Record of Telephone Conversation, September 6, 2012 - HPC, Cord Blood BLA 125432

- Product:
  HPC, Cord Blood

  Applicant:
  LifeSouth Community Blood Centers, Inc.

  Telecon Date/Time: 06-Sep-2012 01:00 PM Initiated by FDA? Yes

  Telephone Number:
  Communication Categorie(s):
  1. Inspection Related

  Author: CANDACE JARVIS
  Telecon Summary:
  Pre-Request List and AI for the September 24-28, 2012 Facility Inspection
  FDA Participants: Grace M.B. Deneke, CSO (CBER/OCBQ/DMPQ)

  Marion Michaelis, Team Leader (CBER/OCBQ/DMPQ)
  Mohammad Heidaran, Ph.D., Biologist (CBER/OCTGT/DCGT)
  Candace Jarvis, RPM (CBER/OCTGT)
  Non-FDA Participants: Jill Evans, Vice President of Quality
  Lori Masingil (Technical Communications Manager)
  Tammy Lawson, (Validation Coordinator)
  Amy Lambert, (Manager Cellular Therapies)
  Evan Baser
  Richard Jones
  Ed Downey
  Tamara Cannady
  Lindsay Hertel
  Jessica Drouillard
  Trans-BLA Group: No

  Related STNs: None
  Related PMCs: None
  Telecon Body:
  FDA requested a brief teleconference with Life South to discuss the Pre-Request list for the Inspection dated for September 24-28, 2012. Below is the information sent to the sponsor:

PRE-REQUESTs and Additional Information FOR LIFESOUTH PRE-LICENSE INSPECTION (PLI)
(Gainesville, FL, September 24 – 28, 2012)

Administrative Issues:

1. Inspection Time

- September 24-28, 2012
- Start at 8:30 AM on September 24, 2012

2. Inspectors

Grace Deneke, CSO, CBER/OCBQ/DMPQ – Lead Inspector
Marion Michaelis, CSO, CBER/OCBQ/DMPQ – Co-lead
Mohammad Heidaran, Ph.D., CBER/OCTGT/DCGT
Eric Dollins, Ph.D., CBER/OCTGT/DCGT
Helen Ricalde, CSO, CBER/OGROP/ORA/ORO/DDFI/TBS

Information to Be Provided to FDA Before the Inspection:

1. Provide the name and contact information of LifeSouth contact person for inspection related correspondence.
2. Provide the name and title of LifeSouth's most responsible person who will be present at the opening of the inspection.
3. We will be observing cord blood unit (CBU) processing and testing at capacity which is close to the maximum production capacity established in the LifeSouth Gainesville facility.
   - Provide the maximum production capacity for cord blood processing in your manufacturing facility 1 week prior to the inspection.
   - Provide detailed production and testing schedules with approximate start and finish times noted, or the duration of the process on a daily basis during the PLI, 1 week prior to the inspection.

Expectation for Introductory Presentation and Walkthrough:

- A 5 min presentation on facility history.
- A 15 min presentation on production processes, including collection, processing, cryopreservation and storage, packaging and labeling, and shipping.
- A 15 min presentation on firm's quality system.
- A 10 min presentation on firm's computer system.
- A brief walk-through of the facility after the opening presentation.

To facilitate the upcoming PLI, please have the following information ready upon our arrival at the start of the inspection (one copy for each inspector except where indicated)

1. List of names and titles of LifeSouth attendees who will be presenting at the opening of the meeting. Provide also a copy of the introductory presentations.
2. Detailed organizational charts showing relationship of quality, production and management functions.
3. A brief history of business as it relates to CBUs production. Please provide hours of operations and number of employees for your entire company.

4. Large, legible facility drawings/floor plans, including room numbers and functions.
5. Large, legible diagrams illustrating AHUs, room classifications, pressure differentials, and flows of materials, product, equipment, personnel and wastes
6. An accessible copy of the BLA STN 125432/0 (one electronic copy is fine).
7. List of all SOPs, including titles, document numbers and approval dates, used in production and testing of the product (including collection, donor testing, transportation, processing, cryopreservation & storage, packaging & labeling, QC testing, shipping, and thawing, CAPA, non-conforming materials, handling of OOS and deviations etc.).
8. SOPs for handling deviations and Out of Specifications (OOS).
9. SOPs for facility and equipment cleaning/sanitization (two copies).
10. SOPs for environmental monitoring of the facility (two copies).
11. Quality unit manual/procedures.
12. SOP for Internal Audit Program along with a schedule for internal audits.
13. SOP for vendor/supplier qualifications.
14. Provide the latest media fill for the manufacturing of CBUs.
15. Schematic flow diagrams illustrating the production processes, indicating in-process sampling points, tests to be performed, specifications, and hold times.
16. List of in-process and final product release specifications.
17. List of all change controls made to production facilities, equipment, QC testing, and production processes since the establishment of the LifeSouth facility.
18. List of all deviations/OOS for all CBUs processed since the establishment of the LifeSouth facility
19. Summary report of routine EM data (including viable and non-viable particles and surface) with trending, excursions, investigations, analysis and corrective actions for the processing room since the establishment of the LifeSouth facility (two copies).
20. Summary report of the HVAC systems including pressure differentials, temperature and humidity monitoring data for the processing room since the establishment of the LifeSouth facility (two copies).
21. List of all CBUs processed in the LifeSouth facility, including their dispositions (including those being discontinued or discarded).
22. All qualification/validation protocols and final reports related to the facility, equipment, processing and testing (no copies are need unless specifically requested at the time of inspection by individual investigators).
23. Batch records (including donor eligibility and QC test) for all CBUs processed at the LifeSouth facility should be available (no copies are need unless specifically requested).

Additional Notes:

- Although we are making pre-requests, all information in support of the BLA submission should be readily available to us in a timely manner during the inspection if requested
- At the conclusion of the inspection, we will expect you to provide a list of names and titles of LifeSouth employees we have interviewed and the subjects we covered on a daily basis during the PLI. An electronic copy is preferred.
- We may have to schedule as needed an additional teleconference with you prior to the September 24, 2012 inspection.
- Have available to us access to standards you may have referenced in the submission (electronic is fine).