



Technical Transfer Product Information Request “PIR”

Cangene bioPharma (CBI) has extensive experience in manufacturing a wide range of sterile injectables. The variety of products CBI encounters demands strict attention to the physical characteristics of each product. A key part of receiving a quote from CBI is your accurate completion of this PIR Form. It provides each department at CBI with the information needed to create an accurate quote. Your CBI business contact will work with you to assist in the completion process, if you would like.

CBI requests the following documents when available to assist in the project review for a proposal:

1. MSDS
2. Certificate of analysis (C of A) for the API, excipients, bulk drug, last product fill
3. Formulation process diagram
4. Batch record from most recent fill of product
5. Test methods for each test to be done at CBI (including a stability protocol, if needed)
6. This completed Product Information Request Form (PIR Form)

****For biologics, summary test data on adventitious agent clearance must be sent**

Date PIR Completed			
Is there a completed confidentiality agreement?		<input type="checkbox"/> Yes <input type="checkbox"/> No Date: (mm/yy)	
Company Name			
Web address			
Contact Name/Title			
Address			
Phone		Fax	
e-mail			
Secondary Contact			
Contact Name/Title			
Address			
Phone		Fax	
e-mail			
Please provide a general description of the product and its intended use as well as its stage in development. Please include information as to the therapeutic category/properties (viscous, aqueous, suspension, hygroscopic)			
Product type:	<input type="checkbox"/> Liquid	<input type="checkbox"/> Lyophilized	<input type="checkbox"/> Other
Please describe:	<input type="checkbox"/> Aqueous	<input type="checkbox"/> Non Aqueous	Regulatory Clinical Phase
Product Name:			<input type="checkbox"/> FDA <input type="checkbox"/> Phase I/II
Administered IV? <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> EMEA <input type="checkbox"/> Phase III
			<input type="checkbox"/> JP <input type="checkbox"/> Site Transfer
Product Characteristics			
1. API / DILUENT			



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3. Container Closure	
A. Vial	
Will you use a CBI qualified vial?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturer	<input type="checkbox"/> Schott <input type="checkbox"/> Alcan (Wheaton) <input type="checkbox"/> Kimble <input type="checkbox"/> Other _____
Type	<input type="checkbox"/> Tubing <input type="checkbox"/> Molded <input type="checkbox"/> Clear <input type="checkbox"/> Amber
Treatment	<input type="checkbox"/> Treated <input type="checkbox"/> Untreated
Size	<input type="checkbox"/> 3 cc <input type="checkbox"/> 5 cc <input type="checkbox"/> 10 cc <input type="checkbox"/> 20 cc <input type="checkbox"/> Other
Finish	<input type="checkbox"/> 13 mm <input type="checkbox"/> 20mm <input type="checkbox"/> other _____ mm
Manufacturer Part # (Drawing Number)	_____
Who will supply?	<input type="checkbox"/> CBI <input type="checkbox"/> Client

B. Stopper	
Will you use a CBI qualified stopper?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturer	<input type="checkbox"/> West <input type="checkbox"/> Westar <input type="checkbox"/> Daikyo <input type="checkbox"/> Helvoet <input type="checkbox"/> Other _____
Coating	<input type="checkbox"/> Siliconized <input type="checkbox"/> Teflon <input type="checkbox"/> Fluorotec <input type="checkbox"/> B2 <input type="checkbox"/> Other _____
Finish	<input type="checkbox"/> 13 mm <input type="checkbox"/> 20mm <input type="checkbox"/> other _____ mm
Manufacturer Part #	_____
Who will supply?	<input type="checkbox"/> CBI <input type="checkbox"/> Client

C. Aluminum Seal	
Will you use a CBI qualified seal?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturer	<input type="checkbox"/> West <input type="checkbox"/> Other
Type	_____
Color	_____
Manufacturer Part #	_____
Who will supply?	<input type="checkbox"/> CBI <input type="checkbox"/> Client

D. Syringe – CBI can fill syringes presented in a nested format	
Manufacturer	<input type="checkbox"/> BD <input type="checkbox"/> Schott <input type="checkbox"/> Other
Size	<input type="checkbox"/> 1 cc <input type="checkbox"/> 2 cc <input type="checkbox"/> 2 ¼ cc <input type="checkbox"/> Other _____
Plunger	Formulation _____ Manufacturer _____
Manufacturer Part #	_____
Who will supply	<input type="checkbox"/> CBI <input type="checkbox"/> Client



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4. Equipment Cleaning –Background Information

A. Toxicity LD50 (mg/Kg Oral mouse)

B. USP solubility Category Select Category

USP Solubility Category	Descriptive Term	Appropriate Volume of Aqueous Solvent In Milliliters Per Gram of Solute
1	Very soluble	Less than 1 part solvent needed to dissolve 1 part solute
2	Freely soluble	From 1 to 10 parts solvent needed to dissolve 1 part solute
3	Soluble	From 10 to 30 parts solvent needed to dissolve 1 part solute
4	Sparingly Soluble	From 30 to 100 parts solvent needed to dissolve 1 part solute
5	Slightly Soluble	From 100 to 1000 parts solvent needed to dissolve 1 part solute
6	Very Slightly Soluble	From 1000 to 10,000 parts solvent needed to dissolve 1 part solute
7	Practically insoluble	More than 10,000 parts solvent needed to dissolve 1 part solute

C. Therapeutic dose (mg of active)

D. Largest Daily dose (mL of formulated product)

E. Estimated % Carbon

F. Estimated batch size: **Minimum (L)** **Maximum (L)**



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Manufacturing		
5.		
A. Product Compatibility (Check if Compatible)		
<input type="checkbox"/> Stainless Steel	<input type="checkbox"/> Platinum cured silicone	<input type="checkbox"/> Polycarbonate
<input type="checkbox"/> Glass	<input type="checkbox"/> Teflon	<input type="checkbox"/> EPDM
<input type="checkbox"/> Filter membrane (Durapore, PVDF)	<input type="checkbox"/> Polypropylene	<input type="checkbox"/> Polystyrene
<input type="checkbox"/> Silicone		
List any other incompatible surfaces:		
B. Filtration		
List sterilizing filter:		
CBI normally uses redundant 0.2 μ filters for filtration.		
Is use of only one filter required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pre-filter required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pore Size Requirements		
Special Instructions:		
Primary Filtration Media and Configuration		
Manufacturer:	Filter Type/Medium:	
Filtration rate and/or other issues (L/minute)?		

C. Batch Size		
Bulk _____ liter(s)	Number of Vials: _____	
Target Fill Volume:	Fill Tolerance:	
D. Does this procedure require any specialized or specific manufacturing equipment? If yes, please list.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
E. Have cleaning procedures been developed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
F. Are there validated analytical methods for product detection on manufacturing equipment? CBI routinely uses Total Organic Carbon (TOC) Please describe.	<input type="checkbox"/> Yes	<input type="checkbox"/> No



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G. Please describe an abbreviated or step-wise procedure for the manufacture of the product



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6. Testing Requirements for CBI				
A. Incoming				
Identity:				
	<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP	
	<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP	
	<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP	
B. In Process	Specification			
Potency/Purity:				
Prefiltration Bioburden:		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
Client Samples for outside testing : _____ units				
C. Finished Product	Specification			
Sterility		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
Endotoxin		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
Particulate Matter (SVP)		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
Potency/Purity		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
		<input type="checkbox"/> USP	<input type="checkbox"/> EP	<input type="checkbox"/> JP
Client Samples for outside testing : _____ units				



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D. Stability Testing is performed on vialled and sealed finished product units taken from the inspected manufactured lot in order to confirm that the lot maintains its potency and quality over the duration of shelf life. Methods generally consist of a subset of methods used for finished product testing. They must be validated at CBI.

ICH Q1A offers the following Storage Test Conditions. These storage conditions are available at CBI . The length of the studies and the storage conditions should be sufficient to cover storage, shipment and subsequent use (e.g. reconstitution or dilution as recommended in the labeling). Please check in the table below the appropriate blocks for the desired storage conditions for the study.

	-70° C	-20 ° C	5 ° C	25 °C/60% RH	30° C/ 60% RH	45° C/ 75% RH
Alternative	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Long Term	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intermediate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accelerated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

E. Reference Standards

Reference standard required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Reference standard provided by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Note: The following information is required		
a. Certificate of Analysis (C of A)		
b. Retest/Requalification/Expiration Date		
c. Stability of Standard		
d. Stability Issues		
e. Storage conditions		
f. Purity		
g. Special Instructions		
h. MSDS		



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7. Labeling/Inspection		
1. Finished product units to be labeled (each with an identical label)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Label spec copy available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Finished product is bulk packaged is this acceptable?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Note: All vials undergo 100% inspection. Is there anything about the product we should know to aid the inspection process (i.e., precipitation , color variations)? _____		

8. Shipping	
1. Finished Product Storage Temperature: <input type="checkbox"/> 2-8°C <input type="checkbox"/> Room Temperature <input type="checkbox"/> -20°C <input type="checkbox"/> -70° C	
CBI routinely ships product in a universal shipper according to CBI SOPS	
2. Is there a validated shipping configuration? <input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Is there a custom shipper? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If "Yes" is checked for either of the above questions please supply additional details as to the requirements. Please attach information	
4. CBI ships product overnight by Federal Express at Client expense. Is this OK? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, list your preferred shipping method: _____	

9. Commercial Requirements					
Current Commercial Forecast must be inserted below:					
Presentation	Year 1 (launch) 200_____	Year 2 (launch) 200_____	Year 2 (launch) 200_____	Year 3 (launch) 200_____	Year 4 (launch) 200_____
	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total
	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total	____ units ____ lots ____ Total