

## Business Operation Evaluation (STEP 2)

Company Name \_\_\_\_\_  
Address \_\_\_\_\_  
City/Province/Postal Code \_\_\_\_\_  
Phone \_\_\_\_\_ Fax \_\_\_\_\_  
Business Info E-mail \_\_\_\_\_

### PRODUCTION

Physical site (address) \_\_\_\_\_

Responsible person, Name \_\_\_\_\_ ; Rank (Responsibility) \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ E-mail \_\_\_\_\_

Number of workers in production \_\_\_\_\_ Do they work on night-shift? \_\_\_\_\_ Yes \_\_\_\_\_ No

Major production equipment and support systems

1. \_\_\_\_\_ Are they in same site? \_\_\_\_\_ Yes \_\_\_\_\_ No
2. \_\_\_\_\_ Are they in same site? \_\_\_\_\_ Yes \_\_\_\_\_ No
3. \_\_\_\_\_ Are they in same site? \_\_\_\_\_ Yes \_\_\_\_\_ No
4. \_\_\_\_\_ Are they in same site? \_\_\_\_\_ Yes \_\_\_\_\_ No
5. \_\_\_\_\_ Are they in same site? \_\_\_\_\_ Yes \_\_\_\_\_ No

More description \_\_\_\_\_

List FIVE best products and annual production capability of each (metric tons).

1. \_\_\_\_\_ Pharm grade \_\_\_\_\_ Reagent grade \_\_\_\_\_
2. \_\_\_\_\_ Pharm grade \_\_\_\_\_ Reagent grade \_\_\_\_\_
3. \_\_\_\_\_ Pharm grade \_\_\_\_\_ Reagent grade \_\_\_\_\_
4. \_\_\_\_\_ Pharm grade \_\_\_\_\_ Reagent grade \_\_\_\_\_
5. \_\_\_\_\_ Pharm grade \_\_\_\_\_ Reagent grade \_\_\_\_\_

Are you a reseller of any? Describe \_\_\_\_\_

List FIVE best technical capabilities in production (e.g. reaction process, fermentation, purification, micronization, crystallization, etc.)

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

How do you perform process validation? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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How long do you keep your production batch records? \_\_\_\_\_

### Facility

Do you produce penicillin and other potent products on the site? \_\_\_\_\_ Yes \_\_\_\_\_ No; If Yes, how do you prevent cross contamination? \_\_\_\_\_

Do you use water in processing and how do you manage water quality? \_\_\_\_\_

How do you manage equipment cleaning? \_\_\_\_\_

Where do you handle final stage processing steps-filtration, drying, milling and packaging, etc? Is there any gowning procedure in place?  
\_\_\_\_\_  
\_\_\_\_\_

Do you have a pest control program in place? \_\_\_\_\_

### Material

How do you procure your raw and processing materials? Describe supplier qualification program \_\_\_\_\_  
\_\_\_\_\_

How do you manage your materials storage? Describe inventory management procedure \_\_\_\_\_  
\_\_\_\_\_

Do you have a formal product stability program? Describe warehouse conditions and definition of expiry  
\_\_\_\_\_  
\_\_\_\_\_

Do you use recovered materials and how do you manage it?  
\_\_\_\_\_  
\_\_\_\_\_

Do you use materials of animal origins and how do you manage it?  
\_\_\_\_\_  
\_\_\_\_\_

## QUALITY AND ANALYTICAL CONTROLS

Physical site (address) \_\_\_\_\_

Responsible person, Name \_\_\_\_\_ ; Rank (Responsibility) \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ E-mail \_\_\_\_\_

Number of workers in QA/QC \_\_\_\_\_ Do they work on night-shift? \_\_\_\_\_ Yes \_\_\_\_\_ No

Do you have a quality manual? What is the role of QA vs Production? \_\_\_\_\_

Provide a list of major instruments used in on-site testing for in-process materials and final product for release.

1. \_\_\_\_\_ Calibrated \_\_\_\_\_ Yes \_\_\_\_\_ No

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2. \_\_\_\_\_ Calibrated \_\_\_\_\_ Yes \_\_\_\_\_ No  
3. \_\_\_\_\_ Calibrated \_\_\_\_\_ Yes \_\_\_\_\_ No  
4. \_\_\_\_\_ Calibrated \_\_\_\_\_ Yes \_\_\_\_\_ No  
5. \_\_\_\_\_ Calibrated \_\_\_\_\_ Yes \_\_\_\_\_ No

Who performs instrument calibrations and how it is done?

Describe \_\_\_\_\_

Do you have a formal lab reagents (including stock solutions) program?

Describe \_\_\_\_\_

Do you have a reference standards management program? Do you use both compendial and in-house reference standards? \_\_\_\_\_

How do you document laboratory results? Do you use loose pages?  
\_\_\_\_\_

Do you have a formal method development and validation program?

Describe \_\_\_\_\_

Do you have a formal program for investigation of failure results? Do you use outlier tests?

Describe \_\_\_\_\_

How do you verify and validate the data generated from computer systems?  
\_\_\_\_\_

Do you delete errant data? How do you manage error corrections?  
\_\_\_\_\_

How do you assure computer data integrity and security?  
\_\_\_\_\_

How do you manage tests conducted by external contractors?  
\_\_\_\_\_  
\_\_\_\_\_

### PERSONNEL

Do you have a formal program for personnel training?

Describe \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Can you provide an organogram in which communication lines are clearly displayed?

\_\_\_\_\_ Yes \_\_\_\_\_ No; If No, provide reason (s) \_\_\_\_\_

## Business Operation Evaluation (STEP 2)

### BUSINESS PROPOSAL

Please describe how you would like to collaborate\_(including the logistics how you would ship and store the products)

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Please describe how you would like to share profit

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Please describe how you would like to pay

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Other comments

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**This questionnaire is completed by:**

Name \_\_\_\_\_ Signature \_\_\_\_\_ Business Seal \_\_\_\_\_

Date \_\_\_\_\_