



Swiss
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PROJECT CHARTER

Today's Date:

Swiss-American Point of Contact:

Revision Level *(Start 00 for original, the first time this charter is filled. For subsequent changes to this document use 01, 02, 03):*

Part 1. - Preliminary Client Information:

Company Name:

Primary Contact:

Project Name:

Start Date:

Ready to Ship Date:

ENTER THE DATE THE PRODUCT IS RELEASED AND READY TO BE SHIPPED FROM SWISS-AMERICAN.

Part 2.A - Project Formula Specifications:

PROJECT MODEL:

☐ Tech Transfer

☐ Re-Engineering

☐ Private Label

☐ New Development & Innovation

☐ Pipeline Library

☐ Other:

Regulatory Certification:

☐ Cosmetic

☐ Medical Device

☐ OTC

☐ RX

☐ Other:

☐ N/A

Product Size grams/ounces:

Product Format:

☐ Lotion

☐ Cream

☐ Gel

☐ Aqueous Solution

☐ Other:

Project Description:



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Part 2.B - Project Packaging Specifications:

Primary Packaging Components:	<input type="checkbox"/> Bottle <input type="checkbox"/> Airless Bottle <input type="checkbox"/> Bellow <input type="checkbox"/> Jar <input type="checkbox"/> Airless Tube <input type="checkbox"/> Tube <input type="checkbox"/> Cap <input type="checkbox"/> Disc Cap <input type="checkbox"/> Sprayer <input type="checkbox"/> Cap for Jar <input type="checkbox"/> Heat Seal <input type="checkbox"/> Label Application <input type="checkbox"/> Foil/Packette Seal <input type="checkbox"/> Pre-printed Component <input type="checkbox"/> Spot Label Application <input type="checkbox"/> BOV Other:
Secondary Packaging Components:	<input type="checkbox"/> Insert <input type="checkbox"/> Unit Carton <input type="checkbox"/> Shrink Sleeve <input type="checkbox"/> Intermediate Carton <input type="checkbox"/> Other:
Tertiary Packaging Components:	<input type="checkbox"/> Shipper with Dividers <input type="checkbox"/> Shipper without Dividers <input type="checkbox"/> Kraft/Standard Brown <input type="checkbox"/> Standard White <input type="checkbox"/> Other:
Unit Configuration/ Pack-Out:	
Other Specifications: <small>LIST ANY OTHER SPECIFICATIONS.</small>	

Part 3. - Sales Distribution:

Key Launch Regions:	<input type="checkbox"/> United States <input type="checkbox"/> Canada <input type="checkbox"/> Asia: <input type="checkbox"/> Europe <input type="checkbox"/> Australia Latin America: <input type="checkbox"/> Middle East <input type="checkbox"/> Other:
Secondary Launch Regions:	<input type="checkbox"/> United States <input type="checkbox"/> Canada <input type="checkbox"/> Asia: <input type="checkbox"/> Europe <input type="checkbox"/> Australia Latin America: <input type="checkbox"/> Middle East <input type="checkbox"/> Other:
Other Launch Specifications:	
Desired MOQ:	<input type="checkbox"/> 10,000 <input type="checkbox"/> 25,000 <input type="checkbox"/> 50,000 <input type="checkbox"/> Other:
Product Distribution Channel: <small>WHERE WILL THIS PRODUCT BE SOLD?</small>	
Expected Annual Volumes:	
Target Finished Product COGS: <small>*REQUIRED.</small>	



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Part 4.A - Research, Innovation & Development - FORMULATION REQUIREMENTS

CHECK THIS BOX IF THIS IS A PACKAGING CHANGE ONLY & SKIP PARTS 4 & 5 ☐

Existing Formulation for Tech.
Transfer or Re-Engineering:

Do you have the Quantitative Formulation?

☐ Yes ☐ No ☐ N/A

Do you have the Process/mixing Instructions?

☐ Yes ☐ No ☐ N/A

What is the product marketing story?

Who are the targeted
consumer populations?

What are current benchmark
products?

TOP TWO BENCHMARK SAMPLES TO BE PROVIDED BY THE
CLIENT AT THE START OF THE PROJECT.

What is the sensory experience of
the product?

PLEASE PROVIDE DETAILS.



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Part 4.B - Research, Innovation & Development - FORMULATION REQUIREMENTS

What are the physical specifications of the product?	Appearance: Odor: pH:	Color: Texture: Viscosity:	Scent: Other:	
What are the mandatory claims and key benefits of the product?				
What are the secondary claims of the product? <small>PLEASE NOTE: THE CLAIMS LISTED HERE ARE NOT GUARANTEED TO BE CLAIMED ON THE FINAL FORMULA OR PRODUCT.</small>				
Are there any key raw materials required in the formulation?	TRADE NAME / INCI	SUPPLIER	CLAIM(S) SUPPORTED	REQUIRED USAGE LEVEL
Are there any raw materials NOT allowed in the formulation?	TRADE NAME		INCI	
Do you have an ingredient policy? <small>PLEASE PROVIDE PROHIBITED / RESTRICTED INGREDIENT LIST, IF AVAILABLE.</small>	<input type="checkbox"/> Yes, PLEASE PROVIDE DETAILS. <input type="checkbox"/> No			
Samples for formula evaluation:	Quantity:	(3 @ 1 oz. is standard)	Size:	Package:



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Part 5. - Regulatory, Efficacy & Clinical Testing

Test	Value	Required			Responsible	
FDA SPF		Yes	No	N/A	SA	Client
ISO 24444 SPF		Yes	No	N/A	SA	Client
Broad-Spectrum/Critical		Yes	No	N/A	SA	Client
Wavelength* ISO 24443 in vitro UVA		Yes	No	N/A	SA	Client
(3:1 UVB:A) ISO 24442 UVA/PFA		Yes	No	N/A	SA	Client
Water-Resistant		Yes	No	N/A	SA	Client
Phototoxicity*		Yes	No	N/A	SA	Client
Irritation-Tested/ HRIPT*		Yes	No	N/A	SA	Client
Skin Cancer Foundation Seal*		Yes	No	N/A	SA	Client
Very Water-Resistant		Yes	No	N/A	SA	Client
Photoallergy		Yes	No	N/A	SA	Client
Photostability*		Yes	No	N/A	SA	Client
<input type="checkbox"/> Dermatologist-Tested		Yes	No	N/A	SA	Client
<input type="checkbox"/> Allergy/Irritation (HRIPT) <input type="checkbox"/> 50 Subject <input type="checkbox"/> 100 Subject		Yes	No	N/A	SA	Client
<input type="checkbox"/> Allergy Testing (Kligman Human Max		Yes	No	N/A	SA	Client
<input type="checkbox"/> Hypoallergenic (200 person HRIPT)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Facial Sting (Lactic Acid +)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Non-Comedogenic		Yes	No	N/A	SA	Client
<input type="checkbox"/> Suitable for Sensitive Skin		Yes	No	N/A	SA	Client
<input type="checkbox"/> Ophthalmologist-Tested		Yes	No	N/A	SA	Client
<input type="checkbox"/> Non-Animal Ocular Irritation		Yes	No	N/A	SA	Client
<input type="checkbox"/> Contact Lens-Wearers		Yes	No	N/A	SA	Client
<input type="checkbox"/> Safety-in-Use		Yes	No	N/A	SA	Client
<input type="checkbox"/> Non-Acneogenic		Yes	No	N/A	SA	Client
<input type="checkbox"/> Primary Irritation (hours)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Cumulative Irritation(days)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Moisturizes (hours days)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Bioinstrumentation (method)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Expert Grader (claim)		Yes	No	N/A	SA	Client
<input type="checkbox"/> Consumer Questionnaire		Yes	No	N/A	SA	Client
<input type="checkbox"/> Clinical Photography		Yes	No	N/A	SA	Client
<input type="checkbox"/> Leaping Bunny		Yes	No	N/A	SA	Client
<input type="checkbox"/> Reef Safe		Yes	No	N/A	SA	Client
<input type="checkbox"/> Other:		Yes	No	N/A	SA	Client

▲ SPF TESTING IS REQUIRED FOR SPF CLAIM.

* REQUIRED TESTING FOR SCF SEAL.

* PRODUCT SAFETY / CLINICAL WILL CONTACT TO OBTAIN FURTHER DETAILS.

Do you need any 3rd party
certifications from Swiss-American?

PLEASE NOTE: ADDITIONAL COST AND TIMING MUST BE
CONSIDERED IF SWISS-AMERICAN DOES NOT CURRENTLY
HOLD THE REQUIRED CERTIFICATION.



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Part 6. - Stability & Specifications Testing

Commercial Stability Testing:	TEST	RESPONSIBLE PARTY	
	Preservative Challenge Testing	SA	<input type="checkbox"/> Client
	Packaging Compatibility Testing	SA	<input type="checkbox"/> Client
	Is Stability Testing Required? If Checked 'No', Discussion with QRA Required. <small>STABILITY TESTING REQUIRED FOR MEDICAL DEVICES AND DRUG.</small>	Yes Client Name:	<input type="checkbox"/> No
	Required Stability before First Lot Release	SA	<input type="checkbox"/> Client
	Concurrent Stability - First Lot	SA	<input type="checkbox"/> Client
	Annual Stability	SA	<input type="checkbox"/> Client
	Risk Assessment <small>TO BE PROVIDED BY CLIENT IF REQUIRED.</small>	<input type="checkbox"/> Yes	No
	Number of lots required for initial stability	1 3	



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APPENDIX I

Please include any necessary images and tables that pertain to your project.



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APPENDIX II

Please include any necessary images and tables that pertain to your project.



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Document Revision History

ONCE THIS DOCUMENT IS SUBMITTED TO SWISS-AMERICAN (REV 00) ANY SUBSEQUENT CHANGES SHOULD BE REFLECTED WITH A NEW REVISION LEVEL IN PAGE 1 AND ALL CHANGES SHOULD BE DOCUMENTED IN THE TABLE BELOW. USE ONE ROW PER CHANGE.

PART (section of charter) <small>ENTER THE PART # OF THE CHARTER CHANGED.</small>	REVISION <small>ENTER THE REVISION LEVEL OF THIS DOCUMENT (ORIGINAL IS ALWAYS 00, FOR EACH SUBSEQUENT CHANGE ENTER LEVEL 01, 02, 03...)</small>	DATE <small>ENTER THE DATE THE CHANGE WAS MADE.</small>	DESCRIPTION OF CHANGE <small>BRIEFLY DESCRIBE THE CHANGE IN ONE LINE.</small>



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Company Name:

Today's Date:

Signature: