RESPONSE TO REQUEST FOR CLARIFICATIONS REGARDING RFPS-DAN-2014-501868 – PROVISION OF LABORATORY SERVICES

Question 1:
Do we have register at www.ungm.org?

Response:
You should register on UNGM but the registration does not stop you from submitting your proposal for now. You can either register now or later before contract issuance if you are the selected vendor.

Question 2:
Is there a specific template for the technical proposal and the commercial proposal? Is so, could you please provide it?

Response:
Guidance is already provided on format for technical proposal (see Point 7 under annex I)

Question 3:
Regarding the proof of our experience working with UN organizations, are invoices to UNICEF accepted?

Response:
Yes, you can use the invoices and if there are any other documents to back up your claims of working with UNICEF, it is also acceptable.

Question 4:
Would there be any restrictions in case we intend to participate both to this tender related to testing services and to the inspection and sampling services one due before November 2014?

Response:
There are no linkages between the RFPS Laboratory Services and Inspection services therefore, one company can bid for both.

Question 5:
Would it be acceptable for you that the same company performs pre-delivery inspection, sampling and testing? For instance, kindly note that currently we are regularly performing sampling inspections on RUTF ordered by your colleagues at UNICEF SD under current LTA for inspection services.

Response:
Yes it is acceptable. Kindly refer to response to question 4 above.

Question 6:
Kindly confirm whether LTA resulting from this RFP will include sampling inspection or if will cover just the testing part.
Response:
LTA will only cover analytical and/or microbiological testing

Question 7:
What do you mean by “individual specification testing”? (ref. point 4 Deliverables § 4 and Annex II test TAT Compliance Form)

Response:
Individual specification testing is defined as testing of a single parameter included in the specification profile of a product (e.g. “content uniformity” is considered a single parameter included in the specification profile of a product)

Question 8:
Do you have some electronic option for filling the RFPS?

Response:
No. There is no electronic option for filing the proposal. Your proposal should be submitted in hard copies as stipulated on the cover page of the RFPS document.

Question 9:
Do you have specifications for your QA/QC requirements for each Lot/product type?

Response:
Specifications and test results for each product lot are included in the Certificate of Analysis provided by the manufacturer, accompanying each product lot

Question 10:
In the RFPS, methods are referred in the specifications of RUTF, F75/F10, CSB and WSB nutrition products. Are these methods suggestions, thus could similar methods be used?

Response:
The specifications and methods described in the RFPS must be followed

Question 11:
Regarding the testing on Corn Blend with Sugar, can we propose different methods than the one specified in the annexe V for chemistry and microbiology testing, if we believe they are equivalent?

Response:
The specifications and methods described in the RFPS must be followed

Question 12:
We have one additional important question: Is it possible to fulfill the RFPS requirements cited below, if the proposing company does not hold exactly, but similar/higher quality and experience levels?

Response:
RFPS implies that the laboratory should at least operate according to WHO standards. So higher or equivalent standards are acceptable.
**Question 13:**
For example, we are a global company serving CRO and routine services to the top 19 global pharmaceutical companies, but we do not have a record with neither WHO nor other such organizations. Could we be ‘pre-qualified’ from our other extensive experiences?

**Response:**
RFPS implies that Laboratories should have a proven record of working with UN organisations or international organization such as e.g. WHO, WFP or the Global. However, laboratories with no such record but that could provide evidence of their extensive experience are not automatically disqualified. As such, you can go ahead and submit your proposal and submit evidences of your extensive experiences with other global organizations alongside your proposal.

**Question 14:**
In the frame of the preparation of our response to the RFP for UNICEF (ref in subject), we have questions regarding the part Lot I - Pharmaceuticals - Bednets - Medical Devices (sterility)
According to the document made available within the web site, (Annexe I, in attachment), the products listed for the Lot I have to be fully tested following the relevant Pharmacopoeial monographs ([i.e. The International Pharmacopoeia (Ph. int.), The British Pharmacopoeia (BP), The United States Pharmacopoeia (USP)] or the approved in-house specifications should be performed)

This last point is not clear to us:
-What do you mean by 'approved in-house specifications'?

**Response:**
Product specifications are evaluated and approved by UNICEF. In general it is expected that products comply with the relevant pharmacopoeial monograph (BP, USP, Int). When this is not possible the in-house specifications (analytical methods) developed by the company and approved by UNICEF are used.

**Question 15:**
When do we have to choose the Pharmacopoeia (and which one: BP, USP, Int?), when do we have to perform the ‘approved in-house specifications? Such information is of first importance for our pricing calculation: which monograph for which product. Unless if I’m wrong, this information is not specified in the documents provided. We thank you in advance for clarifying this point.

**Response:**
The CoA of each product provides information on what Pharmacopoeia should be followed (e.g. if the CoA states Paracetamol BP tabs 500mg/tab, then the BP monograph should be followed). When there is no reference to a compendial monograph then the in-house specifications on the CoA should apply. UNICEF will be responsible for providing the relevant analytical methods.
Question 16:
Considering the geographical constraint of personally reviewing the document, I request you to provide us the following details before we buy the document: Please note that UNICEF RFPS is not for sale and the RFPS document is accessible for free on the following websites:

https://www.ungm.org/Public/Notice/27958
http://www.unicef.org/supply/index_74218.html

- List of Items, Schedule of Requirements, Scope of Work, Terms of Reference, Bill of Materials required - You can find the details on the RFPS document
- Soft Copy of the Tender Document through email - You can also find that on the RFPS document
- Names of countries that will be eligible to participate in this tender – It is an international competitive processes so countries from all countries are entitled to bid
- Information about the Tendering Procedure and Guidelines: It is on the RFPS document
- Estimated Budget for this Purchase: It is a competitive procurement process, so we do not provide budget
- Any Extension of Bidding Deadline? No
- Any Addendum or Pre Bid meeting Minutes? If there is an addendum, it will be published on the follow2 websites listed above.