FDA Collection Process Validation Plan - ALLOCORD

DESIGN PROPOSAL

Principle:

The St Louis Cord Blood Bank shall define policies and procedures that describe and demonstrate the validation of operational activities. This includes the validation of the collection procedures to demonstrate consistent quality of units collected for donor purposes to the SLCBB. This will be demonstrated by the ability to meet predefined quality parameters.

Purpose:

For the purpose of submission for Biologics License Application (BLA) with the Food and Drug Administration (FDA), as stated in the Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for HematopoieticReconstitution for Specified Indications (October 2009), this validation will confirm by examination and provision of objective evidence that collection procedures consistently result in obtaining cord blood units that meet predetermined specifications.

Background:

The collection must be performed by processes that maintain purity, potency and safety of the product. Validation of collection procedures will be performed on --------(b)(4)------- collected UCB units. This should require approximately ---(b)(4)---. The validation plan shall provide data related to all aspects of the collection process: quality collection, transport, handling and donor safety.

Validation Period:

The validation period will begin on 11/13/2012 and continue until the data set value of (b)(4) is met.

Specimen:

Umbilical Cord Blood Harvest in (b)(4) CPD anticoagulant.

Equipment, Reagents and Supplies:

Refer to individual procedures for procedure specific supplies, reagents and equipment.

Procedure:

CL.03.07 Donor and Family Screening
CL.05.06 Maternal Consent
CL.06.08 Method of Collection of Cord Blood
CL.07.06 Labeling Maternal Samples and Cord Blood Units at the Collection Site
CL.08.05 Storage of Cord Blood at the Collection Site Before Transportation to the St Louis Cord Blood Bank
CL.11.05 Delivery of Cord Blood Collection Supplies
CL.13.09 Assessment of Donor Eligibility by Cord Blood Bank
CL.17.09 Transport of Umbilical Cord Blood Collections

Acceptable Results:

The parameters were chosen to present an adequate evaluation of the overall quality of the units collected by obstetricians and midwives for the SLCBB to produce a pure, potent, and safe product.

Parameter	**Definition**	**Rationale**
% of units with acceptable volume	Cord Blood volume collected	The collected volume of cord blood is the first factor in determining whether the collected product will proceed to manufacturing. Volume is not a release parameter.
% of units deferred due to technical errors	Technical errors include: mislabeled unit or maternal tubes, compromised collection bag integrity, clotted cord blood unit, or unacceptable elapsed time from collection	The technical expertise of the collection team has direct impact on the quality of the cord blood collection.
Incidence of storage temperature deviations	The temperature of the storage site at each of the 29 hospitals. Target temp range ----------(b)(4)----------	Storage and transport of Cord Blood units must occur under controlled conditions. Based on historical observations, temperatures within this range are not expected to have an adverse effect on product integrity.
Incidence of transport temperature deviations	The temperature of the environment during transport of the cord blood units to the SLCBB. Target temp range ----------(b)(4)----------	
Microbial Cultures	The percent of units that are sterile post processing.	Sterility of the cord blood unit is dependent upon both the collection process and the manufacturing process.
Maternal and Donor Safety	Adverse events associated with collection are communicated to the SLCBB	Cord Blood collection should not pose any risk to mother or baby.

Historical data was obtained by analysis of the following parameters for units received at the SLCBB between March 1 and May 31, 2012. The analysis was performed by breaking the time period into week long intervals and calculating the percent per week. The mean and standard deviation were calculated from these percentages.

(b)(4)

(b)(4)

Any transport temperature deviations that may occur will be evaluated using Mean Kinetic Temperature to evaluate the impact on the cord blood product.

References:

"Collection Site Temperature Monitoring" Cord Blood Symposium 2011, San Francisco

"The Effect of Pre-Processing Storage Temperature on the Stability of UCB Units Delayed for Processing", SLCBB internal study, Sept. 2011

Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for HematopoieticReconstitution for Specified Indications (October 2009)

All SLCBB SOPs as referenced in "Procedure" section.

Biostatistician
Approval_____Date:_____

Quality Specialist
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Scientific Director
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Executive Director
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REPORT

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