachment 9**

Do you maintain an electronic and/or manual Management Information System that can ensure full traceability of products up to the customers?	☐ Yes ☐ No If yes: Please detail below Please provide the templates of all distribution documents, i.e. documents that are provided to the customers (invoice, packing list, delivery note…) as **Attachment 10**

9. Summary of attachments

Please make sure that all required attachments are provided with your application. Please number each document with the attachment number.

Attachment number	Description	Provided:
Attachment 1a	Registration document with National Regulatory Authority	☐ Yes ☐ No ☐ Not applicable
Attachment 1b	Good Distribution Practices Certificate	☐ Yes ☐ No ☐ Not applicable
Attachment 1c	Special authorisation for import of non-registered products	☐ Yes ☐ No ☐ Not applicable
Attachment 1d	Controlled substances license / authorisation	☐ Yes ☐ No ☐ Not applicable
Attachment 1e	ISO 9001 certificate	☐ Yes ☐ No ☐ Not applicable
Attachment 1f	Certificate(s) or document(s) of approval from international organisations	☐ Yes ☐ No ☐ Not applicable
Attachment 1g	Other certifications	☐ Yes ☐ No ☐ Not applicable
Attachment 1h	Inspection report / documentation	☐ Yes ☐ No ☐ Not applicable
Attachment 2	Quality manual	☐ Yes ☐ No ☐ Not applicable
Attachment 3a	Organisation chart	☐ Yes ☐ No ☐ Not applicable
Attachment 3b	Job description of the quality manager (or equivalent)	☐ Yes ☐ No ☐ Not applicable
Attachment 4a	Self-inspection (internal quality audit) SOP	☐ Yes ☐ No ☐ Not applicable
Attachment 4b	Latest self-inspection report	☐ Yes ☐ No ☐ Not applicable
Attachment 5a	Product prequalification SOP(s) ((equivalent to preselection programme)	☐ Yes ☐ No ☐ Not applicable
Attachment 5b	SOP(s) describing the qualification of suppliers (manufacturers and wholesalers) including GMP audits, within the prequalification programme	☐ Yes ☐ No ☐ Not applicable

Attachment 6	Product reception SOP(s)	☐ Yes ☐ No ☐ Not applicable
Attachment 7a	Product temperature monitoring SOP(s)	☐ Yes ☐ No ☐ Not applicable
Attachment 7b	Temperature mapping study report of the main warehouse	☐ Yes ☐ No ☐ Not applicable
Attachment 8	Management of returned product SOP(s)	☐ Yes ☐ No ☐ Not applicable
Attachment 9	Product recall SOP	☐ Yes ☐ No ☐ Not applicable
Attachment 10	Templates of distribution documents	☐ Yes ☐ No ☐ Not applicable

Comments

10. Confirmation and sign-off

"I certify that all information is correct and true and documentation that will validated all responses is available upon request."

Name:	
Position:	
Date:	
Signature or e-signature:	