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2022-04-26
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HPFB File #: C1892-100390
REF: H-2122-CAL-W

Erin Vandendyck
Regional Regulatory Compliance & Enforcement Officer, GMP Inspection West
Regulatory Operations and Enforcement Branch
Health Canada

Dear Erin Vandendyck:

Re: Responses to Health Canada Inspection of Wholesale Activities at Calgary Operations from 2022-03-22 to 2022-03-25

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-03-31.

C.02.014 – Quality control department

1. Contrary to the corrective action response form the firm dated 2020-08-25, procedures and/or contracts have been revised to include guidance from the supplier(s) to make an informed decision regarding the restock of the returned product.

Note: This is a repeat observation from Health Canada's 2020 Initial Inspection, observation #1 (Exit Notice dated 2020-07-21).

DEV-22-002741 was initiated on 2022-04-13.

Canadian Blood Services will send a formal communication describing our processes which allow for the reissue of previously returned plasma protein and related products (PPRP) to each PPRP supplier. A written response will be requested of each supplier by 2022-06-01 and retained as evidence of awareness and acceptance of this process.

C.02.015 – Quality control department

2. There were no written procedures detailing root cause investigations when temperature deviations occur.

The review of investigations during this inspection showed that for deviation reports DEV-20-009010, DEV-21-008032, DEV-21-008827, investigations were not carried out and documented to determine the root causes of the deviations.

Note: This is a repeat observation from Health Canada's 2020 Initial Inspection, observation #2 (Exit Notice dated 2020-07-21).

As a result of the initial observation, several changes were made to the quality event management process work instructions and training materials and were implemented on 2022-03-28. The changes

describe the requirements to document the investigations into the root cause of deviations. Whereas previously some documentation guidelines were provided, these are now requirements. For example: a step was added in work instruction 09 231 Deviation/Minor Quality Event - Operational Review to require an investigation to determine probable root cause for deviations involving plasma protein and related products. The results of these investigations are to be included in the "Final Operational Review Comments" section of the deviation. In addition, a new 14-lesson e-learning module named Deviation/Minor Quality Event Documentation, revision January 4, 2022, was developed and released to describe documentation requirements for all deviation/minor quality event management procedures.

C.02.013 – Quality control department

3. Corrective actions were not implemented and completed in a timely manner.

a) The Quality Unit did not perform their function to ensure corrective actions were implemented. At the time of the inspection, it was observed that the corrective actions had not been implemented contrary to the firm's corrective action response dated 2020-08-25 to address the observations #1 and #2 from the Health Canada initial inspection on 2020-07-14. There was no rationale or justification for the lack of implementation of corrective actions.

b) In regards to the change request titled "High Complexity: Segregation and Identification of Quarantined PPRP" (dated 2022-02-03), the change request was still in draft form and had not yet been approved at the time of this inspection. This change request was created as a result of the audit observations received during the Health Canada GMP Wholesale audits at the Winnipeg site (inspection date of 2021-08-09), Dartmouth site (inspection date of 2021-10-18) and the Vancouver site (inspection date of 2021-11-16). There was no documented rationale to explain the lack of approval and implementation of the change request.

Canadian Blood Services acknowledges that as part of its audit management process the quality unit needs to ensure that defined corrective actions are implemented. This gap will be closed by 2022-08-31.

C.02.014 – Quality control department

4. Written procedures mentioned "physical segregation" and "signage" (for example, in SOP "Managing Retrievals for Plasma Protein and Related Products – sites rev 8, WI 12 802"), but did not detail the site's physical quarantine practices which included the use of quarantine cages, visual signs, tamper indicating devices (TIDs) and stanchions. There were no detailed instructions in procedures for the physical marking and segregation of returns and quarantined products although electronic quarantine procedures were in place.

A minimum standard of how plasma protein and related products will be physically and visually segregated will be defined in procedures.

The associated procedures will be assessed and revised by 2022-12-12 to include requirements for identification of quarantine locations including physical markings as well as segregation requirements for quarantined, recalled, on hold and returned products. This is an extension to the work already underway, which has identified operational challenges to standardization given differences in space and storage capacity at each wholesale location, thus requiring additional work to ensure an operationally feasible solution for all sites.

C.02.015 – Quality control department

5. There were no written procedures and records for the conditioning of the temperature monitoring devices (TMDs) that were used for shipment of product.

Work instructions will be developed and/or revised to reflect temperature monitoring device conditioning requirements/specifications and to capture that the conditioning time has been met prior to use by 2022-12-12.

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,

Christian Choquet

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

cc: Betty Palma
Regional Regulatory Compliance & Enforcement Officer
Regulatory Operations and Enforcement Branch