**Drug Product Starting Material:**

Hematopoietic Progenitor Cell, Apheresis (HPC-A)

Hematopoietic Progenitor Cell, Marrow (HPC-M)

Hematopoietic Progenitor Cell, Cord Blood (HPC-C)

**Manufacture Information**

Date of Drug Product Manufacture\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proportion of CD34+ cells \_\_\_\_\_\_\_\_\_

Total Colonies Formed: \_\_\_\_\_\_ per \_\_\_\_\_\_\_ cells

Expression of globin chain of interest:

Qualitative Assay:  Positive  Negative

Quantitative Assay: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Were any additional drug product potency assays performed on drug product?

Yes  No

If yes, describe and report result\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of Modification:

Integrating Vector

Gene Editing Nuclease

Stem Cell Expansion

**POPULATE SECTION A FOR INTEGRATING VECTOR CELL PRODUCT**

**POPULATE SECTION B FOR GENE EDITED CELL PRODUCT**

**Section A**

Type of Integrating Vector:  Retrovirus  Lentivirus  Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Drug Product VCN\_\_\_\_\_\_

Percentage of cells positive for integrating vector \_\_\_\_\_\_\_\_\_

Drug Product VCN/cell \_\_\_\_\_\_\_\_

**Section B**

Type of Editing:  CRISPR-Cas 9  ZFN  TALEN  Cytosine Base Editing

Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mode of nuclease delivery:  mRNA by EP  RNP by EP  AAV

Other

gRNA target gene\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Mode of Delivery\_\_\_\_\_\_\_\_\_\_\_

**Donor Template used?**  Yes  No

If Yes, mode of delivery:  ssODN  AAV  Other

Drug Product:

On-target Indels\_\_\_\_\_\_ Verified off-target indels\_\_\_\_\_\_\_\_\_

Conversion \_\_\_\_\_\_\_%