ColdStash Cell Therapy Cassette Specification Questionnaire

Company Contact Phone Contact Email Date

1) How is the therapy packaged/stored?

Cryo Bag Cryo Vial Other

2) What size of storage package do you use?

What size is the Cryo bag or vial? How many milliliters?

3) What make and model of bag are you using (Please provide supplier part number)?

Bags

Origen

Macopharma

Charter

Saint Gobain

Miltenyi

Other

4) If using Cryo Bags...

a. Is the bag "standard" from the manufacturer or custom? If custom, what are the overall dimensions and port dimensions?

Standard

Custom

b. Will you be using over wrap pouch?

Yes (if yes, what are dimensions of product once over-wrapped?)

No

Undecided

c. How will you be labeling?

In bag

On the cassette

Both



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d.	Will you be using bag manufacturers label pouch	۱?
	Yes	
	No	

e. Do you want windows in cassette that align with your label?

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Yes (If yes, why? Ease of scanning, location spec, etc) No
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- f. Where will Patient Information Literature (PILS) be stored?
- g. What are you plans for "tamper evident" seals?

5) LN2 Storage Freezers

What brand, make and model# freezer(s) do you use?

6) Time and quantity requirements

- a. What stage of development is the program?
- b. What is the status of clinical trials?
 - i. Timing
 - ii. Projected # patients
 - iii. Projected number of units required (doses)
- c. What is your current expectation for Commercialization?
 - i. Target commercialization date
 - ii. Projected volumes upon commercialization

7) Shipping Therapies

- a. Have you investigated options for shipper/logistics?
- b. Have you chosen a shipping partner?
- 8) Other things we should know?

