MANUFACTURING PROJECT INITIATION FORM

CLIENT INFORMATION:

Contact Name:		Title:	
Company Name:		Email Address:	
Mailing Address:		Phone #:	
City, State, Zip:		Fax #:	

PROJECT SUMMARY:

PRODUCT INFORMATION:

Drug Substance Name:	
Drug Product Name:	
Dose Form/Formulation Type:	
Strength/Vial:	
Therapeutic Indication(s):	
Development Phase:	☐ Pre-IND ☐ I ☐ II ☐ III ☐ FDA Approved ☐ Other _____
Location of Clinical Trials:	☐ US ☐ EU ☐ Canada ☐ Asia ☐ Other _____
API Storage:	☐ Ambient ☐ 2-8C ☐ Frozen
Finished Product Storage/Shipping:	☐ Ambient ☐ 2-8C ☐ Frozen

SAFETY INFORMATION:

Hazardous: ☐ Unknown ☐ No ☐ Yes _____	Special Handling Requirements: _____
DEA Controlled: ☐ No ☐ I ☐ II ☐ III ☐ IV ☐ V	SafeBridge Level: ☐ I ☐ II ☐ III ☐ IV ☐ Cytotoxic

TIMELINE:

Requested Start Date:		Requested End Date:	
Date API Will be Available:			

COMPONENT REQUIREMENTS:

Stopper Size and Description:	☐ Check for Avrio standard component
Vial Size and Description:	☐ Check for Avrio standard component
Overseal Description:	☐ Check for Avrio standard component
Filter Membrane:	☐ Check for Avrio standard component
Special Manuf. Conditions:	☐ Protection from Light ☐ Protection from Oxygen ☐ Foaming ☐ Other
Product Incompatibilities:	
Temp. Control (List Specific Range):	

MANUFACTURING REQUIREMENTS:

Placebo Description:	☐ Check if N/A
Aseptic Fill/Terminal Sterilization:	☐ Aseptic Fill ☐ Terminal Sterilization ☐ Other _____
Number of Vials (Each Strength):	
Fill Volume (Each Strength):	
Number of Batches (Each Strength):	
Viscosity:	
Bulk Concentration:	
Labeling and Packaging:	

FORMULATION INFORMATION:

Liquid Formulation	Description	Client to Supply Information	Avrio to Perform Development
Particle Size and Distribution:		☐	☐
Solubility Profile:		☐	☐
pKa and/or Log P/Log D:		☐	☐
Thermal Analysis:		☐	☐
Spectroscopy Data (IR, etc.):		☐	☐
Oxygen Sensitivity:		☐	☐
Moisture Sorption (Hygroscopicity):		☐	☐
pH Stability:		☐	☐
Other: _____			
Lyophilization ☐ Check if N/A	Description	Client to Supply Information	Avrio to Perform Development
Lyo Cycle Duration:		☐	☐
Reconstitution Buffer:		☐	☐
Reconstituted Volume:		☐	☐
Post Reconstitution pH:		☐	☐
Other: _____			

ANALYTICAL PROTOCOL SUMMARY:

REQUIRED USP/COMPENDIA TESTING:

	In Process:	Release Test:	Stability Test
Appearance:	☐	☐	☐
Container Closure Integrity			
USP <660> for Glass:	☐	☐	☐
USP <661> for Plastics:	☐	☐	☐
USP <381> for Elastomeric Closures:	☐	☐	☐
Density:	☐	☐	☐
Osmolality:	☐	☐	☐
Particulates:	☐	☐	☐
pH:	☐	☐	☐
Other: _____	☐	☐	☐

ANALYTICAL METHOD TRANSFERS AND DEVELOPMENT (SEE PARAMETERS BELOW):

Method (List/Describe):	Non GMP	In Process	Release Test	Stability Test
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐

METHOD 1:

Description:
☐ Method Provided by Client
☐ Method to be Developed by Avrio
☐ Transfer
☐ Qualification Phase I/II
☐ Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
☐ Linearity	☐ System Suitability
☐ Accuracy	☐ Intermediate Precision
☐ Precision	☐ Limit of Detection
☐ Range	☐ Limit of Quantification
☐ Specificity	☐ Standard (Sample) Solution Stability
☐ Robustness	☐ Other (Please Describe): _____

METHOD 2:

Description:
☐ Method Provided by Client
☐ Method to be Developed by Avrio
☐ Transfer
☐ Qualification Phase I/II
☐ Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
☐ Linearity	☐ System Suitability
☐ Accuracy	☐ Intermediate Precision
☐ Precision	☐ Limit of Detection
☐ Range	☐ Limit of Quantification
☐ Specificity	☐ Standard (Sample) Solution Stability
☐ Robustness	☐ Other (Please Describe): _____

METHOD 3:

Description:
☐ Method Provided by Client
☐ Method to be Developed by Avrio
☐ Transfer
☐ Qualification Phase I/II
☐ Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
☐ Linearity	☐ System Suitability
☐ Accuracy	☐ Intermediate Precision
☐ Precision	☐ Limit of Detection
☐ Range	☐ Limit of Quantification
☐ Specificity	☐ Standard (Sample) Solution Stability
☐ Robustness	☐ Other (Please Describe): _____

ADDITIONAL ANALYTICAL TESTS:

☐	Extractables/Leachables Studies:
☐	Freeze/Thaw Studies:
Other (List/Describe):	

MICROBIOLOGY TESTING:

	Routine Testing:	Stability Testing:	Method Transfer:	Method Validation:
Endotoxin:	☐	☐	☐	☐
Bulk Endotoxin:	☐	☐	☐	☐
Bioburden:	☐	☐	☐	☐
Sterility:	☐	☐	☐	☐
Bulk Sterility:	☐	☐	☐	☐

STABILITY INFORMATION:

Chamber Conditions:	
☐ ICH Storage Condition: 25°C/60%RH	☐ Storage Condition: -30°C
☐ ICH Storage Condition: 30°C/65%RH	☐ Storage Condition: -70°C
☐ ICH Storage Condition: 40°C/75%RH	☐ ICH Special Storage Condition: 25°C/40%RH
☐ Storage Condition: 25°C	☐ ICH Special Storage Condition: 40°C/25%RH
☐ Storage Condition: 60°C	☐ Photostability Option II Storage Detailed Description:
☐ Storage Condition: 5°C	☐ Special Storage Condition Request Detailed Description:
☐ Storage Condition: -20°C	

Dimension or Size of Each Sample:	
Number of Samples per Batch or Lot:	
Total Number of Samples:	
Storage Orientation:	☐ Upright ☐ Inverted ☐ Tilted ☐ Other (Please Describe): _____

STABILITY TESTING TIMEPOINTS:

Perform Stability Testing According to ICH Conditions: ☐ Yes ☐ No (if not, please complete conditions and time points tables below)

Condition	Test Interval										
	Release (T=0)	T=1M	T=2M	T=3M	T=6M	T=9M	T=12M	T = 18M	T = 24M	T =36M	T = 48M
Condition 1 = 2-8°C											
Condition 2 = 25°C/60%RH											
Condition 3 = 40°C/75%RH											
Other:											
Tests/Methods											