

# Wrap Up Meeting Minutes, October 6, 2011 - Hemacord

**Sponsor:** New York Blood Center  
**BLA#:** BL125397/0  
**Product:** Hematopoietic stem/progenitor cells, cord (HPC-C)  
**Date:** October 6, 2011  
**Time:** 3:30 – 5:00 PM

**Meeting Attendees:** Witten, Celia; Nguyen, Loan; Rees, Renee; Riggins, Patrick; Hyde, John; McCright, Brent; Syin, Chiang; Karandish, Safa; Heidaran, Mohammad; Eltermann, John; Simek, Stephanie; Benton, Kimberly; Wonnacott, Keith; Quagraine, Mercy; Joshi, Bharat; McFarland, Richard; Haudenschield, Changting; Bryan, Wilson; Przepiorka, Donna; Green, Damon

## 1. Introductions

## 2. Important dates

**Action Due Date:** November 10, 2011  
**Concurred Reviews:** October 31, 2011

## 3. Identification of Remaining Issues

### • CMC – Communicated by Mercy Quagraine

Two issues were identified to remain, 1) the review was awaiting the sterility validation data for slow growers and 2) from DMPQ - the issue of retention samples where the current plan -----(b)(4)----- lot release testing if necessary, specifically, potency testing will not be possible with the current proposal.

### • DMPQ – Mohammed Heidaran, Chiang Syin, John Eltermann

Two remaining issues were identified: 1) regarding monitoring of the Biological Safety Cabinet (BSC), an action limit and alert limit must be set. If the BSC is labeled as --- (b)(4)---, it must be monitored to a ----(b)(4)-- level. 2) The batch record though improved, should provide a narrative account of the history of a lot, and the current format is difficult to follow.

### • Clinical – Communicated by Donna Przepiorka

No outstanding issues, and the planned telecon with the Applicant on 10/7/11 at 2 PM would not be necessary at present.

### • Stats – No remaining issues

### • APLB – Labeling review is underway and proceeding

## 4. Action Items

- DMPQ will use the time slot on 10/7/11 to communicate the issues identified above. Patrick Riggins contacted Eva Quinley to inform her that the standard telecon would not happen, but that the DMPQ team had some issues it would need to discuss.
- An NDC code was still needed at this point and the applicants would be reminded of this.

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