QUAMED
Quality Certification Programme

APPLICATION QUESTIONNAIRE FOR MANUFACTURERS 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:	
Main physical address:	
Manufacturing site address:	
Year of establishment:	

2. Contact Details:

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

3. Description of the pharmaceutical facilities and products manufactured

List of products authorised to be manufactured	Please attach a list of products. **Attachment 1**

Annual product capacity per dosage form (number of units per year)	Dosage form 1 (tablets etc)	Annual capacity:
	Dosage form 2 (tablets etc)	Annual capacity:
	Dosage form 2 (tablets etc)	Annual capacity:
	Dosage form 2 (tablets etc)	Annual capacity:
Do you have sterile production facilities?	☐ Yes ☐ No If yes, please provide details below:	
How many staff members (expressed in full time equivalent) are employed by your organization?		
Do you outsource some GMP/GSDP related activities (manufacturing, packaging, storage, quality control, distribution, transport etc)	☐ Yes ☐ No If yes, please detail below:	
Which GMP standard(s) does your organisation follow?	☐ WHO current Good Manufacturing Practices (GMP) ☐ USFDA Good Manufacturing Practices ☐ European current Good Manufacturing Practices ☐ Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme (PIC/Sstandards ☐ National GMP 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 pharmaceutical facility, please make sure to attach all relevant certificates).
Do you have a Good Manufacturing 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 one or more finished pharmaceutical products prequalified by WHO prequalification programme	☐ Yes ☐ No If yes: please list the products with their generic names and attach a copy of the relevant WHO/PQP acceptance letter signed by your company as **Attachment 1c**.

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 1d**
Is your company "approved" or "audited with positive outcomes" by an international organization (please tick the relevant boxes)?	☐ UNICEF Supply Division ☐ UNFPA ☐ Global Drug Facility (GDF) ☐ International Committee of the Red Cross (ICRC) ☐ USAID / OFDA ☐ Médecins Sans Frontières (MSF) ☐ Others (please specify below) Please provide certificate(s) or document(s) as **Attachment 1e** 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 1f**
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 GMP, 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 1g**

7. Audit scope:

Scope of the certification: Do you wish to be audited for all facilities / production lines / activities?	☐ Yes ☐ No ☐ Partially (only a selection of production lines) (please detail below) If No: Please specify :					
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**
Do you have a site master file?	☐ Yes ☐ No If yes: Please detail below Please provide the quality manual as **Attachment 3**
Do you have drawings of the HVAC system detailing the GMP grade of each room?	☐ Yes ☐ No If yes: Please provide drawings of the HVAC system detailing the GMP grade of each room as **Attachment 4**
Do you have a supplier quality audit programme for Active Pharmaceutical Ingredients?	☐ Yes ☐ No If yes: Please detail below Please provide - The API supplier quality audit SOP as **Attachment 5a** - the latest API supplier quality audit report as **Attachment 5b**
Do you have a validation master plan?	☐ Yes ☐ No If yes: Please provide it as **Attachment 6**
Do you have a quality risk matrix?	☐ Yes ☐ No If yes: Please provide the latest version of the quality risk matrix as **Attachment 7**
Do you have a batch release SOP?	☐ Yes ☐ No If yes: Please provide the Management of OOS/Out of trends SOP as **Attachment 8**
Do you provide certificate of analysis?	☐ Yes ☐ No If yes: Please provide an example of a certificate of analysis of a product manufactured in the last month as **Attachment 9**
Do you have a SOP for the management of Out-Of-Specifications / Out of Trends?	☐ Yes ☐ No If yes: Please provide the Management of OOS/Out of Trends SOP as **Attachment 10**
Do you have a SOP to manage product recalls?	☐ Yes ☐ No If yes: Please detail below

	Please provide the product recall SOP as **Attachment 11**

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 Manufacturing Practices Certificate	☐ Yes ☐ No ☐ Not applicable
Attachment 1c	Copy of the relevant WHO/Prequalification programme acceptance letter for each WHO prequalified product	☐ Yes ☐ No ☐ Not applicable
Attachment 1d	ISO 9001 certificate	☐ Yes ☐ No ☐ Not applicable
Attachment 1e	Certificate(s) or document(s) of approval from international organisations	☐ Yes ☐ No ☐ Not applicable
Attachment 1f	Other certifications	☐ Yes ☐ No ☐ Not applicable
Attachment 1g	Inspection report / documentation	☐ Yes ☐ No ☐ Not applicable
Attachment 2	Quality manual	☐ Yes ☐ No ☐ Not applicable
Attachment 3	Site Master File	☐ Yes ☐ No ☐ Not applicable
Attachment 4	Drawings of the HVAC system detailing the GMP grade of each room	☐ Yes ☐ No ☐ Not applicable
Attachment 5a	API supplier quality audit SOP	☐ Yes ☐ No ☐ Not applicable
Attachment 5b	Latest API supplier quality audit report	☐ Yes ☐ No ☐ Not applicable
Attachment 6	Validation master plan	☐ Yes ☐ No ☐ Not applicable
Attachment 7	Latest version of the quality risk matrix	☐ Yes ☐ No ☐ Not applicable
Attachment 8	Batch release SOP	☐ Yes ☐ No ☐ Not applicable
Attachment 9	Example of a certificate of analysis of a product manufactured in the last month	☐ Yes ☐ No ☐ Not applicable
Attachment 10	Management of OOS/Out of Trends SOP	☐ Yes ☐ No ☐ Not applicable
Attachment 11	Product recall SOP	☐ Yes ☐ No ☐ Not applicable

Comments

10. Confirmation and sign-off

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

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