Questionnaire for CCS & Device E/L Studies

When finished, please email reply to: Business Development, Chemic Labs
Email: customerservice@ChemicLabs.com

Today's Date:	
Primary Contact:	
Company or Institution:	
Product Type:	☐ Container Closure System ☐ Device ☐ Combination Device
Services Requested:	☐ Controlled extraction study ☐ Method Development for Leachables ☐ Method Validation for Leachables ☐ Migration Study/Leachables ☐ Full Leachables Study ☐ USP <661.1> ☐ USP <661.2> ☐ USP <1663> ☐ Other:
Drug Product, if applicable:	
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
Phase of Drug Product Development, if applicable:	☐ Preclinical ☐ Phase 1 ☐ Phase II ☐ Phase III ☐ Other
What agency will this product be regulated by?	☐ FDA ☐ EMEA ☐ Health Canada ☐ Other
Desired/Target Completion Date:	

Questionnaire for E/L Studies

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

2. **Product and Intended Use (Skip if Not Applicable)**
   a. Please briefly describe **the formulation, including API, and dosing regimen** of your Drug Product.

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

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

   d. Are the following available:
      ☐ Placebo formulation
      ☐ Qualified reference standards
      ☐ Compound specific information, if available please briefly describe the following:

         - Structure:
         - pKa/s
         - Solubility
         - Special handing 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 (if you have a materials specification sheet, please include it with the questionnaire).

b. If requesting a leachables stability study with storage, please provide the dimensions of the container, including secondary or tertiary packaging, if applicable.

4. Safety Information (Applies to Drug Product)

a. Please describe any applicable safety information.

b. Do you have an SDS or Material Specification Sheet for the product(s) and/or material(s)? Please include as attachment, if available.

☐ Yes
☐ No

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