Questionnaire Manufacturing Services

When finished, please email reply to:

Business Development, Chemic Labs
Email: customerservice@chemiclabs.com

Today's Date:	
Primary Contact:	
Company or Institution:	
Drug Substance:	
CDA required prior to initiating activities?	☐ Yes ☐ No
Services Requested:	☐ API Synthesis & Purification: ☐ R&D ☐ cGMP ☐ Reference Standard Synthesis ☐ Process Development ☐ In-house Stability ☐ Assay Development ☐ Other:
Phase of drug substance development, if applicable:	☐ Discovery ☐ Preclinical ☐ Phase I ☐ Phase II ☐ Other
What agency will this product be regulated by?	☐ FDA ☐ EMEA ☐ Health Canada ☐ WHO ☐ Other
Is the material a controlled substance?	☐ Yes ☐ No If yes: ☐ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V
Is the target compound cytotoxic? **If safe bridge III, initial discussion should be scheduled ASAP to determine if project is appropriate fit.*	☐ Yes ☐ No If yes: ☐ Safe bridge I ☐ Safe bridge II ☐ Safe bridge III
Material needed by target date of:	

1. **How did you hear about Chemic Laboratories?**
   ☐ Referral ☐ Conference/Meeting ☐ Previous Client ☐ Internet Search
   ☐ Social Media ☐ Other

2. Manufacturing:

a. Do you have a synthetic process? If yes, what is the scale of the current process and what is the desired overall yield? Are any special purification processes necessary (e.g., flash chromatography, reverse-phase chromatography)?

b. Are the following available:

☐ Reference standards

☐ Compound specific information, if available please briefly describe the following:

- Physical state (e.g., solid, liquid, oil):
- Structure:
- p$K_{a(s)}$
- Solubility
- Unique compound specifications or release specifications:
- Special handing conditions:

c. Raw Materials: Please list any specialized raw materials or vendors for your existing process. Please note any specialized testing that may be required for raw materials, if applicable.

3. Product and Intended Use

a. This product is intended for use in (check all that apply):

☐ Topical/Oral

☐ Injectable/Inhalation/Ophthalmic/Other

☐ Other:

b. Please briefly describe storage conditions and/or shelf-life conditions, if known:

4. Container Closure System

a. Please briefly describe the intended bulk container closure system:

5. For method development, optimization, transfer, validation, please describe the intent of the methods (e.g., release, stability):

Assay:

a. Is a potency/purity method available? ☐ Yes ☐ No
   If yes, please describe:

b. Are there specifications for this testing?

c. Is the method currently stability indicating? ☐ Yes ☐ No

6. Are there any additional CMC services also requested (e.g., forced degradation, degradate product quantitation, and chemical & physical characterization studies)?

7. Please provide any other information that may be pertinent.