



A Pharmaceutical Development Company.

ANALYTICAL DEVELOPMENT 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"/> Extractables/Leachables	<input type="checkbox"/> Extend to Stability
<input type="checkbox"/> GC	<input type="checkbox"/> Method Validation	<input type="checkbox"/> Extend to QC
<input type="checkbox"/> HPLC	<input type="checkbox"/> Cleaning Validation	
<input type="checkbox"/> LC/MS	<input type="checkbox"/> Method Optimization	
<input type="checkbox"/> GC/MS	<input type="checkbox"/> Method Feasibility	
<input type="checkbox"/> Dissolution Testing I <input type="checkbox"/> or II <input type="checkbox"/>	<input type="checkbox"/> Other (please describe)	

PRODUCT INFORMATION:

Name of Product: Product Description: (# of strengths / # of lots) Sample Type: <input type="checkbox"/> Drug Substance <input type="checkbox"/> Placebo <input type="checkbox"/> Drug Product Placebo included? <input type="checkbox"/> Y or <input type="checkbox"/> N	Product Matrix <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) _____	Development Phase <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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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:

Method Development Characteristics: <input type="checkbox"/> Method will be provided by client Type of Method: <input type="checkbox"/> Assay <input type="checkbox"/> Assay & Related Substances <input type="checkbox"/> Related Substances <input type="checkbox"/> Identification <input type="checkbox"/> Stability-Indicating <input type="checkbox"/> Dissolution <input type="checkbox"/> Preservative <input type="checkbox"/> Antioxidant <input type="checkbox"/> Other:	Method Validation Characteristics: <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"/>	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:	

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"/>
•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, 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 AC	<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: _____	Client Shipping Account Number: _____
Address: _____	

ADDITIONAL NOTES (attach other pages as needed):