PRE-SUBMISSION FORM

Prequalification of immunization-related products and devices

How to complete this form

This form has been designed to assist WHO in capturing necessary information about a product submitted for WHO prequalification assessment. The information provided by the manufacturer in this form helps WHO to determine whether a product is eligible for WHO prequalification assessment and, if so, the type of assessment that the product will undergo (i.e. full or abridged assessment). The information in this form is also used for planning out the components of the prequalification assessment for each product. Therefore, it is crucial that the form is both complete and accurate.

This pre-submission form does not replace PQS product dossier requirements. A separate prequalification dossier must be submitted by the manufacturer once their product has been deemed eligible for WHO prequalification assessment.

Type in text or tick boxes (■) as required for each field. Where information is not available or the field is not applicable, type in N/A.

Contents

1. Manufacturer Information

1.1 Legal manufacturer

1.1.1	Name of manufacturer		
1.1.2	Manufacturer physical address	Street Name and No.:	
		City:	
		Postcode:	
		Country:	
1.1.3	Manufacturer postal address	Street Name and No.:	
		Postal Office Box No.:	
		City:	
		Postcode:	Country:
1.1.4	Manufacturer telephone		
1.1.5	Manufacturer email		
1.1.5	Manufacturer website		
1.1.6	Name of parent company		

1.2 Authorised contacts for the manufacturer[1]

1.2.1	Name of first authorised contact		
1.2.2	Authorised contact postal address	Department:	
		Street Name and No.:	
		City:	
		Postcode:	Country:
1.2.3	Authorised contact telephone	Fixed line:	Mobile phone:
1.2.4	Authorised contact email		
1.2.5	Name of second authorised contact		
1.2.6	Authorised contact postal address	Department:	
		Street Name and No.:	
		City:	
		Postcode:	Country:
1.2.7	Authorised contact telephone	Fixed line:	Mobile phone:
1.2.8	Authorised contact email		

[1] [**ATTACHMENT:** Attach a signed letter from the manufacturer stating that the above person/people is/are authorized to represent the manufacturer for the purposes of prequalification of this product.]

2. Product Information

2.1 Product name and product code/catalogue number for WHO prequalification assessment

2.1.1 State product name:	
2.1.2 State manufacturer product reference:	
2.1.2 Product WHO PQS performance specification reference:	

2.2 Product Testing

2.2.1 Name of testing laboratory	
2.2.2 Has the manufacturer self-tested the product?	Yes ☐ No ☐
If you answered yes to 2.2.2, please attach a copy of the testing report. Tick if attached: ☐	

3. Licences

3.1 Company licence / Registration document	Formal document no.:
	Issue date (DD-MM-YY):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐
3.2 Manufacturing licence (if applicable)	Formal document no.:
	Issue date (DD-MM-YY):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐
3.3 Other	Formal document no.:
	Issue date (DD-MM-YY):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐

4. Certificates

4.1 ISO 9001 (Required for all PQS categories except E008 and E013)	Certification body:
	Certification verification (e.g. web link):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐
4.2 ISO 14001 (Required for PQS categories E001, E003 and E004)	Certification body:
	Certification verification (e.g. web link):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐
4.2 ISO 13485 (Required for PQS categories E008 and E013)	Certification body:
	Certification verification (e.g. web link):
	Expiry date (DD-MM-YY):
	Tick if attached: ☐

5. WHO History of Product

5.1 Has WHO previously assessed this product?	□	Yes	Date
	□	No	
5.2 Has WHO previously assessed this product under a different name?	□	Yes	Date
	□	No	
If you answered yes to 5.2, please provide the name of the previously assessed product:			

8. Manufacturer Declaration

The undersigned duly authorised representative of the Manufacturer makes the following declarations on behalf of the Manufacturer and, in signing this pre-submission form, declares that he/she has the power and authority to bind the Manufacturer.

I declare that:

- I am authorised to represent the manufacturer specified in this prequalification pre-submission form (the "Manufacturer") for the purposes of WHO diagnostics prequalification of the product specified in this pre-submission form (the "Product").

- All the information provided in this form is current, complete and correct.

- Any changes to the information provided in this form will be readily communicated by the Manufacturer to WHO.

- The Manufacturer holds data in support of all claims made in this pre-submission form.

- The Manufacturer understands and agrees that, in the event that WHO agrees to undertake prequalification assessment of the Product: (i) the Manufacturer must complete and sign a Letter of Agreement with WHO relating thereto and must pay WHO the prequalification fees; (ii) WHO will have absolute, exclusive, unfettered control over the manner in which the prequalification assessment process is carried out (including the performance evaluation and/or the publication of results of the prequalification assessment, regardless of the outcome); and (iii) WHO reserves the right to share the results of the prequalification assessment and the full assessment and inspection reports, including any drafts thereof and including (subject to appropriate obligations of confidentiality) any confidential information to which WHO may gain access in the course of the prequalification process, with the relevant authorities of any interested Member State and with relevant intergovernmental organizations.

- The Manufacturer understands and agrees that the purpose of the prequalification process is to provide guidance to interested UN agencies and WHO Member States in their procurement decisions. In this regard, the results of the prequalification assessment, the participation in the WHO prequalification assessment process, the inclusion of any product in the WHO list of prequalified immunization products and devices, and/or the WHO name and emblem, may not be used by manufacturers or any other party for commercial and/or promotional purposes.

- The Manufacturer understands and agrees that the validity of the prequalification status is dependent on the fulfilment of post-qualification requirements including:
    - prequalification commitments;
    - annual reporting;
    - reporting of changes;
    - post-market surveillance obligations;
    - receiving re-inspection; and
    - ongoing compliance with WHO prequalification technical specifications.

Name of the Duly Authorised Representative of the Manufacturer:

Signature of the Duly Authorised Representative of the Manufacturer: _____

Date: