

CLEANING VALIDATION 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"/> Method Development	<input type="checkbox"/> Method Validation	<input type="checkbox"/> Method Transfer
<input type="checkbox"/> Method Optimization	<input type="checkbox"/> Feasibility	<input type="checkbox"/> QC

PRODUCT INFORMATION:

Name of Product: Product Description: (# of strengths / # of lots)	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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ADDITIONAL INFORMATION:

Swab Type <input type="checkbox"/> Texwipe <input type="checkbox"/> Cotton <input type="checkbox"/> Other: _____	Surface Type <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Rubber <input type="checkbox"/> Stainless Steel <input type="checkbox"/> Fiberglass <input type="checkbox"/> Other: _____ <input type="checkbox"/> Client to provide coupons for specified surface
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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 3 – 5 Weeks	Method Validation 5 – 7 Weeks	

TECHNOLOGY:

Type of Technology Please describe (i.e. HPLC) _____	
Analytical Parameters to be evaluated: <input type="checkbox"/> Linearity <input type="checkbox"/> Accuracy <input type="checkbox"/> Spike Swab Recovery <input type="checkbox"/> Spike Surface Recovery <input type="checkbox"/> Intermediate Precision <input type="checkbox"/> System Suitability <input type="checkbox"/> Limit of Detection <input type="checkbox"/> Limit of Quantification	Other Information: Approximate Concentration: _____ Approximate pKa: _____ Functional Groups / Related Structures : _____ _____



A Pharmaceutical Development Company.

<input type="checkbox"/> Range	<input type="checkbox"/> Solution Stability	Chromatographic conditions: _____ _____ _____
<input type="checkbox"/> Repeatability	<input type="checkbox"/> Selectivity	
<input type="checkbox"/> Robustness (please describe parameters): _____ _____	<input type="checkbox"/> Other (please describe): _____ _____	

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"/>
•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 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):