Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2023-01-16
CBS Control #: CBS6722
Drug GMP Inspection Program File #: 79801-100390Q
REF: H-2223-NF-W

Shannon Paiement
Regional Regulatory Compliance & Enforcement Officer
GMP Inspections, Central
Regulatory Operations and Enforcement Branch
Health Canada
2301 Midland Avenue
Toronto, ON, M1P 4R7

Dear Shannon:

Re: Responses to Health Canada GMP Inspection of St. John's Operations Wholesale activities on 2022-11-23

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Exit Notice dated 2022-12-19.

C.02.015 - Quality control department

1. **Deficiencies were observed in the investigation of deviation reports. For example, the investigation in DEV-22-002407 to address surplus product inventory that was observed during the cycle count process was inadequate:**

   1) Contrary to the quality event management procedure WI-001519, which was revised in 2022 to require that a thorough baseline investigation be completed for each quality incident, a thorough baseline investigation was not completed.

   2) No details were documented regarding assessment of the root cause including possible root cause(s). The deviation only stated that the operator did not observe the count discrepancy for the product while packaging it with a large order, which is not considered the root cause analysis.

   3) Corrective and/or preventive actions to adequately address the deviation were not proposed

   Further investigation was completed for DEV-22-002407 and additional information was added to the deviation on 2022-12-16 outlining the probable root cause(s) and follow-up.

   A refresher training module regarding the operational review of deviations involving plasma protein and related products (PPRP) will be developed and assigned to current operational reviewers and quality assurance approvers across the organization to complete by 2023-02-10 and the initial training for new performers will be strengthened. A review of plasma protein and related product deviations initiated between 2023-02-11 and 2023-04-11 will be completed by 2023-05-31 to determine if improvement has been achieved.

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In the interim, a reminder to complete the base-level investigation was sent to all operational approvers and quality assurance approvers across the organization by 2022-12-22.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

C Christian Choquet

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505