Questionnaire CMC Chemistry Services

When finished, please email reply to:

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

Today's Date:	
Primary Contact:	
Company or Institution:	
Drug Product/Substance:	
Is a CDA required prior to project initiation?	☐ Yes ☐ No
Services Requested:	☐ Method Development ☐ Method Optimization ☐ Method Transfer ☐ Method Validation ☐ Degradate Product Quantitation ☐ Chemical and Physical Characterization Studies ☐ Forced Degradation ☐ Shelf-life Stability. If so, temperature: ☐ Accelerated Stability. If so, temperature: ☐ Other:
Phase of Drug Product/Substance Development, if applicable:	☐ Preclinical ☐ Phase I ☐ Phase II ☐ Phase III ☐ 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
What agency will this product be regulated by?	☐ FDA ☐ EMEA ☐ Health Canada ☐ Other
Desired completion date:	

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

2. **Product and Intended Use**
   a. Please briefly describe the formulation, including API, and dosing regimen of your Drug Product/Substance:

   b. This product is intended for use in (check all that apply):
      ☐ Topical/Oral
      ☐ Injectable/Inhalation/Ophthalmic/Other

   c. Therapy Type
      ☐ Vaccine
      ☐ Cell Therapy
      ☐ Antimicrobial
      ☐ Oncology
      ☐ Other:

   d. Are the following available:
      ☐ Placebo formulation
      ☐ Qualified reference standards
      ☐ Drug substance specific information, if available please briefly describe the following:
         - Structure:
         - $pK_{a(s)}$
         - Solubility
         - Special handling conditions

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

3. **Container Closure System (Skip if Not Applicable)**
   a. Please briefly describe the container closure system, including composition of materials.

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

Assay:

a. Does a starting point/method exist? ☐ Yes ☐ No

b. What are the specifications for this testing?

c. Does the method need to be stability indicating? ☐ Yes ☐ No

d. Is a formal method SOP required at the conclusion of the study: ☐ Yes ☐ No

e. Will the method need to be transferred from Chemic to another party? ☐ Yes ☐ No

f. Other:

5. For services regarding Forced Degradation, Degradate Product Quantitation, and Chemical & Physical Characterization studies, please provide any additional information that you think is relevant:

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