USAID
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GLOBAL HEALTH SUPPLY CHAIN – QUALITY ASSURANCE

QA.APP.GEN-65.03

Medical Gas: Technical Questionnaire

This questionnaire is used to collect information from vendors with regards to Medical Gas as part of the response to COVID-19 pandemic activities. Additional documentation may be required and/or requested at the discretion of GHSC-QA.

Offeror may send questions and request for clarifications specific on how to fill this questionnaire to aguta@fhi360.org. When requested, GHSC-QA staff will set up a conference call to answer questions and provide clarifications.

Instructions:
Fill out the information that is applicable to the product. Complete one questionnaire per product presentation.

- *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.*
- Refer to *Instructions for Creating a GHSC-QA Technical Questionnaire Submission* and *Instructions to Access and Upload Documentation to GHSC-QA SharePoint Site* to complete the submission.

List of the countries with recognized USAID SRAs:
Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States.

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1.0 APPLICANT INFORMATION

The information in this questionnaire may be shared confidentially between USAID|GHSC and partner organizations upon establishing appropriate agreements.

☐ objection to sharing information between USAID and implementing partners, and/or other organizations.

Request for Proposal Number		
Questionnaire Submission Date *(DD/MON/YYYY)*		
Legal Business Name *(name of company submitting bid)*		
Doing Business As (if different than legal business name)		☐ Not Applicable
Physical address		
Postal address		
Telephone number		
Fax		
Website		
e-mail		
Organization capabilities	*(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		
Regulatory		
General Inquiries		

2.0 PRODUCT IDENTIFICATION

Medical Gas Establishment Type	☐ **Transfiller**: *A firm that manufactures medical gas by transferring the gas, either in a liquid or gaseous state, from a larger container into smaller containers, either high-pressure cylinders or cryogenic vessels, are filled from larger containers (in a process known as "cascading") or from permanently mounted tanks.* ☐ **Air Separation Unit:** *These units separate atmospheric air into its constituent gases of oxygen, nitrogen, and argon through a process of pre-cleaning, compression, cooling, and fractional distillation of liquefied air.* ☐ **Chemical Synthesizer or processor:** *sites that produce bulk nitrous oxide or carbon dioxide.* ☐ **Other: Specify:**
Product Identification Number (including any variant)	
Brand name	
Generic name of the product	☐ Medical grade nitrogen ☐ Medical grade oxygen ☐ Medical grade liquid oxygen ☐ Oxygen 93 ☐ Other: Specify:
Sterility	☐ Sterile ☐ Non Sterile
Purity	
Standard Claimed	☐ USP ☐ Ph Eur ☐ Other (Specify);
Intended Purpose	
Level of Use	☐ Health post; ☐ Health centre; ☐ Hospital; regional hospital, ☐ Emergency vehicles; ☐ Home care.
Shelf-life (months)	
Storage Conditions	
Packaging Type	☐ Medical gas cylinder ☐ Medical gas cylinder, portable ☐ Oxygen Plant (central oxygen supply system) ☐ Bulk liquid oxygen generated off-site and stored in a large tank and supplied through a central pipeline system. ☐ Other (Specify)
Country Regulatory Registration	
Manufacturing Site(s)	
Distributors	
Supply chain process:	

Describe step-by-step the supply chain process of medical gas provision from the manufacturing site(s) up to the delivery site. Identify all manufacturers involved in the process, all sites (name, address) involved in manufacturing activities including medical gas production, testing and release as well as containers filling, packaging (including labelling), transport and storage as well as all additional locations where product is intended to be shipped, stored and distributed. Identify all containers used in the transport and storage of product offered from the manufacturing site to the delivery point. Provide corresponding evidence to document the supply chain process.

3.0 DOCUMENTATION REQUEST

3.1 Supplier (Medical Gas) Documentation

- ☐ Attach a copy of Business Certificate of Registration (Commerce license) that includes all relevant sites demonstrating business registration status and scope of work.
- ☐ Attach a copy of valid ISO 9001: 2015 certificate or equivalent. If a documented Quality Management System is not available past performance or other alternative means may be considered.

3.2 Manufacturer (Medical Gas) Documentation

- ☐ Attach a copy of valid GMP Certificate for each relevant manufacturing site
- ☐ Attach a copy of Certificate of Manufacture or commerce license issued by the country of business location

3.3 Product (Medical Gas) Documentation

- ☐ Attach a copy the Product Datasheet
- ☐ Attach product specifications and claimed standard (BP, USP, Ph Eur)
- ☐ Attach a copy of a recently issued Certificate of Analysis. A Certificate of Analysis for each lot offered for supply will also be required.
- ☐ Attach a copy of the Label Artwork

3.4 Regulatory and Licensing Documentation

- ☐ Provide proof of regulatory compliance (e.g. registration, clearance, approval) by a USAID recognized Stringent Regulatory Authority).
- ☐ Attach a copy of regulatory registration in export country.
- ☐ Attach a copy of regulatory registration in the country(ies) of intended use.

3.5 Packaging, Transport and Storage Container (Cryogenic Vessel) Documentation

- ☐ Attach copy of the Product(s) (Cyogenic Vessel(s)) Datasheet
- ☐ Attach copy of a sample metal identification plate for the cyogenic vessel(s)
- ☐ Attach a procedure for cleaning, evaluation and decommissioning of containers prior to re-use
- ☐ Attach a certificate of inspection certifying cryogenic vessel used for transport and storage has been inspected by third-party inspection agency or notified bodies in accordance with applicable regulations and standards according to set regulations and requirements
- ☐ Attach any additional documentation or reports that supports the container’s safety clearance