Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2024-11-20
CBS Control #: CBS6850
HPFB File #: C1892-100390
REF: H-2425-HO-W

Craig Turk
Regional Regulatory Compliance & Enforcement Officer
GMP Inspection Central
Regulatory Operations and Enforcement Branch (ROEB)
Health Canada
Government of Canada

Dear Craig:

Re: Responses to Health Canada Inspection of Wholesale Activities at Head Office 2024-10-07 and 2024-10-08

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2024-10-24.

C.02.015 Quality Control Department

1. **The temperature and/or humidity control was inadequate. The calibration, inspection, and/or qualification of the equipment, including computerized systems, was inadequate:**
a) The most recent temperature mapping study for the ambient warehouse, completed in 2012, did not take into account seasonal variations; specifically, there was no winter study performed.

Canadian Blood Services will perform temperature mapping as per current protocol for the defined area the Head Office warehouse. The executed protocol will include seasonal mappings in both heating and cooling modes of the defined area and will include a rationale of the final placement of the on-going temperature monitoring probes based on the mapping data. The planned completion date including review of the executed protocol is 2025-10-31.

In addition, Canadian Blood Services will perform an assessment of other site warehouses that store biological drug products to determine if those applicable areas have been mapped in both heating and cooling modes. The assessment will be used to determine which sites will require supplemental mapping. Mapping of these determined sites will be scheduled following the assessment. The assessment is to be completed by 2025-01-30.

b) There was no requirement to perform re-qualification activities for the drug product storage areas, nor was there a requirement to evaluate existing qualifications at an appropriate frequency with supporting data to ensure that they were still valid. For example, the firm had not assessed whether the temperature mapping studies performed in 2012 for the ambient warehouse, and 2006 for the walk-in refrigerators (R000021270, R000019391, R000021272), were still valid.

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Canadian Blood Services will implement a periodic review process to assess the need to re-validate our drug storage areas. This process will provide Canadian Blood Services with assurances that our drug storage areas remain in control (temperature and humidity) and continue to function as designed. If this review finds that our drug storage areas are not in control, corrective action will be taken and where required re-validation.

The process will be designed, and implementation plan will be developed by 2025-06-01.

2. **The assessment, recording, follow-up, and/or investigation of complaints and/or other information about potentially defective products was inadequate. The firm did not adequately follow-up on complaints, specifically, those that were referred to the manufacturer for investigation (also known as problem notifications). For example, there were problem notifications that had been open since June, 2023 (7703) and December 2023 (7433 and 7434), without any written explanation or justification. This is contrary to the procedure, "Managing Plasma Protein and Related Products Problem Notifications" (WI-00583, Revision 1), which stated that the firm would follow-up with the manufacturer if they had not received a response within 180 days, and that they would document this follow-up accordingly in their SAP system.**

Integrated Supply Chain Planning staff will be trained, or retrained as required, to WI 00583 Manage Plasma Protein and Related Products Problem Notifications to ensure there is a thorough understanding of their role and the requirements in relation to the management of Problem Notifications, specifically highlighting that the information which is entered into SAP must be comprehensive and timely. This will be completed by 2024-12-31.

Following completion of training, all Problem Notifications from June 2023 to current month, inclusive, will be reviewed and updated per the process outlined in WI 00583 Managing Plasma Protein and Related Products Problem Notifications in addition to updating SAP to ensure that it includes all required information. This will be completed by 2025-06-31.

In addition, one Problem Notification from each month prior to June 2023, back to January 2022, will be randomly checked for completion. Should any be found to be incomplete, all Problem Notifications from January 1st, 2022, will be checked and completed, as required. This will be completed by 2025-06-31.

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,

Mr. David Howe
A/Vice-President
Quality & Regulatory Affairs