

## **Monthly Team Meeting #2**

**DATE:** July 23, 2012  
**Time:** 12:00 -1:00 PM EST  
**Sponsor:** LifeSouth  
**BLA #:** BLA 125432  
**Product:** HPC, Cord Blood

**FDA Attendees:** Candace Jarvis, Mohammed Heidaran, Juanita Williams-Gould, ,Atm S.Hoque, , Stan Lin, ,Karoll Cortez, Keith Wonnacott, Loan Nguyen, Jalal Sheikh, Joydeep Ghosh, Mark Borigini, , Ilan Irony, Wilson Bryan, Stephanie Simek, Kimberly Benton, Marion Michaelis, Lori Tull, Ted Stevens, Eric Dollins,

**Call in information:** (b)(4)

### **Agenda:**

#### **1. Administrative Updates**

- Eric Dollins replaces Ramjay as 2<sup>nd</sup> product reviewer
- Fatima Abassi has been added by product to review Flow Cytometry
- Filing letter issued on July 16, 2012; Deficiencies identified in this letter
- GRMP timeline (subject to change)

#### **2. Review Updates**

##### **a. CMC:**

- Stability data not submitted; determine unit expiration
- Barcode exemption inadequate
- Set up t-con with sponsor

##### **b. DMPQ :**

Inspection date set for the week of September 24-28, 2012. The following individuals will be conducting the inspection:

- Grace Deneke (CBER/OCBQ/DMPQ)
- Marion Michaelis (CBER/OCBQ/DMPQ)
- Mohammad Heidaran (CBER/OCTGT/DCGT)
- Eric Dollins (CBER/OCTGT/DCGT)
- Helen Ricalde (ORO/DDFI/TBS)

Sponsor's POC for inspection: Jill Evans, Vice President of Quality

- Additional discussion on manufacturing capacity with the sponsor is needed. In a previous conversation the sponsor

stated that their maximum capacity is (b)(4) When we indicated that we would need to observe during the inspection manufacturing at maximum capacity for which approval is being sought. LifeSouth indicated that they could only demonstrate (b)(4) on inspection. After discussing this subject of capacity with DMPQ management it was determined that we need to have additional conversation with the firm.

- c. PHARM/TOX:
    - Will cover Biocompatibility and toxicological issues of the submission; completed filing review memo
  - d. CLINICAL:
    - No new updates; deficiencies identified in filing letter
  - e. STATS:
    - No new updates
  - f. LABELING:
    - Container Labels: if the product has two container labels, partial and full, the partial label requires very minimal requirement. ISBT 128 labels also are partial and full labels. The partial label requires the product code, which LifeSouth partial label doesn't have. If the partial label meets ISBT 128, it more likely will meet FDA partial label requirement. Need to check with sponsor whether or not they will add the product code on the partial label.
3. Upcoming Dates:
- Next team Mtg: August 27, 2012
- 4. Other Issues
  - 5. Issues/Questions for sponsor discussion