



## **Project Questionnaire**

Thank you for considering Bio-Processing Alliance Inc. (BPAI) as a potential partner for your important project. This questionnaire is a critical step to further understand your project and the services you are looking to obtain. By now you should have a Confidentiality Agreement established with BPAI, which allows us to freely exchange information regarding your project in a confidential manner. If this is not the case, and it is your desire, please contact Terry Cochrane to establish the agreement prior to completing the questionnaire. All project information documented in this questionnaire will be treated in the utmost confidential manner.

Please complete the questionnaire, in its entirety, to the best of your knowledge. The technical team at BPAI will evaluate the questionnaire and set-up a conference call to clarify any areas that remain unclear and to obtain further understanding of your custom needs. Following this technical conference call BPAI will write up a custom Preliminary Estimate for you based on our understanding of the project and your specific needs.

We look forward to establishing a relationship with you and your company and having an opportunity to provide a custom solution to your biologics development and manufacturing project.

For further information, please contact:

Terry Cochrane, Managing Director  
Phone/Fax: (289) 878-5969  
Email: [tcochrane@bioprocessingalliance.com](mailto:tcochrane@bioprocessingalliance.com)  
Web: [www.bioprocessingalliance.com](http://www.bioprocessingalliance.com)

**Your Contact Information**

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

E-Mail: \_\_\_\_\_

Web Page: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**General Project Information**

(1) Describe the product and indication.

(2) Describe your product development timelines and give an estimate of when you require:

a) Non-GMP Material:

b) GMP Material:

(3) What estimated quantity of Non-GMP and GMP material do you require?

(4) Do you have either a GMP master cell bank or working cell bank?

Circle:        No    or    Yes

If 'Yes', can you provide characterization data for the cell bank? Circle: No or Yes

If 'No', do you require cell banking and stability? Circle: No or Yes

**Manufacturing & Quality Control**

(5) Does a process exist for manufacturing the product? If so, is it a GMP process?  
What scale(s) has the process been performed at?

(6) Please provide the following process information:

- a. Host organism: \_\_\_\_\_
- b. Expression system: \_\_\_\_\_
- c. Is the expression system licensed? \_\_\_\_\_
- d. Is antibiotic selection pressure maintained for production? \_\_\_\_\_
- e. Is the host organism genetically modified? \_\_\_\_\_
- f. Is the protein recombinant? \_\_\_\_\_
- g. Is the product soluble? \_\_\_\_\_
- h. Is the origin and history of the cell line documented and well known? Y / N  
If 'No' please explain: \_\_\_\_\_
- i. What is the fermentation expression yield? \_\_\_\_\_
- j. What is the purification yield? \_\_\_\_\_
- k. Does the product have an affinity tag? Y / N If 'Yes', is there a cleavage sequence? Y / N
- l. Is refolding required? \_\_\_\_\_
- m. What is the formulation of the bulk product? Has bulk product stability been demonstrated? If so, please indicate.
  
- n. Other product characteristics (solubility, pI, molecular weight, aggregation issues, etc.).

(7) Complete the chart below for the fermentation process to the best of your ability. Provide any further information under the 'additional details' section. If possible, append a process flow diagram outlining the information below and the process steps.

| Process Step           | Process Time | Temp | pH | dO | O2 Sup.              | Agitation | Media / Feed / Inducer | Other Parameters |
|------------------------|--------------|------|----|----|----------------------|-----------|------------------------|------------------|
| Pre Culture #1         |              |      |    |    | Not Applicable (N/A) |           |                        |                  |
| Pre Culture #2         |              |      |    |    | Not Applicable (N/A) |           |                        |                  |
| Batch Fermentation     |              |      |    |    |                      |           |                        |                  |
| Fed-Batch Fermentation |              |      |    |    |                      |           |                        |                  |
| Induction Phase        |              |      |    |    |                      |           |                        |                  |

Cell harvest details (homogenization, centrifugation, filtration, etc.):

If refolding is required, please detail methodology:

Additional Details:

(8) Complete the chart below for the purification process. Provide any further information under the 'additional details' section. If possible, append a process flow diagram outlining the information below and the process steps.

| Process Step                     | Parameters   | Details |
|----------------------------------|--|---------|
| Pre-Capture UF/DF Adjustment     | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Membrane Area:<br>UF Factor:<br># of Exchanges:<br>Constant or Conc/Dil:<br><br>Additional Info: |         |
| Capture Chromatography           | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Column Dimensions:<br>Resin Type & CV:<br>Linear Flow Rate:<br><br>Additional Info:              |         |
| Post-Capture UF/DF Adjustment    | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Membrane Area:<br>UF Factor:<br># of Exchanges:<br>Constant or Conc/Dil:<br><br>Additional Info: |         |
| 1st Polishing Chromatography     | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Column Dimensions:<br>Resin Type & CV:<br>Linear Flow Rate:<br><br>Additional Info:              |         |
| Post-1st Polish UF/DF Adjustment | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Membrane Area:<br>UF Factor:<br># of Exchanges:<br>Constant or Conc/Dil:<br><br>Additional Info: |         |

| Process Step                   | Parameters   | Details |
|--------------------------------|--|---------|
| 2nd Polishing Chromatography   | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Column Dimensions:<br>Resin Type & CV:<br>Linear Flow Rate:<br><br>Additional Info:              |         |
| Final UF/DF Adjustment         | Operation Time:<br>Buffers:<br>Temperature:<br>pH:<br>Membrane Area:<br>UF Factor:<br># of Exchanges:<br>Constant or Conc/Dil:<br><br>Additional Info: |         |
| Bulk Drug Substance Dispensing | Operation Time:<br>Temperature:<br>Unit Volume:<br>Container Type:<br><br>Additional Info:   |         |

Additional purification unit operations (oxidation, column refolding, activation, etc.):

Additional Details:

(9) Please complete the table below indicating the bulk drug substance specifications.

| Classification | Methodology       | Method Status <sup>†</sup><br>(E/V/D) | Transfer?<br>( <u>Y</u> es/ <u>N</u> o) | Used for In-process<br>Monitoring?<br>( <u>Y</u> es/ <u>N</u> o) | Reference<br>Standard<br>Available<br>( <u>Y</u> es/ <u>N</u> o) | Additional<br>Comments |
|----------------|-------------------|---------------------------------------|---|--|--|------------------------|
| Physiochemical | Appearance        | E                                     | N                                       |  |  |                        |
|                | pH                | E                                     | N                                       |  |  |                        |
|                | Concentration     |                                       |   |  |  |                        |
|                | Other             |                                       |   |  |  |                        |
| Identity       |                   |                                       |   |  |  |                        |
| Purity         |                   |                                       |   |  |  |                        |
| Potency        |                   |                                       |   |  |  |                        |
| Safety         | Microbial Limit   | E                                     | N/A                                     | N  | N  |                        |
|                | Endotoxin         | E                                     | N/A                                     |  |  |                        |
|                | Host Cell Protein |                                       |   |  |  |                        |
|                | Host Cell DNA     |                                       |   |  |  |                        |
|                | Other             |                                       |   |  |  |                        |

<sup>†</sup>Method Status: E=method exists in a documented format, V= method exists and is validated, D = method does not exist and requires development

(10) Are there any critical control requirements in the process that BPAI should be made aware of?

Circle:        No   or   Yes (if 'Yes' please indicate)

(11) Are solvents used in the process? If so, at what concentrations and volumes?

Circle:        No   or   Yes (if 'Yes' please indicate type, conc. and volumes)

(12) Are there any hazardous materials or cytotoxins used or consumed in the process?

Circle:        No   or   Yes (if 'Yes' please indicate)

(13) Are there any animal derived materials in the process, such as media components or resins?

Circle:        No   or   Yes (if 'Yes' please indicate)

(14) Do you require stability testing of the bulk drug substance?

Circle:        No   or   Yes

**Process Development**

(15) Does the process require process development? If so, please detail the specific unit operations that require development and what level of improvement is desired?

Circle:        No   or   Yes (if 'Yes' please indicate)

(16) Is there any identified transfer or scale-up issues with the existing manufacturing process?

Circle:            No   or   Yes (if 'Yes' please indicate)

(17) Are there publications that describe the product or process?

Circle:            No   or   Yes (if 'Yes' please attach)

### **Safety**

(18) What is the origin and Biosafety Level (BSL) rating of the host organism?

(19) Can a Material Safety Data Sheet be supplied for the product?

Circle:            No   or   Yes (if 'Yes' please attach)

(20) Please indicate key toxicological properties, mode of action and target organs/tissues/systems of the product as well as any special operator handling conditions that BPAI should be aware of for routine handling of the product.

### **GMP Documentation**

(21) For an existing manufacturing process, do instructions in the form of batch or developmental records exist?

Circle:            No   or   Yes (if 'Yes' please attach)

(22) Does a qualified list of raw materials and consumables for the process exist?

Circle:            No   or   Yes (if 'Yes' please attach)

(23) Do qualified or validated cleaning methods exist for your product?

Circle:        No   or   Yes (if 'Yes' please attach)

(21) Is regulatory support required for the project?

Circle:        No   or   Yes (if 'Yes' please indicate what is required)

(24) Are there any additional information or comments that would help BPAI prepare a Preliminary Estimate for your project?

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