

RFI-GHSC-PSM-EC-2023-09

Instructions for completing QA documentation: Finished Pharmaceutical Product Questionnaire: Abbreviated

Only offers of products outlined in the RFI and meeting eligibility criteria outlined in the RFI will be considered eligible for review. FHI 360 (through the U.S. Agency for International Development [USAID] Global Health Supply Chain-Quality Assurance Program [GHSC-QA]) will provide GHSC-PSM with a quality assurance (QA) score that will be included as part of the overall offer evaluation criteria. Offerors are required to provide confirmation to GHSC-PSM that they have read and understood the instructions for creating a GHSC-QA Technical Questionnaire Submission and confirm that they have uploaded the required documentation to the GHSC-QA website in accordance with *ALL.WI.GEN-101.00 Instructions for Creating and Submitting Technical Documentation to FHI 360*.

Carefully read the instructions below to help ensure an accurate completion of *ALL.APP.FPP-107: Finished Pharmaceutical Product Questionnaire: Abbreviated*.

Offerors of new products/manufacturing sites/presentations (i.e. not currently eligible) by GHSC-QA: Complete *ALL.APP.FPP-107.00 Finished Pharmaceutical Product Questionnaire- Abbreviated* and provide the information requested.

Eligible suppliers of products/manufacturing sites/presentations evaluated by GHSC-QA and whose previously submitted technical documentation remains valid and that do not have updates to report, are requested to complete the following sections of *ALL.APP.FPP-107.00M Finished Pharmaceutical Product Questionnaire- Abbreviated* for each offered product/manufacturing site and product presentation:

- Section 1.0 Applicant Information
- Section 2.0 Product Identification
- Section 7.0 Product Quality Review
- Section 10 Authorization and Commitment

Eligible suppliers that have technical updates to report are requested to complete the relevant sections in *ALL.APP.FPP-107.00 Finished Pharmaceutical Product Questionnaire- Abbreviated* to provide updated information and documentation (e.g., updated FPP Specifications and Analytical Methods, nitrosamine risk assessment; updated FPP packaging, labelling, updated stability data to support FPP Shelf-life or storage conditions, updated API information). The following sections are required to be completed regardless of the technical update incorporated:

- Sections 1 Applicant Information,
- Section 2 Product Identification,
- Section 7 Product Quality Review
- Section 10: Authorization and Commitment

Offers that do not include the appropriate authorization and commitment signatures may not be considered for review.