



## 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**



## Technical Transfer Product Information Request "PIR"

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				
<b>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)</b>				
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



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<b>Product Characteristics</b>		
<b>1. API / DILUENT</b>		
General Description	<input type="checkbox"/> Small Molecule (NCE) <input type="checkbox"/> Protein <input type="checkbox"/> DNA <input type="checkbox"/> Other _____	
Is a MSDS available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is this a controlled substance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is this material hazardous? Explain	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are operator protective measures required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are special clean-up/spill procedures required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are there special material disposal requirements?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are there any handling requirements or sensitivities? List. _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o Temperature	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o Foaming	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o Light	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o Oxygen	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o Other	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Who will supply API / Diluent/Excipients?	<input type="checkbox"/> Client	<input type="checkbox"/> CBI
What is the storage temperature for API / Diluent/Excipients : <input type="checkbox"/> 2-8°C <input type="checkbox"/> Room Temperature <input type="checkbox"/> -20°C <input type="checkbox"/> -70° C		
The API/Bulk Product will be shipped in Container material: <input type="checkbox"/> Glass <input type="checkbox"/> PTE bottle <input type="checkbox"/> Bag	<input type="checkbox"/> Single container	<input type="checkbox"/> Multiple containers
When will API be available? <i>CBI requests that a piggyback sample be shipped with the incoming material, the sample will be sent back to you or laboratory you designate for identity testing.</i>		

<b>2. Formulation</b>	Concentration g/L			
API:				
Excipients:		<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
Any unusual aspects about formulation? If so, describe:				



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<b>3. Container Closure</b>	
<b>A. Vial</b>	
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>B. Stopper</b>	
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

<b>C. Aluminum Seal</b>	
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

<b>D. Syringe – CBI can fill syringes presented in a nested format</b>	
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		
<b>5.</b>		
<b>A. Product Compatibility (Check if Compatible)</b>		
<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>B. Filtration</b>		
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)?		

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



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



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<b>H. Process Parameters for Lyophilization</b>			
Specify product temperature (thermocouple) or shelf temperature control <input type="checkbox"/> Thermocouple <input type="checkbox"/> Shelf Temperature		Chamber loading shelf temperature ____ °C	
		Hold ____ hrs.	
		Total Lyo Cycle Length: ____ hrs.	
<b>Freezing</b>			
Ramp Rate	Temperature °C	Hold (hours)	
Condenser Temperature ____ °C			
<b>Primary Drying</b>			
Ramp Rate	Temperature °C	Vacuum (microns)	Hold (hours)
<b>Secondary Drying</b>			
Ramp Rate	Temperature °C	Vacuum (microns)	Hold (hours)

Stoppering Under Vacuum: ____ psia (11 psia standard)	<input type="checkbox"/> Sterile Air
	<input type="checkbox"/> N <sub>2</sub>
End product moisture specification less than	
Magnitude of Hygroscopicity after drying	<input type="checkbox"/> Low
	<input type="checkbox"/> Moderate
	<input type="checkbox"/> High



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<b>6. Testing Requirements for CBI</b>				
<b>A. Incoming</b>				
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>B. In Process</b>	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
<b>Client Samples for outside testing: _____ units</b>				
<b>C. Finished Product</b>	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
<b>Client Samples for outside testing : _____ units</b>				



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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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<b>7. Labeling/Inspection</b>		
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)? _____		

<b>8. Shipping</b>	
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	
<b>CBI routinely ships product in a universal shipper according to CBI SOPS</b>	
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: _____	

<b>9. Commercial Requirements</b>					
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