



A Pharmaceutical Development Company.

## BIOPHARMACEUTICAL 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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<input type="checkbox"/> Method Development	<input type="checkbox"/> AAA	<input type="checkbox"/> Extend to Stability
<input type="checkbox"/> GC/MS	<input type="checkbox"/> Extractables/Leachables	<input type="checkbox"/> Extend to QC
<input type="checkbox"/> LC/MS	<input type="checkbox"/> Method Validation	<input type="checkbox"/> Other (please describe)
<input type="checkbox"/> ELISA	<input type="checkbox"/> Cleaning Validation	
<input type="checkbox"/> CE	<input type="checkbox"/> Method Optimization	
<input type="checkbox"/> Gel Electrophoresis	<input type="checkbox"/> Method Feasibility	

### PRODUCT INFORMATION:

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

### TECHNICAL BACKGROUND:

<input type="checkbox"/> Physical and Chemical Properties
<input type="checkbox"/> Previous Work at Irvine
<input type="checkbox"/> Special Equipment Needs? Identify _____

### TIME FRAME:

Requested Start Date:	End Date:
Standard Time Frame:	Method Development 4 – 6 Weeks      Method Validation 6 – 8 Weeks

### ANALYTICAL DEVELOPMENT DETAILS:

<b>Method Development Characteristics:</b> <input type="checkbox"/> Method will be provided by client  Type of Method: <input type="checkbox"/> Assay <input type="checkbox"/> Gel <input type="checkbox"/> Related Substances <input type="checkbox"/> Identification <input type="checkbox"/> Stability-Indicating <input type="checkbox"/> CE <input type="checkbox"/> Preservative <input type="checkbox"/> Inorganic Residues <input type="checkbox"/> CE <input type="checkbox"/> Other:	<b>Method Validation Characteristics:</b>  <input type="checkbox"/> Linearity <input type="checkbox"/> System Suitability <input type="checkbox"/> Accuracy <input type="checkbox"/> Intermediate Precision <input type="checkbox"/> Precision <input type="checkbox"/> Limit of Detection <input type="checkbox"/> Range <input type="checkbox"/> Limit of Quantification <input type="checkbox"/> Specificity <input type="checkbox"/> Standard (Sample) solution stability <input type="checkbox"/> Robustness <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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**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"/> IAL <input type="checkbox"/>
•Method Validation Protocol:	Author: Client <input type="checkbox"/> Irvine <input type="checkbox"/>	SOP: Client <input type="checkbox"/> IAL <input type="checkbox"/>
•Degradation Products:		
•Impurities:		
•Formulation Ingredients:		
•Placebo:		

**STANDARDS, COLUMNS, AND RAW DATA:**

Reference Standards provided by:	<input type="checkbox"/> Client <input type="checkbox"/> Irvine *	Notes: _____
Reference Standards characterized by:	<input type="checkbox"/> Client <input type="checkbox"/> Irvine *	_____
Columns provided by:	<input type="checkbox"/> Client <input type="checkbox"/> Irvine *	_____

\* Project specific materials, purchased through Irvine Pharmaceutical Services, will be charged to Client at Irvine invoiced price

**QUALITY ASSURANCE:**

<input type="checkbox"/> Full QA Review <input type="checkbox"/> Peer Review <input type="checkbox"/> Other: _____
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**FINAL REPORT:**

<input type="checkbox"/> Irvine Template <input type="checkbox"/> Client Template <input type="checkbox"/> Other: _____
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**TECH TRANSFER:**

<input type="checkbox"/> Back to client <input type="checkbox"/> To Irvine's Analytical Chemistry <input type="checkbox"/> Other: _____
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**DISPOSAL OF SAMPLES:**

Standard (30 days post report): <input type="checkbox"/> Special Handling (return to client): <input type="checkbox"/> Attention: _____ Address: _____ _____	Client Shipping Account Number: _____
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**ADDITIONAL NOTES (attach other pages as needed):**