QA.APP.GEN-36.03

|  |
| --- |
| Medical Device Product Questionnaire |

This questionnaire is used to collect information from vendors with regards to medical devices that fall in any of the categories below:

* Product has been reviewed and approved by US FDA,
* Product is WHO prequalified, and/or
* Product is CE Marked

Products that do not meet the above criteria may be considered on a case by case basis and may require additional documentation at the discretion of USAID | GHSC - QA.

*Instructions:*

*Fill out the information that is applicable to the product. Complete one questionnaire per product.*

*Complete the fields in this questionnaire as applicable.*

* *Tick or place an X in any of the blocks that are true/applicable.*
* *Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.*
* *In some instances, it may be required to duplicate sections, copy the section and paste as needed. Alternatively, duplicate copies of the section may be completed and attached.*
* *Update the table of contents when completed.*

Table of Contents

[1.0 Applicant Information 3](#_Toc879279)

[2.0 Product Identification 4](#_Toc879280)

[3.0 Manufacturer Information 5](#_Toc879281)

[3.1 Manufacturer Identification 5](#_Toc879282)

[3.2 Manufacturing Activities 5](#_Toc879283)

[3.3 Key Suppliers 5](#_Toc879284)

[3.4 Manufacturer Quality Management System 5](#_Toc879285)

[3.5 Inspections and Audits 6](#_Toc879286)

[4.0 Product INFORMATION 7](#_Toc879287)

[4.1 Product Description and Design 7](#_Toc879288)

[4.2 Device Composition 7](#_Toc879289)

[4.3 Raw Materials, components, intermediate products /sub-assembles specification 7](#_Toc879290)

[4.4 Final Product Specifications 8](#_Toc879291)

[4.5 Non-Clinical Performance Data 8](#_Toc879292)

[4.5.1 Manufacturing Methods 8](#_Toc879293)

[4.5.2 Sterile Aspects of the Product 9](#_Toc879294)

[4.6 Packaging Information 9](#_Toc879295)

[4.7 Shelf-life and Storage Conditions 10](#_Toc879296)

[5.0 Safety and Efficacy and/or Therapeutic Equivalence 11](#_Toc879297)

[5.1 Clinical Evaluation 11](#_Toc879298)

[6.0 Risk management 11](#_Toc879299)

[7.0 Product Quality Incidents and Recalls 11](#_Toc879300)

[8.0 Regulatory and licensing status 12](#_Toc879301)

[8.1 Licensing Status 12](#_Toc879302)

[8.2 US FDA Status 12](#_Toc879303)

[8.3 CE Marking Status 12](#_Toc879304)

[8.4 WHO Prequalification Status 12](#_Toc879305)

[8.5 Global Registration/Marketing approvals 13](#_Toc879306)

[9.0 Checklist of Attachments 14](#_Toc879307)

[10.0 Authorization and Commitment 15](#_Toc879308)

[10.1 Authorization for sharing information with other Agency(ies) 15](#_Toc879309)

[10.2 Commitment 15](#_Toc879310)

# Applicant Information

*The information in this questionnaire can be shared confidentially between USAID and its implementing partners, WHO and The Global Fund for procurement purposes. If approved, the approval (including product identification, manufacturing sites, approved specifications and publicly available information) may also be shared with other procurement agencies. If applicant has any objections, mark an X in the box:*  objection to sharing information between USAID and implementing partners, and/or other organizations.

|  |  |
| --- | --- |
| Request for Proposal Number |  |
| Questionnaire Submission Date *(DD/MON/YYYY)* |  |
| Company Name (Supplier)  (*name of company submitting bid*) |  |
| Physical address |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |
| Link to product | *(Select all that apply)*  Marketing license holder  Distributor/wholesaler  Manufacturer  Other (Specify): |
| Provide contact information for each of the following: | |
| Technical Specifications and Quality Assurance | Name:  Telephone:  Cell phone:  E-mail: |
| Regulatory and patent | Name:  Telephone:  Cell phone:  E-mail: |
| General Inquiries | Name:  Telephone:  Cell phone:  E-mail: |

# Product Identification

|  |  |  |
| --- | --- | --- |
| Brand name |  | |
| Generic name of the product |  | |
| Regulatory Version | US FDA  CE Mark  ROW  Only one regulatory version available  Other (Specify) | |
| Product Category | *[State the GMDN category of the device. If the device is not categorized according to GMDN and is coded based on other system, please specify]* | |
|  | |
| Intended Use | *[State the intended use of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate.]* | |
|  | |
| Target Population | *[Describe the target patient population for which the device is intended. Specify if the device is for pediatric use.]* | |
|  | |
| Pediatric use | |
| Use | *[Identify if the device is intended for single or multiple use]* | |
| Single Use  Multiple Use | |
| Sterility | Sterile  Non-sterile | |
| Storage Conditions | [State the storage conditions for the device.] | |
| Product Suitable for use in the following climatic zones: | Zone I;  Zone II;  Zone III;  Zone IVa;  Zone IVb; Other (Specify)\_\_\_\_ | |
| Shelf-life | 24 months  36 month  48 months  60 months  Other (*Specify*) | |
| Packaging Type | Blister Pack  Bottle  Vial  Ampule  Other (*Specify*): | |
| Manufacturer Product Identification Number (including any variant)\* | | Device Description |
| *[List the identifier (bar code, catalogue number, model number or part number, UDI) for each variant model configuration/component/accessory that is the subject of the submission.]* | | *[Statement of the name/description for the product and each variant/component]* |
|  | |  |
|  | |  |
|  | |  |
|  | |  |
|  | |  |
|  | |  |

\**Each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit set, unless the component is available for sale independently.*

# Manufacturer Information

## Manufacturer Identification

* *Attach a copy of the Manufacturer Site Master File*
* *Provide a copy of the business registration certificate*

|  |  |
| --- | --- |
| Manufacturer Name |  |
| Physical address: |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |

## Manufacturing Activities

*[List all sites that are involved in the manufacture of this product. Include all stages of manufacture (for example, design, production, warehousing, quality control, and release for supply). Include subcontractors when applicable].*

|  |  |  |  |
| --- | --- | --- | --- |
| Business Name | Activity | License No. | Address   * *Include plot/unit/production line information if applicable)* * *Identify SRA vs Non SRA unit/production lines* |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Key Suppliers

*List key suppliers which supply products/components/services for the manufacture of this product*

* *Provide a copy of the system certificates: i.e. ISO 9001:2000; ISO 13485:2003; ISO: 9001:2008; or others (specify)*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of the component/product/service supplied | Supplier Name | Address   * *Include plot/unit/production line information if applicable)* | Certifications  (eg. ISO 9001, 13485 other) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Manufacturer Quality Management System

* *Provide a copy of the system certificates: i.e. ISO 9001:2000; ISO 13485:2003; ISO: 9001:2008; or others (specify)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Business Name | Authority | Certificate No. | Date Issued  *(DD/MON/YYYY)* | Valid until  *(DD/MON/YYYY)* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## Inspections and Audits

* *Provide a copy of the inspection certificate and/or audit certificate (when available) in the last 3 years*

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Inspection | Authority | Inspection Dates  *(DD/MON/YYYY)* | CAPA Status |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Product INFORMATION

## Product Description and Design

* *Attach a copy of the design drawings, diagrams, photos*

|  |
| --- |
| *[Provide a general description on design, characteristics and performance of the device. The description should also include information on device packaging.]* |
|  |

## Device Composition

|  |
| --- |
| *[Provide a summary of the composition of the device, including at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user/patient.* |
|  |
| Indication of biological material or derivate used in the medical device. |
| Biological material or derivate is used in the medical device. (If yes, specify origin (human, animal, recombinant or fermentation products or any other biological material; source (blood, bone, heart any other tissue or cells) and the intended reason for its presence and if applicable, its primary mode of action.  Not applicable |
| API or Drug Components |
| *If the device contains an active ingredient (API) or drug, and indication of the substance should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action.* |
| Device contains an API or Drug  Not applicable |

## Raw Materials, components, intermediate products /sub-assembles specification

* *Include a discussion when deviations to the standard occur*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Raw Material/Component, Intermediate product and or Sub-assemble identification | Standard | Edition | Year Published | Specify if Full of Partial Compliance | If partial compliance, list the sections of standard that are not applicable to device, have been adapted. |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Final Product Specifications

*[Describe functional characteristics and technical performance specifications for the device including as relevant, accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.]*

* *Attach a copy of the release and shelf-life specifications for the final product*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Functional characteristic  / technical performance specification | Standard | Edition | Year Published | Specify if Full of Partial Compliance | If partial compliance, list the sections of standard that are not applicable to device, have been adapted. |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Non-Clinical Performance Data

* *Attach a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.*
* *Attach a copy of Certificate of analysis of the of the last year or 10 batches released (whichever is greater)*

## Manufacturing Methods

|  |  |
| --- | --- |
| *Summarize the results of verification and validation studies undertaken to demonstrate compliance of the device with Essential Principles that apply.* | |
|  | |
| Manufacturing methods for each standard batch size have been validated. | |
| Specify the batch size of the validated batches (minimum and maximum size) |  |
| Specify the reference number for the process validation report |  |
| Specify the manufacturing dates of the validated batches (*BATCH ID: (DD/MON/YYYY))* |  |
| Validation reports are not available. | |
| Specify the reference number for the process validation protocol |  |

## Sterile Aspects of the Product

Complete this section only for sterile products.

* *Attach the data on validation of the sterile aspects of the product as applicable.*

|  |
| --- |
| *If the device is sterilized, provide an indication of who is to perform the sterilization and what method. Describe the method of sterilization used including conditions such as temperature, time, pressure, if applicable. Include a statement of validation of the sterilization method.* |
|  |

## Packaging Information

* *Attach a copy of the primary packaging and secondary packaging artwork.*
* *Attach a copy of the package insert/leaflet*
* *Attach a copy of the patient information leaflet*

|  |
| --- |
| *Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary packaging and any other packaging associated. Specific packaging of accessories marketed together with the medical devices shall also be described.* |
| Packaging materials used for primary packaging, pack size (quantity per pack). |
|  |
| Packaging Specifications |
|  |
| Primary packaging label language:  English  French  Portuguese  Spanish  Other (Specify): |
| Description, pack size and material used for secondary packaging. |
|  |
| Secondary packaging label language:  English  French  Portuguese Spanish  Other (Specify): |
| Instructions for Use/Package Insert/ Leaflet language:  English  French  Portuguese  Spanish  Other (Specify): |
| Patient Information Leaflet language:  English  French  Portuguese  Spanish  Other (Specify): |

## Shelf-life and Storage Conditions

* *Attach report for accelerated and long-term stability studies completed, status report for any ongoing stability studies and protocol for any planned stability studies. Please provide data of transport studies conducted. Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and study conclusions.*

|  |  |
| --- | --- |
| Stability testing data for this product is available.  The stability data available is for a product of the same formula, same API source(s), manufactured in the same site and packed in the same packaging materials declared for the product that will be shipped. If not, describe the differences: | |
| Stability testing studies are ongoing. Specify the studies that are ongoing: | |
| Stability testing studies are planned. Specify the studies that are planned:  . | |
| Shelf-life as it appears on the packaging | 24 months  36 months  48 months  60 months  Other *(Specify*): |
| Storage conditions for this product as they appear on the packaging and based on stability studies |  |
| Product suitable for use in: | Zone I  Zone II  Zone III  Zone IVa  Zone IVb  Other (Specify)\_\_\_\_ |

# Safety and Efficacy and/or Therapeutic Equivalence

## Clinical Evaluation

|  |
| --- |
| *Provide a summary of the clinical evaluation of the product, as applicable* |
|  |

# Risk management

* *Attach a copy of the Results of risk management, per product family.*

|  |
| --- |
| *Provide a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to its benefits. When a standard is followed identify the standard.* |
|  |

# Product Quality Incidents and Recalls

|  |
| --- |
| *Provide a summary of Product Quality Incidents and recalls associated with this product for the past 3 years.* |
|  |

# Regulatory and licensing status

## Licensing Status

* *Attach a copy of the licenses that apply*

|  |  |  |
| --- | --- | --- |
| Product registered and currently marketed in the country of manufacture | | |
|  | Country of Manufacture: | |
|  | Issuing Agency: | |
| Product registered but NOT marketed in the country of manufacture | | |
|  | Country of Manufacture: | |
|  | Issuing Agency: | |
| Product registered for export only | | |
|  | Country of Manufacture: |  |
|  | Issuing Agency: |  |
| Product NOT registered in the country of manufacture. (*Please Explain)* | | |

## US FDA Status

* *Provide copies of US FDA approval/registration*

|  |
| --- |
| Product is approved by the US FDA: (specify authorization number)  PMA#  510K#  Other (Specify): |
| Product submitted for US FDA evaluation. Awaiting registration approval.  Date of Submission *(DD/MON/YYYY)*: |

## CE Marking Status

* *Provide a copy of the relevant CE Mark certificate for each applicable variant*

|  |
| --- |
| Product is CE Marked  Product is not CE Marked |
| Product submitted for CE Mark evaluation, but not yet approved*.*  Date of Submission *(DD/MON/YYYY)*: |

## WHO Prequalification Status

* *Provide a copy of the relevant WHO Prequalification acceptance letter signed by the company or provide a copy of the WHO acceptance letter for product dossier review signed by the company.*
* *Provide a recent as well as historical deficiency letters issued by the WHO Prequalification Programme in relation to the specific product dossier*

|  |
| --- |
| Product is in the list of WHO prequalified products. |
| Product submitted for WHO prequalification, but not yet prequalified*.*  Date of Submission *(DD/MON/YYYY)*:  WHO reference number: |
| Product not submitted for WHO prequalification.  *(Provide Rationale for not submitting product for prequalification in instances where a WHO Expression of Interest has been released.)* |

## Global Registration/Marketing approvals

* *List of countries where the device has obtained marketing approvals.*
* *Provide a copy of the valid marketing authorization*

|  |  |  |  |
| --- | --- | --- | --- |
| List all countries where this product has been registered and is currently marketed. | | | |
| *Country* | *Agency* | *Registration Number* | *Valid Until*  *(DD/MON/YYYY)* |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Checklist of Attachments

Manufacturer Information

Manufacturer Site Master File

Copy of the business registration certificate

Recent/valid system certificates (ISO 9001, ISO 13485, other)

Product Information

Copy of design drawings, diagrams, phots

Device Composition

Copy of the release and shelf-life specifications for final product

Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Copy of Certificate of Analysis of the of the last year or 10 batches released (whichever is greater)

validation of the sterile aspects of the product as applicable

Primary Packaging Artwork

Secondary Packaging Artwork

Package insert/leaflet

Protocol and report for accelerated and long-term stability for each presentation

Status report for any ongoing stability studies

Protocol for any planned stability studies

Safety and Efficacy and/or Therapeutic Equivalence

Clinical Evaluation Report

Incidents and recalls associated with the product for the past 3 years

Risk Management

Copy of results of risk management, per product family

Regulatory and Licensing Status

Copy of the License

US FDA Approval

CE mark Certificate

WHO Prequalification approval letter signed by your company

WHO acceptance letter for product dossier review including WHO reference number assigned for this specific product

Provide a recent as well as historical deficiency letters issued by the WHO Prequalification Programme in relation to the specific product dossier.

Registration and Marketing Documentation (SRA, Country of Origin and all other)

Global Registration/Marketing Approvals

List of countries where the device has obtained marketing approvals

Copy of valid marketing authorization

Authorization and Commitment

Authorization to share information

Commitment

# Authorization and Commitment

## Authorization for sharing information with other Agency(ies)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned [ENTER FULL NAME], confirm that the company has no objection to the information contained herein being shared with USAID and implementing partners, WHO and/or The Global Fund. If approved, the approval (including product identification, manufacturing sites, approved specifications and publicly available information) may also be shared with other procurement agencies. I, the undersigned, understand that any publicly available information may also be subject to disclosure by USAID under the Freedom of Information Act.  I, the undersigned [ENTER FULL NAME], object to sharing the information contained herein with [SPECIFY]. However, I, the undersigned, understand that any publicly available information may also be subject to disclosure by USAID under the Freedom of Information Act. | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
|  |  |  |  |  |

## Commitment

* *Provide a copy of a power of attorney in instances where a manufacturer authorizes a distributor to submit the questionnaire.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned (ENTER FULL NAME), certify that:  The product offered is identical in all aspects of manufacturing and quality to that US FDA approved product (NDA/ANDA: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) including, formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information. The following exceptions apply: (Describe)  or  The product offered is identical in all aspects of manufacturing and quality to that registered and marketed in [SPECIFY COUNTRY / Registration No.] including, formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information. The following exceptions apply: (Describe)  I, the undersigned (ENTER FULL NAME), certify that the information provided above is accurate, correct, complete, up-to-date and true at the time of submission.  If any changes occur to the information provided after submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible. | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
| Company seal/stamp |  |  |  |  |