Telecon, October 12, 2011 - Hemacord

Date/Time of Call: October 12, 2011 @ 9:00 A.M.

CBER Representative: Mohammad Heidaran, Biologist, CBER/DMPQ
Laurie Norwood, Deputy Director, DMPQ
John Eltermann, Director, DMPQ

Organization Representative: Eva Quinley
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Michael Zdanowski

Organization: **New York Blood Center Inc.**

Subject: Batch Record

STN: **125397/0**

The following deficiencies to the current NYBC batch record were discussed on October 12, 2011 during a telecon with NYBC:

1) We noted that there were some units that appeared to be ----------(b)(4)---------- numbered units. We asked whether there was a requirement for a separate batch records for (b)(4) units? We asked NYBC to provide a copy of the batch record for the (b)(4) unit, -----(b)(4)----- so we could review the information and determine if separate batch records were necessary.

2) In regard to the labeling reconciliation we asked to clarify whether that labels for each unit were reconciled as part of the process. NYBC indicated that labels are made at each station and reconciled by the operator. Accordingly this information will be reflected in the batch record.

3) We noted that there wasn't an indication on the batch record where the processing took place. NYBC also agreed to include the location for cord blood processing and cryopreservation steps.

4) During the review of the batch record we noted that it was difficult to follow, reconcile volumes added, and concentration of the cryopreservation solution that is added during the process. In the cryopreservation section they agreed to include the starting volume, volume of cryopreservation media added and concentration of stock solution.

5) Due to the potential impact on cord blood units there appeared to be a need to include the time it took to add the cryopreservation solution as part of the batch record. NYBC will include the start time of the DMSO addition and include information about the accepted parameter for the time and rate of DMSO addition.

6) Under cryopreservation section NYBC will include how the final approximate volume of 25 mL was derived using the information provided at the beginning of this section.

7) The freezing rates were not on the batch record per se but were found on the individual attached printouts. There weren't instructions in the batch records to allow the operator to verify the freezing conditions or acceptable range of time for the freezing steps. For controlled rate freezer, NYBC indicate the start and end time of the freezing process will be added to the batch record.

8) NYBC will document how the time from collection to end of freezing was calculated

9) NYBC will include the accepted parameter for cryopreservation/freezing and combine J and K into one line.

10) Retention sample location will be added to the section Blood samples freezers location

11) We agreed that accompanying record(s) can be cross referenced in the batch record.

NYBC agreed to make the changes discussed and send the revised Batch Record for review.