BCG VACCINE LABORATORY, GUINDY, CHENNAI-32

	Format name:	Vendor qualification Questionnaire		
B G C	Format number:	Revision Number:	Effective date:	
	QAD/SOP/GEN/003-01	01	01/12/2015	

Annexure -01

Vendor /manufacturer qualification query form

S.No	QUESTION	PRODUCT NAME: ANSWER	REMARKS
1.0 Administrative Information			
1.1	Vendor Name		
1.2	Address-: Head Office		
1.3	Address-: Manufacturing Unit		
1.4	Contact Person -: Technical Matters		
1.5	Contact Person -: Commercial dept		

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32

Format name	Vendor qualification Questionnaire		
Format number	Revision Number	Effective date	
QAD/SOP/GEN/003-01	01	01/12/2015	

PRODUCT NAME:

S. No	QUESTION	ANSWER	REMARKS
1.6	Contact Person -: Quality Assurance		
1.7	The firm intends to enter into the rate contract or intends to supply the following to the institute : chemicals/reagents/media/disinfectants/cleaning agents /others (please specify)	❑ Yes ❑ No ❑ NA	
1.8	Annex the list of your products		
1.9	Total Manufacturing Site Area		
1.10	Total Constructed Area		
1.11	Is your company ISO certified? If yes please specify the year and certification body & type of certification	❑ Yes ❑ No ❑ NA	
1.12	Have your manufacturing facility been inspected by NRA/WHO agencies etc? if yes please provide the copy of NRA certificate?	❑ Yes ❑ No ❑ NA	
1.13	Is the requested products as per Indian pharmacopeia and its version	❑ Yes ❑ No ❑ NA	

PRODUCT NAME:			
S. NO	QUESTION	ANSWER	REMARKS
1.14	Have your facility been inspected by any regulatory body within last 2 years if yes please give the name of agency, date & status of audit?	☐ Yes ☐ No ☐ NA	
1.15	Do you inform us about the changes in your manufacturing facility and manufacturing process including change in the vendor of your input material?	☐ Yes ☐ No ☐ NA	
1.16	Details of Storage facilities	☐ Yes ☐ No ☐ NA	
1.17	i) Will the firm (inclusive of its supply chain) be willing to be inspected by the institute's vendor audit team ii) If yes period of prior notice required for inspecting your firm	☐ Yes ☐ No ☐ NA	

	Format name	Vendor qualification Questionnaire		
B C G	Format number	Revision Number	Effective date	
	QAD/SOP/GEN/003-01	01	01/12/2015	

2.0 Technical Information			
2.1	Do you have the written instruction and policies to implement Quality System?	☐ Yes ☐ No ☐ NA	
2.2	Whether Quality Unit is independent from the manufacturing department?	☐ Yes ☐ No ☐ NA	
2.3	Does the quality system include change control, deviation control, document control, self-inspection & vendor qualification policy?	☐ Yes ☐ No ☐ NA	
2.4	Does your company have annual training plan for the personnel?	☐ Yes ☐ No ☐ NA	
2.5	Do you have written validation program and validation is executed as per the program?	☐ Yes ☐ No ☐ NA	
2.6	Do you have the written calibration program for measuring & testing instruments?	☐ Yes ☐ No ☐ NA	
2.7	Do you have the written preventive maintenance program for equipments?	☐ Yes ☐ No ☐ NA	
2.8	Do you have the IN-HOUSE testing facility under the control of QA/QC for testing and release the inputs and the finish products?	☐ Yes ☐ No ☐ NA	
2.9	Does your warehousing and production facility have appropriate measures for the segregation of the material and prevention of mix-up and cross contamination?	☐ Yes ☐ No ☐ NA	

2.10	For **Material manufactures-**: Compliance to standards	❑ Yes ❑ No ❑ NA	
3.0	**Technical Package:** Provide following information as technical package.		
3.1	Brief of the manufacturing site	❑ Yes ❑ No ❑ NA	
3.2	Release and /or regulatory specifications	❑ Yes ❑ No ❑ NA	
3.3	Impurity profile (if applicable)	❑ Yes ❑ No ❑ NA	
3.4	Process flow chart	❑ Yes ❑ No ❑ NA	
3.5	Process validation reports (If available)?	❑ Yes ❑ No ❑ NA	
3.6	Material release specification and standard test procedure	❑ Yes ❑ No ❑ NA	
3.7	Drawing & Material of construction (MOC) certificate for packing material	❑ Yes ❑ No ❑ NA	
3.8	Stability data	❑ Yes ❑ No ❑ NA	
3.9	Equipment list with qualification documents.	❑ Yes ❑ No ❑ NA	
3.10	Packing details	❑ Yes ❑ No ❑ NA	
3.1	Mode of despatch	❑ Yes ❑ No ❑ NA	

3.2	If material is to be stored at or below temperature , how does the company ensure the material is held at the required temperature during transport		
3.3	Certificate of Analysis	☐ Yes ☐ No ☐ NA	

Note:

1. Indian manufacturers/distributor/suppliers are required to ensure that their reply reaches us within 20 days of issue of this letter, while Indian agents/distributors(of foreign principals) are required to get details from their manufacturers and forward the same to us within 30days of receipt of this letter.
2. Please list out major consumer of your products in parental drug, vaccine and sera manufacturers.
3. Documents once submitted can only be modified with the permission of the committee.
4. All pages submitted should be signed in full and overwriting/corrections should be initialed.
5. IT PAN number and sales tax number.
6. All correspondence should be addressed to The Director, BCG Vaccine Laboratory, Guindy, Chennai – 32.

BCG VACCINE LABORATORY, GUINDY, CHENNAI-32

	Format name	Vendor qualification Questionnaire		
B C G	Format number	Revision Number	Effective date	
	QAD/SOP/GEN/003-01	01	01/12/2015	

CERTIFICATE

I/We M/s_____ with office at

_____ do hereby undertake that the information provided are true to my knowledge and any changes in the above form QAD/SOP/GEN/003-01 will be intimated to concerned within 7 days of occurrence, failing which BCGVL.Guindy Will be in its powers to take any action as deemed fit.

Dated

Authorized Signatory

For_____

Name_____

Designation_____