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**Annex 6 - Diagnostic Product Questionnaire [[1]](#footnote-1)**

Potential manufacturers supplying diagnostic products for USAID | GHS-PSM Project are required to provide documentation of their manufacturing capabilities, technical and specifications standards of the processes used to manufacture the diagnostic product. Incomplete submission of this document may negatively affect the bidder’s eligibility and may result in GHSC-PSM not considering the offer. Documents in languages other than English must include a translation and should be submitted in addition with the original non-translated document.

**For each diagnostic product submitted in the offer, please fill out one separate questionnaire. However, the same questionnaire can relate to different commercial presentations if their contents, in nature, are essentially similar. If this is relevant please indicate explicitly in the corresponding sections.**

**Offeror:**

|  |
| --- |
|  |

**Section 1: Administrative section**

* 1. **Contact Details of Legal Manufacturer**

|  |  |
| --- | --- |
| Name of company |  |
| Physical address |  |
| Postal address |  |
| City |  |
| Country |  |
| Telephone |  |
| E-mail |  |
| Website |  |
| Authorized contact legal manufacturer (Please specify): |  |

* Other authorized contacts, e.g. if Legal Manufacturer has identified a third party for this submission (Please complete following table):

|  |
| --- |
|  |

* 1. **Contact Details for Responsible Persons**

|  |  |  |  |
| --- | --- | --- | --- |
| Function/responsibility | Name of contact person: | Telephone/  cell phone: | Email: |
| Technical specifications & product quality |  | Tel:  Cell: |  |
| Regulatory & patent |  | Tel:  Cell: |  |
| Commercial/business |  | Tel:  Cell: |  |
| General enquiries |  | Tel:  Cell: |  |

**Section 2: Diagnostic Product**

* 1. **Product Identification**
* Product name (Full):

|  |
| --- |
|  |

* Product name (Abbreviated, if existing):

|  |
| --- |
|  |

* Product code / Product catalogue No

|  |
| --- |
|  |

* Device code (this code should be allocated in reference to an internationally recognized coding system e.g. ISO 15225, GMDN):

|  |
| --- |
|  |

2.1.1 Packaging formats

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name Pack | Pack size / Number of units | Catalogue N0  / Code | Dimensions L x H x W (cm) | Weight in kg |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Note : Specify sub units if applicable | | | | |

* Is this product on the market under a different brand/trade name?

**☐** Yes **☐** No

* If yes, specify in the following table):

|  |
| --- |
|  |

2.1.2 Product classification regarding hazardous materials

* Please provide Material Safety Data Sheet as per IATA requirements in **Annex A** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Product Description**

2.2.1 Intended use / Intended purpose

* Please provide a short narrative of the intended use:

|  |
| --- |
|  |

* Please describe the principle of operations / of the assay:

|  |
| --- |
|  |

2.2.2 Specimen type & Sample collection

* Please describe the different sample types that can be used for this IVD (e.g. serum, plasma, venous whole blood, capillary blood, urine, oral fluid):

|  |
| --- |
|  |

* Please described sample collection, transport materials including any additives if required:

|  |
| --- |
|  |

2.2.3 Assay Control

* Please describe the use of controls. If applicable, a list of compatible control materials or control material specifications. Please specified if provided by the manufacturer or supplied by external provider:

|  |
| --- |
|  |

2.2.4 Accessories required

* Please specify if specific accessory is required to perform the test (lancets, pipettes, swabs) and if they are provided by the manufacturer as part of the kit or separately or supplied by other provider:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Accessories** ( add rows if required) | Code | Provided in kit/  provided by the manufacturer or supplied by other provider |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |

2.2.5 Photographs

* Please provide photographs of all kit components, both packaged and individual, as **Annex B** (See Checklist in Section 6of this Questionnaire for file naming nomenclature).
  1. **Regulatory Status and Versions**

2.3.1 Regulatory versions:

* Are there different regulatory versions of the offered product?

**☐** Yes **☐** No

* If yes, explain which one is submitted for this RFQ and how it differs from other versions

|  |
| --- |
|  |

2.3.2 Approval /registration status in country of legal manufacture:

* In the country of manufacture. Provide a copy of the license (marketing authorization) as **Annex C** (if applicable) (See Checklist in Section 6of this Questionnaire for file naming nomenclature).

☐Product registered and currently marketed in the country of manufacture

|  |  |
| --- | --- |
| Approval/registration No: |  |
| Valid until  (DDMMMYY) |  |
| Issued by (Agency) |  |
| Country |  |
| Date of commercialization  (DDMMMYY) |  |

☐Product registered for marketing in the country of manufacture but not currently marketed

|  |  |
| --- | --- |
| Approval/registration No: |  |
| Valid until  (DDMMMYY) |  |
| Issued by (Agency) |  |
| Country |  |

☐Product registered for export only

|  |  |
| --- | --- |
| Approval/registration No: |  |
| Valid until  (DDMMMYY) |  |
| Issued by (Agency) |  |
| Country |  |

☐Product not registered in country of manufacture (please explain):

|  |
| --- |
|  |

2.3.3 Approval /registration status in other (exporting) countries:

* This product is registered/licensed and currently marketed in the following countries (insert additional rows as needed):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Country | Approval No. | Valid Until | Issuing Agency | Date Commercialization (DDMMMYY) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* Please provide copies of all Regulatory approvals/registration/certificates that are claimed as **Annex D** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.3.4 WHO Prequalification of In Vitro Diagnostics (IVD) Programme

* Please complete the applicable section as it relates to status of WHO Prequalification

☐WHO Prequalification of IVDs

|  |  |
| --- | --- |
| PQDx number: |  |

* If applicable, please attach a copy of the relevant WHO Prequalification Programme acceptance letter signed by your company as **Annex E** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

☐ Pre-submission for WHO Prequalification of IVDs (please explain)

|  |
| --- |
|  |

* If applicable, indicate date of submission, WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product as **Annex F** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

☐ Not planning to apply to WHO Prequalification of IVDs (please explain)

|  |
| --- |
|  |

2.3.5 Marketing rejections:

* Has a Regulatory Body rejected issuing Marketing Authorization of the offered diagnostic product?

**☐** Yes **☐** No

* If yes, provide an overview of the rejection for Marketing Authorization including the justification for rejection by the corresponding Regulatory Body. Information should be included as **Annex G** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.3.6 Enforcement actions:

* Has the offered diagnostic product been subject to enforcement actions, including suspension of Marketing Authorization, or deficiency letters within the last 5 years issued by a Regulatory Body or WHO?

**☐** Yes **☐** No

* If yes, provide a short description of the enforcement action and the current status and provide a copy of the manufacturer’s response (i.e. CAPA Plan). Additionally, if available provide proof of resolution issued by the corresponding Regulatory Body or WHO. Information should be included as **Annex H** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.3.7 Rebranding:

* Is the offered product a rebranded product?

**☐** Yes **☐** No

* If yes please indicate the name, address and contact details of the Original Manufacturer (OEM)

|  |  |
| --- | --- |
| Name |  |
| Address |  |
| Contact details |  |

* Please provide the terms of the contract between you and the OEM related to access to the technical documentation, complaints management, vigilance and recall as **Annex I** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

|  |
| --- |
|  |

* Please specify if the products subject to this questionnaire are sold for rebranding.

**☐** Yes **☐** No

* If yes, please indicate the name and contact details of the Own Brand Labeller (OBL)

|  |
| --- |
|  |

* 1. **Labeling and Instructions for Use**

2.4.1 Instructions for Use (IFU):

* Please specify the language(s) of the IFU which are/will be available:

|  |  |
| --- | --- |
| Available Languages | ☐ English ☐ French ☐ Portuguese |

* Please provide copy of the IFU in the languages marked above as **Annex J** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.4.2 Labels & packaging:

* Primary packaging:

|  |  |
| --- | --- |
| Description and materials used for primary packaging |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese |

* Secondary packaging:

|  |  |
| --- | --- |
| Description and materials used for primary packaging |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese |

* Tertiary packaging:

|  |  |
| --- | --- |
| Description and materials used for primary packaging |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese |

* Please provide copies of all the packaging labels for the assay, include labels and component labels of primary packaging, labels secondary packaging, and labels outer package (tertiary / transportation package) for all products offered in the languages marked above as **Annex K** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Risk Management**
* Was a risk analysis conducted to identify possible hazards for the IVD medical device, address and control the risks to an acceptable level?

**☐** Yes **☐** No

* If yes, please provide the standard/guideline that was followed:

|  |  |
| --- | --- |
| Name of Risk Management Standard Guideline |  |
| Version |  |
| Year Issued |  |

* Please provide the specific risk report, risk analysis risk management plan and risk control for the related IVD as **Annex L** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please provide an explanation:

|  |
| --- |
|  |

* 1. **Stability Studies**

2.6.1 Description of the stability studies conducted:

* Where studies conducted on stability of the product(s)?

**Note**: Stability testing should be completed on samples taken from three different production lots of the finished product manufactured on the same site and packed in the same packaging material as the product that will be supplied.

**☐** Yes **☐** No

* If yes, please complete section a-c below (complete all applicable sections).
* If no, please provide an explanation:

|  |
| --- |
|  |

1. ☐Satisfactory **accelerated** testing

|  |  |
| --- | --- |
| Temperature |  |
| Relative Humidity |  |
| Duration (Months) |  |
| Number of lots included in study |  |
| Lot sizes |  |
| Date of beginning of the study |  |
| Date of end of the study |  |
| Standard/guideline that was followed to perform the study |  |

* Please provide copies of study protocol and study results, including graphical/pictorial interpretations where applicable as **Annex M** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

1. ☐ Satisfactory **real time** testing

|  |  |
| --- | --- |
| Temperature |  |
| Relative Humidity |  |
| Duration (Months) |  |
| Number of lots included in study |  |
| Lot sizes |  |
| Date of beginning of the study |  |
| Date of end of the study (or planned date) |  |
| Standard/guideline that was followed to perform the study |  |

* Please provide copies of study protocol and study results, including graphical/pictorial interpretations where applicable as **Annex N** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

1. ☐ Stability studies for this product is **ongoing**

* Please provide copies of study protocol of any ongoing stability studies as well as the interim report as **Annex O** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.6.2 In use stability:

* Where in use stability studies conducted on the product?

**☐** Yes **☐** No

* If yes, please provide copies of study protocol and study results, including graphical/pictorial interpretations where applicable as **Annex P** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please provide an explanation:

|  |
| --- |
|  |

2.6.3 Shipping stability:

* Where shipping stability studies conducted on the product?

**☐** Yes **☐** No

* If yes, please provide copies of study protocol and study results assessing the stability during transportation, including graphical/pictorial interpretations where applicable as **Annex Q** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please provide an explanation:

|  |
| --- |
|  |

* 1. **Shelf Life and Storage Conditions**
* Please complete the following tables (3) to summarize shelf life and storage conditions

|  |  |
| --- | --- |
| Guaranteed shelf life (based on stability studies) |  |
| Maximum possible shelf life (upon manufacture, based on stability studies) |  |
| Determination of expiration date as it appears on the outer packaging (i.e, unopened) |  |
| Determination of expiration date of components after primary package is opened (in use stability) |  |

|  |  |
| --- | --- |
| Storage conditions for this product as they appear on the packaging and based on stability studies | |
| Temperature |  |
| Light |  |
| Humidity |  |
| Other (Specify): |  |

|  |  |
| --- | --- |
| Please specify the specific transport conditions, if necessary | |
| Temperature |  |
| Light |  |
| Humidity |  |
| Other (Specify): |  |

* 1. **Product Performance Specifications and Associated Validation and Verification Studies**
* Please provide the performance data relevant for each specimen type claimed. For example: general overall Performance sensitivity (95%C) and specificity (95% CI)

**Note:** It is critical to stress that all the data provided in this section must be obtained with devices produced under a “final” validated production scale (e.g. initial production units recognizing that production equipment or processes might change between production for validation and production for commercial distribution). These points are important as many data can be irrelevant or misleading if not done using products representative of the final product and process conditions. Pilots scale batches will not suffice unless concrete evidence are provided that the difference will have no impact on the quality of the data, except if justified by the innovative aspects of the device.

2.8.1 Analytical performance studies

* Were studies conducted to demonstrate analytical aspects?

**☐** Yes **☐** No

* If no, please provide an explanation:

|  |
| --- |
|  |

* If yes, please provide an overview of the study conducted as per the following table. Please ensure the information is specified for all of the specimen types claimed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Specimen types | Yes | No |
| Specimen Stability |  |  |  |
| Accuracy of measurement |  |  |  |
| - Trueness of measurement |  |  |  |
| - Precision of measurement |  |  |  |
| Analytical sensitivity |  |  |  |
| - LOB / LOD / LOQ |  |  |  |
| - Detection of variants |  |  |  |
| Analytical specificity |  |  |  |
| - Interference studies / cross-reactivity |  |  |  |
| Measuring range |  |  |  |
| Any other |  |  |  |

* Please provide for each study, study protocols and report summarizing the data collected, clearly specifying reference methods used. Submit this information as **Annex R** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

2.8.2 Clinical performance studies

* Were studies conducted to demonstrate performance on clinical specimens?

**☐** Yes **☐** No

* If no, please provide an explanation:

|  |
| --- |
|  |

* If yes, please provide an overview of the clinical studies conducted as per the following table. Please ensure the information is specified for all of the specimen types claimed.

**Note:** Clinical performance data should be collected on samples taken from two different production lots of the finished product manufactured under a “final” validated production scale, except justified by the innovative aspects of the device.

|  |  |  |  |
| --- | --- | --- | --- |
| Clinical evaluations | Specimen types | Yes | No |
| Clinical evaluation\_ Manufacturer |  |  |  |
| Clinical evaluation\_ independent 1 |  |  |  |
| Clinical evaluation\_ independent 2 |  |  |  |

* Please provide for each study, study protocols and summary data conducted by the manufacturer and/or by independent party in intended use settings. Submit this information as **Annex S** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

**Note:** Independent studies are conducted without involvement from the manufacturer, although the reagents and instrument for the study may have been provided free of charge for the study.

2.8.3 Other studies performed to demonstrate product performances

* Were studies conducted to demonstrate performance on clinical specimens?

**☐** Yes **☐** No

* If no, please provide an explanation:

|  |
| --- |
|  |

* If yes, please provide an overview of the other studies conducted as per the following table. Please ensure the information is specified for all of the specimen types claimed.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes | No |
| Robustness |  |  |  |
| Operator error / Usability / Human factor |  |  |  |
| Environmental factors |  |  |  |
| Any other |  |  |  |

* Please provide for each study, the study protocol and the report / summary data as **Annex T** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Commitment:**
* The product used in the above referenced studies is essentially the same as the one that will be supplied (same materials from the same suppliers and same manufacturing method):

**☐** Yes **☐** No

* If no, explain what the differences are and justify that the differences do not have any impact on the product performance specifications:

|  |
| --- |
|  |

**Section 3: Manufacturer**

* 1. **Manufacturing Site(s)**

3.1.1 Manufacturing site of final diagnostic product

* Is the manufacturing site of the final diagnostic product different from location of the Legal Manufacturer as specified in section 1.1?

**☐** Yes **☐** No

* If yes, please proceed to item 3.1.2
* If no, please complete the following table for the manufacturing site of the final diagnostic product:

|  |  |  |
| --- | --- | --- |
| Name of manufacturer | |  |
| Manufacturing License | License No. |  |
| Valid Until |  |
| Issuing Agency |  |
| Country |  |
| Physical address. Please specify  units, and block if existing | |  |
| Telephone number, facsimile number and email contact details | |  |

3.1.2 Activities in the various manufacturing sites

* List of all sites involved in the manufacturing process of the diagnostic product (add additional lines as needed)

|  |  |
| --- | --- |
| Site 1 |  |
| Site 2 |  |
| Site 3 |  |

* For each site described in Section 3.1.2, complete the following table (please add tables as needed):

|  |  |  |
| --- | --- | --- |
| Name of manufacturer | |  |
| Manufacturing License | License No. |  |
| Valid Until |  |
| Issuing Agency |  |
| Country |  |
| Physical address. Please specify  units, and block if existing | |  |
| Telephone number, facsimile number and email contact details | |  |
| Responsibilities/Activity (e.g. packaging) | |  |

3.1.3 Design and development information

* Please provide an overview of the Design and Development Records specific to the diagnostic product(s) offered, including a flowchart of the design process. Please include as **Annex U** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* Please provide copy of the procedure for design changes as **Annex V** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).

3.1.4 Standards

* Please provide an overview of used standards (totally or partially) including the rationales for using standards.

|  |
| --- |
|  |

* Please provide the detailed list of standards referenced in the table above. The list should include the name of standard organization, standard number, standard title, year/version, and if full or partial compliance as **Annex W** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Method of Manufacture and Process Validation:**

3.2.1 Validation processes

* Have the manufacturing methods for each standard batch size been validated?

**☐** Yes **☐** No

* If no, please clarify:

|  |
| --- |
|  |

* If yes, please provide details of validation status in the table below:

|  |  |
| --- | --- |
| The batch size of the validated batches (minimum, maximum size) |  |
| The batch numbers of the validated batches |  |
| Manufacturing dates of the validated batches |  |
| Reference number for the process validation report |  |
| If processes are yet to be validated, the reference number for the process validation protocol should be indicated |  |

3.2.1 Manufacturing and control processes

* Please provide a process flow chart/diagram and a brief narrative describing the manufacturing processes and control processes of the offered product(s) with relevant parameters as **Annex X** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Key Components and Reagents:**
* Please provide a list of the key components and reagents of the offered diagnostic product(s) in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Key component & reagents | Supplier 1 (name & address) | Supplier 2  (Name & address) | Specifications  Yes/No | QC/ release procedure  Yes/no |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* Please provide for each key components and reagents listed, the specifications, quality control criteria, name of suppliers (including supplier name and address) as well as copies of QMS certificates for outsourced components manufacturers as **Annex Y** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).   
  1. **Final Product Specifications and Lot Release Procedures:**

3.4.1 Product specifications:

* Do specifications exist for the final diagnostic product(s) offered?

**☐** Yes **☐** No

* If yes, please provide the final diagnostic product(s) specifications and criteria of acceptance as **Annex Z** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please explain:

|  |
| --- |
|  |

* + 1. Lot release procedure
* Please provide a copy of the procedure for QC of lot release as **Annex AA** (See Checklist in Section X of this Questionnaire for file naming nomenclature).

**Note**: The manufacturer should provide, in the submitted procedure of lot release or an equivalent document, rationale for the definition of lot release testing criteria.

* Please provide copies of Certificates of Analysis for the last 3 lots released as **Annex AB** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  1. **Quality Management System (QMS)**
     1. Implementation of a QMS
* Please provide current version of the quality manual of the manufacturing site of the final diagnostic product defined in Section 3.1.1. Please provide this document as **Annex AC** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* Do all of the manufacturing sites listed in Section 3.1.2 hold an ISO 13485 certificate and the scope of the certification covers the listed manufacturing activity?

**☐** Yes **☐** No

* If yes, please complete the following table (add lines as necessary):

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Site No. | Site Name | Activity | Cert. No. | Cert. Body | Valid Until (MM/YY) | Country |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

* Please provide copies of the valid ISO 13485 certificates for each site listed as **Annex AD** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please explain:

|  |
| --- |
|  |

* + 1. QMS Inspections:
* Please provide information in the following table on any quality audit / quality inspection carried out at the manufacturing site of the final diagnostic product within the last 3 years (complete all that apply and add lines as needed):

|  |  |  |  |
| --- | --- | --- | --- |
| Entity Performing Audit/Inspection | Scope of Audit/Inspection | Date | Outcome |
| WHO Prequalification |  |  |  |
| Regulatory Body of Country of Manufacture |  |  |  |
| Member of IMDRF[[2]](#footnote-2) |  |  |  |
| Regulatory Body of Exporting Country |  |  |  |
| Certification Body |  |  |  |
| Other |  |  |  |

* Please provide most recent inspection/audit reports associated with certification (or CE or USFDA approvals if relevant): two most recent and valid surveillance reports and the most recent valid re-certification report. Include the list of findings associated with each report. Information should be submitted as **Annex AE** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* Has the manufacturing site of the final diagnostic product been subject to any Regulatory Body or WHO enforcement actions or deficiency letters within the last 5 years?

**☐** Yes **☐** No

* If yes, provide a short description of the enforcement action and the current status and provide a copy of the manufacturer’s response (i.e. CAPA Plan). Additionally, if available provide proof of resolution issued by the corresponding Regulatory Body or WHO. Information should be included as **Annex AF** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
  + 1. Key suppliers control:
* Please provide copy of the procedure for the management and evaluation of key suppliers as **Annex AG** (See Checklist in Section X of this Questionnaire for file naming nomenclature).
* Please provide copy of the quality control procedure for received critical reagents and components as **Annex AH** (See Checklist in Section X of this Questionnaire for file naming nomenclature).
  1. **Manufacturing Production Capacity**
* Please complete the following tables

|  |  |
| --- | --- |
| Average batch/lot size: Describe the total number of units manufactured **per** batch/lot | |
| 2011 |  |
| 2012 |  |
| 2013 |  |
| 2014 |  |
| 2015 |  |

|  |  |
| --- | --- |
| Number of batches/lots manufactured per year | |
| 2011 |  |
| 2012 |  |
| 2013 |  |
| 2014 |  |
| 2015 |  |

* Are there any planed changes to the diagnostic product production capacity?

**☐** Yes (Please describe planed changes in box below) **☐** No

|  |
| --- |
|  |

**Section 4: Post Marketing Experience, Training and Support**

* + 1. Post marketing experience:
* Do you have a documented procedure and mechanism or feedback system to provide early warning of quality problems, in place and in particular for handling complain**ts** of your products?

**☐** Yes **☐** No

* If yes, please provide a copy of your handling complain**t** procedure as **Annex AI** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please explain:

|  |
| --- |
|  |

* Do you have a documented procedure and mechanism in place for product recall as part of the post market surveillance of the quality/safety of you products?

**☐** Yes **☐** No

* If yes, please provide a copy of your product recall procedure as **Annex AJ** (See Checklist in Section 6 of this Questionnaire for file naming nomenclature).
* If no, please explain:

|  |
| --- |
|  |

* + 1. Commitment to notify of changes to the product, the quality management system, product recalls or other quality and performance issues:
* The offeror commits to notify GHSC-PSM within 20 working days of any changes to the diagnostic product which h submitted to WHO Prequalification and/or Regulatory Bodies.

**☐** Yes **☐** No

* The offeror commits to notify GHSC-PSM within 20 working days of any changes to the QMS of the manufacturing site of the final diagnostic product which are submitted to WHO Prequalification and/or Regulatory Bodies.

**☐** Yes **☐** No

* The offeror commits to notify GHSC-PSM within 5 working days of any product recalls or other quality and/or performance issues that may arise with the offered diagnostic product(s).

**☐** Yes **☐** No

* + 1. Training and support:
* Please describe and explain the various customer support mechanism available, in particular technical support?

|  |
| --- |
|  |

* Please describe and explain the various types of trainings or training materials offered to customers and indicate the languages of the materials?

|  |  |
| --- | --- |
| Description of trainings and materials |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese |

* + 1. Quality control or proficiency panels:
* Do you have quality controls or proficiency panels available?

**☐** Yes **☐** No

* If yes, please provide a description in the following table:

|  |
| --- |
|  |

* If no, explain why:

|  |
| --- |
|  |

* Is your product compatible with existing proficiency panel providers?

**☐** Yes **☐** No

* If yes, please provide a description in the following table:

|  |
| --- |
|  |

* If no, explain why:

|  |
| --- |
|  |

**Section 5: Certification of Authenticity**

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*List full name and current title in the company, e.g. General Manager, Authorized Person, Responsible Pharmacist*), acting as responsible for the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name of the company)*, certify that the information provided (above) is correct and true,

*(if the product is marketed in the country of origin, select the appropriate box below)*

**☐** and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*country of origin*)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as indicated in Section 4.1.2 of this questionnaire.

|  |  |
| --- | --- |
| Date (dd/mm/yyyy) |  |
| Name |  |
| Title |  |
| Signature |  |

**Section 6: Checklist for the Required Annexes**

Annexes to the questionnaire should be in PDF format and should be well indexed to facilitate review.

Please ensure that all documents necessary to enable objective evaluation of your product are attached.

Nomenclature assigned for each Annex must follow the indications in the table below. Bidder can only modify *Manufacturer name* and *Product name*. The table below indicates the text that can be modified, which is marked by the text in parenthesis [ ].

**No other special characters than underscores should be used**.

For the *Product name*, please use the name of the product as specified in Section 2.1 of this Questionnaire.

The number of characters used for naming PDF files must not exceed 60 characters. Abbreviations can be used (i.e. *Pf* instead of *Plasmodium falciparum*).

|  |  |  |
| --- | --- | --- |
| **Annex** | **File Name (PDF required)** | **Submitted\*** |
|  | ***ANNEX LETTER. ANNEX NAME \_[Insert Manufacturer name\_ Insert Product name]*** | **🗹 or N/A** |
| A | A. MSDS\_Manufacturer name\_Product name |  |
| B | B. PHO\_Manufacturer name\_Product name |  |
| C | C. MA\_Manufacturer name\_Product name |  |
| D | D. REG\_declaration\_Manufacturer name\_Product name |  |
| E | E. WHO PQ\_Manufacturer name\_Product name |  |
| F | F. WHO AL\_Manufacturer name\_Product name |  |
| G | G. MA REJ\_Manufacturer name\_Product name |  |
| H | H. EA-P \_Manufacturer name\_Product name |  |
| I | I. OEM\_Manufacturer name\_Product name |  |
| J | J. IFU\_Manufacturer name\_Product name |  |
| K | K. LB PK\_Manufacturer name\_Product name |  |
| L | L. RSK\_Manufacturer name\_Product name |  |
| M | M. S-ACL\_Manufacturer name\_Product name |  |
| N | N. S-RT\_Manufacturer name\_Product name |  |
| O | O. S-OG\_Manufacturer name\_Product name |  |
| P | P. S-IU\_Manufacturer name\_Product name |  |
| Q | Q. S-SP\_Manufacturer name\_Product name |  |
| R | R. PER-A\_Manufacturer name\_Product name |  |
| S | S. PER-C\_Manufacturer name\_Product name |  |
| T | T. PER-O\_Manufacturer name\_Product name |  |
| U | U. DDR\_Manufacturer name\_Product name |  |
| V | V. DCP\_Manufacturer name\_Product name |  |

|  |  |  |
| --- | --- | --- |
| **Annex** | **File Name (PDF required)** | **Submitted\*** |
|  | ***ANNEX LETTER. ANNEX NAME \_[Insert Manufacturer name\_ Insert Product name]*** | **🗹 or N/A** |
| W | W. STD\_Manufacturer name\_Product name |  |
| X | X. MCP\_Manufacturer name\_Product name |  |
| Y | Y. KC SP\_Manufacturer name\_Product name |  |
| Z | Z. FPS\_Manufacturer name\_Product name |  |
| AA | AA. LRP\_Manufacturer name\_Product name |  |
| AB | AB. COA\_Manufacturer name\_Product name |  |
| AC | AC. QM\_Manufacturer name\_Product name |  |
| AD | AD. ISO C\_Manufacturer name\_Product name |  |
| AE | AE. ISR\_Manufacturer name\_Product name |  |
| AF | AF. EA-M\_Manufacturer name\_Product name |  |
| AG | AG. ECS\_Manufacturer name\_Product name |  |
| AH | AH. QCP-RC\_Manufacturer name\_Product name |  |
| AI | AI. CMP\_Manufacturer name\_Product name |  |
| AJ | AJ. RECP\_Manufacturer name\_Product name |  |

\*Document has been submitted: **🗹;** Document does not apply to this FPP: Not Applicable (**N/A)**

We hereby certify all technical proposal requirements included in this list were reviewed, approved and authorized for submission by our quality assurance or regulatory affairs representative.

|  |  |
| --- | --- |
| Date (dd/mm/yyyy) |  |
| Name |  |
| Title |  |
| Signature |  |

1. This document has been modified based on the Global Fund to Fight Aids, Tuberculosis and Malaria Diagnostic Product Questionnaire for Expert Review Panel for Diagnostic Products (Version 5; Published 22 Feb 2016) [↑](#footnote-ref-1)
2. International Medical Device Regulators Forum (IMDRF); www.imdrf.org [↑](#footnote-ref-2)