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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:	<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 _____
Location of Clinical Trials:	<input type="checkbox"/> US <input type="checkbox"/> EU <input type="checkbox"/> Canada <input type="checkbox"/> Asia <input type="checkbox"/> Other _____
API Storage:	<input type="checkbox"/> Ambient <input type="checkbox"/> 2-8C <input type="checkbox"/> Frozen
Finished Product Storage/Shipping:	<input type="checkbox"/> Ambient <input type="checkbox"/> 2-8C <input type="checkbox"/> Frozen

SAFETY INFORMATION:

Hazardous: <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> Yes _____	Special Handling Requirements: _____
DEA Controlled: <input type="checkbox"/> No <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V	SafeBridge Level: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Cytotoxic

TIMELINE:

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

COMPONENT REQUIREMENTS:

Stopper Size and Description:	<input type="checkbox"/> Check for Avrio standard component
Vial Size and Description:	<input type="checkbox"/> Check for Avrio standard component
Overseal Description:	<input type="checkbox"/> Check for Avrio standard component
Filter Membrane:	<input type="checkbox"/> Check for Avrio standard component
Special Manuf. Conditions:	<input type="checkbox"/> Protection from Light <input type="checkbox"/> Protection from Oxygen <input type="checkbox"/> Foaming <input type="checkbox"/> Other
Product Incompatibilities:	
Temp. Control (List Specific Range):	



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MANUFACTURING REQUIREMENTS:

Placebo Description:	<input type="checkbox"/> Check if N/A
Aseptic Fill/Terminal Sterilization:	<input type="checkbox"/> Aseptic Fill <input type="checkbox"/> Terminal Sterilization <input type="checkbox"/> 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:		<input type="checkbox"/>	<input type="checkbox"/>
Solubility Profile:		<input type="checkbox"/>	<input type="checkbox"/>
pKa and/or Log P/Log D:		<input type="checkbox"/>	<input type="checkbox"/>
Thermal Analysis:		<input type="checkbox"/>	<input type="checkbox"/>
Spectroscopy Data (IR, etc.):		<input type="checkbox"/>	<input type="checkbox"/>
Oxygen Sensitivity:		<input type="checkbox"/>	<input type="checkbox"/>
Moisture Sorption (Hygroscopicity):		<input type="checkbox"/>	<input type="checkbox"/>
pH Stability:		<input type="checkbox"/>	<input type="checkbox"/>
Other: _____			
Lyophilization <input type="checkbox"/> Check if N/A	Description	Client to Supply Information	Avrio to Perform Development
Lyo Cycle Duration:		<input type="checkbox"/>	<input type="checkbox"/>
Reconstitution Buffer:		<input type="checkbox"/>	<input type="checkbox"/>
Reconstituted Volume:		<input type="checkbox"/>	<input type="checkbox"/>
Post Reconstitution pH:		<input type="checkbox"/>	<input type="checkbox"/>
Other: _____			



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ANALYTICAL PROTOCOL SUMMARY:

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REQUIRED USP/COMPENDIA TESTING:

	In Process:	Release Test:	Stability Test
Appearance:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Container Closure Integrity			
USP <660> for Glass:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
USP <661> for Plastics:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
USP <381> for Elastomeric Closures:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Density:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Osmolality:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Particulates:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
pH:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

ANALYTICAL METHOD TRANSFERS AND DEVELOPMENT (SEE PARAMETERS BELOW):

Method (List/Describe):	Non GMP	In Process	Release Test	Stability Test
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

METHOD 1:

Description:
<input type="checkbox"/> Method Provided by Client
<input type="checkbox"/> Method to be Developed by Avrio
<input type="checkbox"/> Transfer
<input type="checkbox"/> Qualification Phase I/II
<input type="checkbox"/> Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
<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): _____

METHOD 2:

Description:
<input type="checkbox"/> Method Provided by Client
<input type="checkbox"/> Method to be Developed by Avrio
<input type="checkbox"/> Transfer
<input type="checkbox"/> Qualification Phase I/II
<input type="checkbox"/> Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
<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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METHOD 3:

Description:
<input type="checkbox"/> Method Provided by Client
<input type="checkbox"/> Method to be Developed by Avrio
<input type="checkbox"/> Transfer
<input type="checkbox"/> Qualification Phase I/II
<input type="checkbox"/> Validation Phase II/III

Transfer, Qualification, and Validation Parameters:	
<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): _____

ADDITIONAL ANALYTICAL TESTS:

<input type="checkbox"/>	Extractables/Leachables Studies:
<input type="checkbox"/>	Freeze/Thaw Studies:
Other (List/Describe):	

MICROBIOLOGY TESTING:

	Routine Testing:	Stability Testing:	Method Transfer:	Method Validation:
Endotoxin:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bulk Endotoxin:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bioburden:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterility:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bulk Sterility:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

STABILITY INFORMATION:

Chamber Conditions:	
<input type="checkbox"/> ICH Storage Condition: 25°C/60%RH	<input type="checkbox"/> Storage Condition: -30°C
<input type="checkbox"/> ICH Storage Condition: 30°C/65%RH	<input type="checkbox"/> Storage Condition: -70°C
<input type="checkbox"/> ICH Storage Condition: 40°C/75%RH	<input type="checkbox"/> ICH Special Storage Condition: 25°C/40%RH
<input type="checkbox"/> Storage Condition: 25°C	<input type="checkbox"/> ICH Special Storage Condition: 40°C/25%RH
<input type="checkbox"/> Storage Condition: 60°C	<input type="checkbox"/> Photostability Option II Storage
<input type="checkbox"/> Storage Condition: 5°C	Detailed Description: <input type="checkbox"/> Special Storage Condition Request
<input type="checkbox"/> Storage Condition: -20°C	Detailed Description:
Dimension or Size of Each Sample:	
Number of Samples per Batch or Lot:	
Total Number of Samples:	
Storage Orientation:	<input type="checkbox"/> Upright <input type="checkbox"/> Inverted <input type="checkbox"/> Tilted <input type="checkbox"/> Other (Please Describe): _____



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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											