PRE AUDIT QUESTIONNAIRE

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CRMO Pharmatech t is conducting a survey to identify contract manufacturing partners with GMP compliant manufacturing facilities, who are able to provide commercial quantities of the key bulk drug intermediates/API identified by us for our reputed clients in India.. This preliminary search is to identify whether your company is a potential candidate for this type of work.

It is for this purpose that we contact you with a request for information on your company, its background and capabilities.

Please will you complete the following questionnaire and provide any additional information regarding your company's capabilities that you consider would be of use to CRMO in our assessment.
CRMO intend to use the information provided by you for the purposes of our assessment only and confirm to keep it highly confidential.

COMPANY DETAILS	
Company Name:	
Address of Site of Manufacture with contact numbers.	
Product to be supplied	
Is this the only site of manufacture for this material? If no please fill out one form for <u>each</u> site.	
e-mail address of person completing this form:	

Contact Persons			
Department	**Name**	**Telephone No.**	**Fax / e-mail**
Quality Assurance			
Production			

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Logistics			
Sales			

I) . Business information:

1.1 What is the history of the company?

1.2 Is it government or privately owned?

1.3 How long has the company been in business?

1.4 What is your core business?

1.5 What are your core business hours? Do you employ shift workers? Please provide breakup of company employed and contract workers..

1.6 Please let us briefly about your policy on contact workers.

1.7 CRMO prefers to conduct all business discussions in English. Is this a requirement that you could fulfill? Please indicate (Yes / No)

1.8 How many sites does the company operate from?

1.9 Do you work as job worker/outsourcing partner for any domestic/overseas companies? If yes please provide information in brief.

1.9 Please provide the organizational chart with manpower strength at each level . Please provide a breakdown of staff qualifications in each department (for example Ph.D., B.Sc.BE, etc.)

1.10 Do you have written job descriptions for all personnel?

1.11 Do you maintain training records?Do you have a procedure on training in place?

1.12 Is there a formal introduction/induction program for new employees? Are refresher training program in place for established employees?

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1.13 Have you been awarded any nationally or internationally recognized Quality standards e.g. ISO 9001, ISO 14001, OHSAS 18000, etc . please list. Please provide us with a copy of your current certificate(s)

1.14 Are you associated with other companies or group of companies? If so, give details.

1.15 Would you allow CRMO personnel to audit and see the facilities and documents relating to the materials supplied to CRMO?

1.16 Would you notify CRMO in writing prior to implementing significant changes in analytical test methods, specifications or manufacturing procedures?

1.17 Would you notify CRMO in writing prior to implementing changes in plant, site of production or contract manufacturing?

II) Process Research & Development (PR&D) and Pilot plant:

2.1 Do you have Process Research and Development facilities? (also known as Chemical development or Process development)

2.2 How many chemists are employed in the Process Research & Development area?

2.3 Do you have dedicated staff working in the Process Research & Development production area, and if so how many?

2.4 Please provide details of qualifications of staff employed in the PR&D production area.

2.5 Please give details of the number of PR&D laboratories you have, how many fume cupboards are there in each? Please give details of the type of fume cupboard (walk in or standard)

2.6 Are your labs GMP compliant?

2.7 Do you have kilo labs? Is the kilo lab GMP compliant?

2.8 Please provide an estimate of the number of new PR&D projects your company works on per year

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2.9 Do you have a pilot plant? How many chemists are employed in the Pilot plant area?

2.10 Do you have dedicated staff working in the Pilot plant area, and if so how many?

2.11 Please provide details of qualifications of staff employed in the pilot plant area.

2.12 Is the pilot plant GMP compliant?

2.13 Has your pilot plant been audited? Please give details of auditors (for example FDA, customers, and major pharma companies).

2.14 How many process streams do you operate?

2.15 Please provide an equipment list (vessels, streams, ovens etc.)

2.16 Have you had any incidents in the pilot plant facility, which have resulted in injury to your staff in the last five years? If so please provide details.

2.17 Do you maintain process safety records?

III) Production Related information;

3.1 How many production units you have at each manufacturing site?

3.2 Do you have a Vendor Evaluation Program? Do you maintain the list of approved vendor?

3.3 Are there written specifications in place for all incoming raw materials?

3.4 How the RM is accepted? Based on the vendor's CoA? Do you carry out any specific tests for critical RMs?

3.5 Do you have procedures that define the control of raw materials including receipt, quarantine, sampling, storage, labelling, dispensing, specifications, processing and packaging of raw materials and packaging components?

3.6 How the RM is issued to production? Is all material accounted for and reconciled?

3.7 Do you use dedicated equipment for the production? If no, is there a procedure in place to prevent cross-contamination? If so, please describe.

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3.8 Do you follow cGMP guidelines for all manufacturing operations?

3.9 Are you audited by any multinationals or their Indian offices? If yes please ` provide the details.

3.10 Do you have any USFDA approvals or approvable facilities?

3.11 Please provide the list of equipments with their MOC, operating temperature and pressure ranges ,etc.

3.12 Do you perform all required IQ/OQ/PQ for equipments/Instruments and validations , such as process validation, cleaning validation, analytical method validation?

3.13 Do you have batch manufacturing record for each batch?

3.14 Are there cleaning procedures in place for each area and piece of equipment?

3.15 Do you have segregation and control of approved, quarantined and rejected material?

3.16 Do you have deviation approval and documentation procedure in place? E.g What happens if the yield for a batch deviates from this range: is it investigated and documented?

3.17 Do all product containers bear identification labels, e.g. stating batch/lot number, product name etc.? Are there storage conditions defined for all materials?

3.18 Are there expiry or re-test dates defined for all materials? How were these expiry or retest dates and storage conditions decided upon?

3.19 Are all steps of the manufacturing performed at this site , including purification, milling,, etc?

3.20 Do you sub contract work? If yes, what is sub contracted?

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3.21 Have you qualified /evaluated sub contractors?

IV)QA/QC and Analytical capabilities:

4. 1What analytical facilities does the company have? Which tests you are capable of performing? Please provide a list of equipment

4.2 Do you have a quality manual that describes your quality policy?

4.3 Do you have validation policy in place? E.g process validation, cleaning validation, etc.

4.4 Please` provide the list of Standard operating procedures and work instructions of every department.

4.5 QA and QC reports to whom?

4.6 Do you have access to the following equipment:

a) NMR
b) LC or GC M/S
c) XRPD
d) IR
e) ICP or Atomic Absorption Spectrometer

4.7 How many analytical chemists are employed in the analytical department?

4.8 How many of these provide support for:

a) Process Research & Development
b) Pilot Plant
c) Production
d) others

4.9 Has your analytical department , QA and QC been audited? Please give details of auditors/audits. (for example FDA, customers, and major pharmaceuticals).

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V) Safety & Environment:

5.1 What facilities are provided to ensure employee safety? (For example personal protection equipment, number of first aiders to overall employees, medical facilities)

5.2 Has your company had any serious incidents in the past five years? (Include fires, employee sensitization, employee accidents, and fatalities). If so, please provide details.

5.3 Do you have an environmental statement? If so, please provide a copy with your response ..

5.4 Do you comply with local and national environmental requirements?

VI) Utilities :

6.1 Please explain various utilities you have e.g. DM Water generation plant, boilers, Nitrogen generation plant ,chilling towers , cooling towers, DG power generation sets, etc.:

VII) Engineering Maintenance and calibrations:

7.1 Is there a maintenance and preventative maintenance program for all pieces of equipment?
7.2 Do you calibrate the production instruments which critical to quality (e.g. thermometer, manometer, stirrer speed etc.)?
7.3 Do you have a calibration policy for weighing and measuring equipment? Are these calibrations traceable back to national standards?
7.4 Are there written procedures and schedules covering these calibrations?
7.5 Do you use food grade oil/lubricant for production equipment (e.g. in pumps)?

VIII) Company Procedures & strengths

8.1 What is your annual turnover?

8.2 How does the annual turnover breakdown into for example Process R&D, custom synthesis, Manufacture, other business (please detail)

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8.3 Please describe your internal technical transfer process:

a) When a project moves from the Process Research & Development laboratories to the pilot plant does the PR&D Project leader go with the project, or does the responsibility transfer to someone else?
b) Please describe your process for transferring a project from the pilot plant to your production plant.

8.4 Please describe your Quality Assurance set up.

8.5 Please describe your laboratory information management (LIMS) system.

8.6 What do you consider to be the main strength of the company?

8.7 Do you have any specialist technology? (for example an aptitude which you believe your competitors may not have, or unusual technology)

8.8 Please detail the types of chemistry which you consider the company to have expertise in

8.9 Likewise, are there any types of chemistry that you cannot perform (for example HF chemistry)?

8.10 Do you hold appropriate export licenses for international sale?

8.11 Does your corporation use an Agent for international / domestic commercial activities?

IX) Confidentiality

9.1 How does your company ensure company confidential information is kept secure within your organization?

9.2 Do you routinely use secrecy agreements with customers?

9.3 Please detail any experience of compiling regulatory submissions

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X) Information Technology (IT)

10.1 Please give details of your IT capability.

10.2 Do key personnel on key sites have access to email and the worldwide web?

10.3 Please provide any additional information that you feel may be of benefit to assist in our assessment of companies with capabilities to perform work under contract for CRMO

Sign Off

We certify that the information provided in response to the questions posed is true, accurate and complete.

Head of Production or Deputy:

(Print)	
(Signature)	
(Date)	

Head of Quality Assurance or Deputy:

(Print)	
(Signature)	
(Date)	

The information you provide will be held confidentially by CRMO and used only for the purpose of assessing the capability of your company to perform GMP manufacture on our behalf. We appreciate your time and effort in responding to this request.

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Please respond by ---------- If you would prefer to receive an electronic version of this questionnaire, please email us at: crmo@crmopharma.com