Telecon, November 11, 2011, noon - HPC Cord Blood

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125391/0 Office: OCTGT
Product:
Hematopoietic Progenitor Cells,Cord (HPC-C)
Applicant:
Clinimmune Labs
Telecon Date/Time: 11-November-2011 12:00 PM Initiated by FDA? Yes
Telephone Number: -----(b)(4)-----
Communication Categorie(s):
1. Inspection Related

Author: RAMANI SISTA
Telecon Summary:
Inspection Related
FDA PARTICIPANTS:
Ramani Sista
Yong Fan
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NON-FDA PARTICIPANTS:
Sharon Miller
----(b)(4)----
Michael Aubrey
Brian Freed arrived later in tcon
------(b)(4)------
Stephanie Warnell
Linda Tapia
Sabine Stockinger

Trans-BLA Group: No
Related STNs: None
Related PMCs: None

Telecon Body:

Max capacity processing during inspections: DMPQ stated that there were some initial discussions to determine the production capacity or number of units processed per shift. DMPQ asked the sponsor the number of units being processed currently in each shift. The sponsor responded that they process (b)(4) units\shift. DMPQ stated that cryopreserving timeline for processing (b)(4) units per shift, (b)(4) in each bio-safety cabinet was too many and not acceptable. The sponsor stated that they have a (b)(4) shift with (b)(4) people working in each hood. DMPQ stated that they saw just one person when they were in the facility during pre-approval inspections. DMPQ will consider the sponsor's proposal to process (b)(4) units at a time and see if they have the capability to process the proposed units within the allotted time concurrently or independently. When the FDA team was in sponsor's facility during inspections they observed (b)(4) units in the morning which took approximately (b)(4). By extrapolation, it may be possible that the sponsor will be capable of processing (b)(4) units in (b)(4). DMPQ reiterated that it was vital to come to the determination based on capability to avoid mix-ups.
Following further clarifications, DMPQ determined (b)(4) units/ shift was acceptable. The sponsor was asked to provide detailed documentation regarding processing, shipping and distribution and make the necessary changes in their SOPs. The sponsor agreed.

The sponsor requested information regarding the dry shipper validation. They asked DMPQ what they would like to see for worst case scenarios. DMPQ stated that they would like to see how temperatures for the product will be controlled or maintained in worse case scenarios such as prolonged time, hot temperatures. The sponsor will have to expose the sample to normal shipping procedures and plan for delays normally associated with shipment and travel such as length of time for travel, environment – hot\cold temperatures. The sponsor will have to draft a protocol for validation and go through the process in the protocol sequentially. The sponsor asked if this was a one time validation or something they will have to do with each shipment. DMPQ explained that they will have to define all their shippers, though there was no need to validate all their shippers. The sponsor will need to subject their sample to a worst case scenario. DMPQ stated that they would be happy to help the sponsor review and comment their protocol.

DMPQ stated that the batch records were greatly improved from before; they plan to have some internal discussions and provide feed back to the sponsor the following week.

The sponsor stated that they will be sending amendment 2, mid December. DMPQ requested the sponsor to send all inspection related information such as complete response to their 483, dry shipper validation protocol in a separate amendment by itself. The sponsor said they would put all inspection related information in a separate folder for easy access. DMPQ requested the information as soon as it becomes available via email if possible since amendment 2 will take some time to get here. The sponsor agreed.