

## MICROBIOLOGY PROJECT INITIATION FORM

### CLIENT INFORMATION:

Contact Name:		Salutation (Mr., Ms., Dr.):	
Title:		Company Name:	
Mailing Address:		City, State, Zip Code:	
Phone #:		Fax #:	
Email address:		Company website:	

### NATURE OF WORK:

<input type="checkbox"/> cGMP	<input type="checkbox"/> non cGMP
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### PRODUCT INFORMATION:

<b>Name of Product:</b> <b>Product Description:</b> (# of strengths / # of lots)  <b>Placebo included?</b> <input type="checkbox"/> Y <input type="checkbox"/> N	<b>Product Matrix</b> <input type="checkbox"/> Tablet <input type="checkbox"/> Capsule <input type="checkbox"/> Powder <input type="checkbox"/> Solution <input type="checkbox"/> Suspension <input type="checkbox"/> Other (please describe) _____	<b>Development Phase</b> <input type="checkbox"/> Pre-IND <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> FDA Approved <input type="checkbox"/> Other (please describe) _____
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### SAFETY INFORMATION:

Hazardous <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> If yes, list type(s): Mass/volume to be sent: Special Handling Requirements:	DEA Controlled No X <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V  Please attach MSDS (required).
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### TIME FRAME:

Requested Start Date:	End Date:
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### TESTING:

<input type="checkbox"/> Heterotrophic Plate Count (Water) <input type="checkbox"/> Bioburden <input type="checkbox"/> Endotoxin Qualification (LAL) <input type="checkbox"/> Kinetic Chromogenic <input type="checkbox"/> Gel-Clot  <input type="checkbox"/> Sterility <input type="checkbox"/> Direct Inoculation <input type="checkbox"/> Open Membrane Filtration <input type="checkbox"/> Closed Membrane Filtration (Steritest) <input type="checkbox"/> Kinetic Chromogenic  <input type="checkbox"/> Microbial Limits Testing  <input type="checkbox"/> Bacterial Identification	<input type="checkbox"/> Antimicrobial Preservative Effectiveness Testing  Qualification Required ( Yes / No ) <input type="checkbox"/> Enhancement / Inhibition Testing  Qualification Required ( Yes / No ) <input type="checkbox"/> Bacteriostasis & Fungistasis  Qualification Required ( Yes / No ) <input type="checkbox"/> Microbial Limits Preparatory Testing <input type="checkbox"/> Microbial Limits Screening Test  <input type="checkbox"/> Bacterial Identification is to be done if bacterial growth is observed during other testing, as a routine requirement
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A Pharmaceutical Development Company.

**REFERENCES, PROTOCOLS, AND MATERIALS:**

•Compendial Method Reference:		
•Client Method Reference:		
•Method Development Protocol:	Author: Client <input type="checkbox"/> Irvine <input type="checkbox"/>	SOP: Client <input type="checkbox"/> Irvine <input type="checkbox"/>
•Method Validation Protocol:	Author: Client <input type="checkbox"/> Irvine <input type="checkbox"/>	SOP: Client <input type="checkbox"/> Irvine <input type="checkbox"/>
•Placebo:		

**QUALITY ASSURANCE:**

Full QA Review     Peer Review     Other:

**FINAL REPORT:**

Irvine Template     Client Template     Other:

**DISPOSAL OF SAMPLES:**

Standard (30 days post report):   
Special Handling (return to client):   
Attention: \_\_\_\_\_ Client Shipping Account Number: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_

**Environmental Monitoring Program Support** (Provide Details Below.)

**Water Monitoring Program** (Provide Details Below.)

**Method Development & Validation** (Provide Details Below.)

**ADDITIONAL NOTES** (attach other pages as needed):