# MANUFACTURER AUDIT QUESTIONNAIRE

This questionnaire is intended to obtain in-depth information regarding the responsibilities, procedures and practices for critical operating systems within your facility. Please provide complete information for all questions. In Support of your written responses, please attach a current copy of the relevant SOP or reference the title and SOP number as part of your response. If necessary, it is acceptable to include your written responses as an attachment to this questionnaire.

**Complete relevant sections: Use NA or appropriate text if necessary.**

Please complete this questionnaire promptly and return it to the individual referenced on the attached cover letter. Thank you in advance for you attention to this questionnaire.

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## Section A: Contractor/Manufacturer Information

**Name of Manufacturer:**

Contractor Corporate Headquarters (Full Address):

Contracting/Manufacturing Site (Full Address):

Name and address of site:

Items currently purchased from this Contractor/Manufacturing Site (include NDC Number or other relevant Identification Code).

Section A of the Questionnaire Completed By:

Title:

Date:

**Section B: Audit Questionnaire**
(This section to be completed by the Manufacturer)

Please respond to each question as fully and completely as possible. Please reference any relevant SOP by number and title. Attach your responses and any reference materials (SOPs, organizational charts, etc.) to this questionnaire.

## 1.0 General Information

1.1 How many shifts operate at this manufacturing site?: _____

1.2 Total number of employees working at this manufacturing site?:_____

1.3 Are temporary employees used at this manufacturing site?:_____

1.4 Is there a SOP in place to notify customers of critical changes prior to implementation?:
_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

1.5 Identify all regulatory standards to which this Contractor manufacturing site complies (such as FDA, EMEA or ISO). If ISO, please list the name of the ISO certifying authority. Does the site have a current GMP Certificate? Please list.
_____
_____

1.6 Are there any open issues brought forth by the regulatory bodies identified in 1.5?

_____
_____

1.7 Are there any subcontractors or other locations used for the referenced product such as for Quality Control testing, packaging,

_____
_____

1.1 Do you provide services for an industry other than the pharmaceutical industry? If yes, please provide list.

_____
_____

1.2 Are any of the following manufactured, packaged or held at the referenced facility? Beta-lactams (penicillin/cepharlosporin), steroids, pesticides/herbicides or cytotoxins.

_____
_____

1.3 If the answer to question 1.9 was yes, please identify the physical and procedural measures in place to prevent contamination and mix-up.

_____
_____

1.4 Do you maintain a program to ensure supplied materials of animal origin meet TSE/BSE requirements per EMEA/410/01.rev.2? Please attach a certificate (if applicable).

_____
_____

1.5 Any of your raw materials are provided from sources Genetically Modified Organism? Please attach a certificate.

_____
_____

1.6 Do you have a risk of melamine contamination? Please attached attach a certificate.

_____
_____

1.8 Do you have a Site Master File?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

## 2.0 Quality

2.1 Is there a written organizational and reporting structure for the Quality Unit?

_____
_____
(Please attach a copy or reference any relevant document by number and title)

2.2 How many employees work in the Quality Unit?

_____
_____

2.3 Is there a written procedure to identify the roles and responsibilities of the Quality Unit?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

2.4 Does the Quality Unit have the authority and responsibility to approve or reject all procedures or specifications?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

2.5 Is there a written procedure for conduct of failure investigations? Does the procedure require client notification?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

2.6 Is there a Quality Unit procedure in place to describe the release of the intermediate or finished product?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

2.7 Is there a written procedure describing how changes to the manufacturing process are authorized?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

2.8 Are rework or reprocessing operations conducted? If so, is there a written procedure to describe the process to approve these operations?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

2.9 Please explain the procedure and responsibilities for returned or salvaged goods. Include established criteria for re-processing, examination, testing or investigation. Describe any additional steps or conditions required prior to returning these goods to the marketplace.

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

2.10 Is there a written procedure describing the system for complaints?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

## 3.0 Manufacturing, Processing, Packaging, Holding or Distribution

3.1 Is a master equipment list maintained?

_____
_____

3.2 Is there a written procedure for the calibration and preventative maintenance of major pieces of equipment?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

3.3 Are temperature and humidity in the warehouse(s) containing raw materials and finished product controlled and/or monitored?

_____
_____

3.4 Are relevant cleaning validation data for applicable equipment used to manufacture/package the referenced product current and on file?

_____
_____

3.5 Is there a written procedure to describe the physical control and identification of rejected or quarantined material stored in the warehouse?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

3.6 Is there a written pest control program? Are records of pest control maintained? Who approves the rodenticides and pesticides selected for use in the facility?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

3.7 Is there written procedure to describe the control measures in place to ensure cleanliness and to prevent mix-up or contamination in the finishing area(s) of the facility?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

3.8 Please provide a description of the lot numbering system with explanation of the coding.

_____
_____

## 4.0 Quality (QC) Laboratory

4.1 Are critical laboratory equipment assigned a unique identification number?

_____
_____

4.2 Is there a written procedure to describe the calibration system for critical pieces of laboratory equipment including responsibilities, documentation, and schedules?

_____
_____
(Please attach a copy or reference any relevant SOP by number and title)

4.3 Is testing performed on raw materials? If so, please describe. If not, are suppliers qualified?

_____
_____

4.4 Are expiration dates supported by a stability program which includes defined test frequencies, conditions, sample storage, and maintenance? What stability conditions are currently maintained?

_____
_____
(Please attach a copy or reference any relevant SOP describing the stability program by number and title)

## 5.0 Training

5.1 Is there a written procedure to describe the training program?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

5.2 Are job specific training requirements defined?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

## 6.0 Training

6.1 Is there a written procedure to describe the training program?

_____

_____

(Please attach a copy or reference any relevant SOP by number and title)

## 7.0 Contact Information

Please provide information for the following critical contact personnel:

| Name | Phone/Fax | E-mail |
|---|---|---|

Section B of the Questionnaire Completed By:

Title:

Date:

## 8.0 Altea Approval

Questionnaire evaluated By:

Title:

Date:

Signature:

## 9.0 Comments