



A Pharmaceutical Development Company.

PREFORMULATION/FORMULATION 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:	

IRVINE AREA MANAGER:

Contact Name:	Charles Petersen	Salutation (Mr., Ms., Dr.):	Dr.
Title:	Dir., Formulation Development	Company Name:	Irvine Pharmaceutical Services
Mailing Address:	10 Vanderbilt	City, State, Zip Code:	Irvine, CA 92618
Phone #:	949-951-4425	Fax #:	949-951-9224
Email address:	charles.petersen@irvinepharma.com	Company website:	http://www.irvinepharma.com

NATURE OF WORK:

<input type="checkbox"/> cGMP	<input type="checkbox"/> non cGMP
-------------------------------	-----------------------------------

<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"/> Preformulation
<input type="checkbox"/> LC/MS	<input type="checkbox"/> Method Validation	<input type="checkbox"/> Formulation
<input type="checkbox"/> ELISA	<input type="checkbox"/> Cleaning Validation	<input type="checkbox"/> API Characterization
<input type="checkbox"/> CE	<input type="checkbox"/> Method Optimization	<input type="checkbox"/> Other (please describe)
<input type="checkbox"/> Gel Electrophoresis	<input type="checkbox"/> Method Feasibility	

PRODUCT INFORMATION:

Name of Product: Product Description: (# of strengths / # of lots) Placebo included? <input type="checkbox"/> Y <input type="checkbox"/> N API: Crystalline: <input type="checkbox"/> Y <input type="checkbox"/> N Aqueous Solubility: <input type="checkbox"/> Y <input type="checkbox"/> N Value: _____ Hydroscopic: <input type="checkbox"/> Y <input type="checkbox"/> N Stable: <input type="checkbox"/> Y <input type="checkbox"/> N Sensitive to Light: <input type="checkbox"/> Y <input type="checkbox"/> N PKa Value: _____ Salt Form: _____ Finished Dosage Form: _____	<table style="width: 100%;"> <tr> <td style="width: 60%;">Product Matrix</td> <td style="width: 40%;">Development Phase</td> </tr> <tr> <td><input type="checkbox"/> DPI <input type="checkbox"/> Nebulized <input type="checkbox"/> MDI</td> <td><input type="checkbox"/> Pre-IND</td> </tr> <tr> <td><input type="checkbox"/> Nasal</td> <td><input type="checkbox"/> I</td> </tr> <tr> <td><input type="checkbox"/> Lyophile</td> <td><input type="checkbox"/> II</td> </tr> <tr> <td><input type="checkbox"/> Solution</td> <td><input type="checkbox"/> III</td> </tr> <tr> <td><input type="checkbox"/> Suspension</td> <td><input type="checkbox"/> FDA Approved</td> </tr> <tr> <td><input type="checkbox"/> Capsule/ Tablet</td> <td><input type="checkbox"/> Other (please describe)</td> </tr> <tr> <td><input type="checkbox"/> Other (please describe) _____</td> <td></td> </tr> </table> Finished Dosage Form: Packaging Configuration: _____ Dosage Form Strength: _____ Excipients: _____	Product Matrix	Development Phase	<input type="checkbox"/> DPI <input type="checkbox"/> Nebulized <input type="checkbox"/> MDI	<input type="checkbox"/> Pre-IND	<input type="checkbox"/> Nasal	<input type="checkbox"/> I	<input type="checkbox"/> Lyophile	<input type="checkbox"/> II	<input type="checkbox"/> Solution	<input type="checkbox"/> III	<input type="checkbox"/> Suspension	<input type="checkbox"/> FDA Approved	<input type="checkbox"/> Capsule/ Tablet	<input type="checkbox"/> Other (please describe)	<input type="checkbox"/> Other (please describe) _____	
Product Matrix	Development Phase																
<input type="checkbox"/> DPI <input type="checkbox"/> Nebulized <input type="checkbox"/> MDI	<input type="checkbox"/> Pre-IND																
<input type="checkbox"/> Nasal	<input type="checkbox"/> I																
<input type="checkbox"/> Lyophile	<input type="checkbox"/> II																
<input type="checkbox"/> Solution	<input type="checkbox"/> III																
<input type="checkbox"/> Suspension	<input type="checkbox"/> FDA Approved																
<input type="checkbox"/> Capsule/ Tablet	<input type="checkbox"/> Other (please describe)																
<input type="checkbox"/> Other (please describe) _____																	

TECHNICAL BACKGROUND:

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



A Pharmaceutical Development Company.

ANALYTICAL DEVELOPMENT DETAILS:

<p>Method Development Characteristics:</p> <input type="checkbox"/> Method will be provided by client	<p>Method Validation Characteristics:</p> <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):
<p>Type of Method:</p> <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"/> SEC <input type="checkbox"/> Preservative <input type="checkbox"/> Inorganic Residues <input type="checkbox"/> CE <input type="checkbox"/> Other:	

SAFETY INFORMATION:

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

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: _____
--

FINAL REPORT:

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

TECH TRANSFER:

<input type="checkbox"/> Back to client <input type="checkbox"/> To Irvine AC <input type="checkbox"/> Other: _____

DISPOSAL OF SAMPLES:

Standard (30 days post report): <input type="checkbox"/>	
Special Handling (return to client): <input type="checkbox"/>	
Attention: _____	Client Shipping Account Number: _____
Address: _____	

ADDITIONAL NOTES (attach other pages as needed):