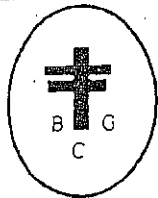


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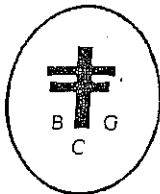
Format name	Vendor qualification Questionnaire		
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Annexure -01

Vendor /manufacturer qualification query form

Product NAME			
S.No	QUESTION	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		

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Format name

Vendor qualification Questionnaire

Format number

Revision Number

Effective date

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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)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.12	Have your manufacturing facility been inspected by NRA/WHO agencies etc? if yes please provide the copy of NRA certificate?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.13	Is the requested products as per Indian pharmacopeia and its version	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

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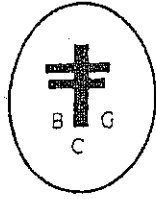


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PRODUCT NAME:

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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
1.16	Details of Storage facilities	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

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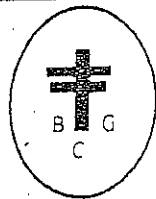


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2.0 Technical Information

2.1	Do you have the written instruction and policies to implement Quality System?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.2	Whether Quality Unit is independent from the manufacturing department?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.3	Does the quality system include change control, deviation control, document control, self-inspection & vendor qualification policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.4	Does your company have annual training plan for the personnel?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.5	Do you have written validation program and validation is executed as per the program?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.6	Do you have the written calibration program for measuring & testing instruments?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2.7	Do you have the written preventive maintenance program for equipments?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

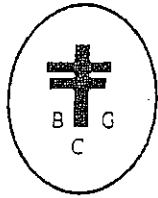
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2.10	For Material manufactures-: Compliance to standards	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
3.0	Technical Package: Provide following information as technical package.	
3.1	Brief of the manufacturing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

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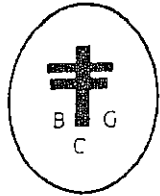
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3.2	If material is to be stored at or below temperature , how does the company ensure the material is held at the required temperature during transport		
3.3	Certificate of Analysis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.

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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 _____