Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2024-02-02
CBS Control #: CBS6785
HPFB File #: C1892-100390
REF: H-2324-WIN-L

Jodie Leiman
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba R3C 4W1

Dear Jodie:

Re: Responses to Health Canada Inspection of Licensed Activities at Winnipeg Operations 2023-11-06 to 2023-11-10

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-11-24.

Section 23 - Establishment Licences

1. The establishment did not notify Health Canada in writing within 30 days after it stopped conducting a licensed activity.

Canadian Blood Services (CBS) Winnipeg Operations personnel in Component Production documented in an email dated July 10, 2023 that production of cryoprecipitate and cryosupernatant had ceased effective immediately. Further, the email indicated staff training and competency requirements would be adjusted to reflect the change.

DEV-23-009586 was initiated on 2023-11-10.

The Blood Establishment Licence amendments with the removal of cryoprecipitate and cryosupernatant as component preparation activities were received on 2023-11-14 for both Calgary and Winnipeg Operations.

An investigation is on-going to develop a process for the assessment of changes regarding the removal of licensed activities to ensure that regulatory requirements pertaining to licence amendments are met. Target implementation of corrective actions is anticipated for 2024-09-30.

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Section 98 - Personnel

2. The records of staff qualifications, training or evaluation of their competency were not always sufficient.

Personnel training for CO-00037 Product Manual: Component Handling Guidelines was identified in the Initial Training Requirements Matrix form F800304 as required training for specific personnel in component production; however, training of personnel was not completed.

DEV-23-009901 was initiated on 2023-11-21.

As explained during the inspection, work instruction WI-00541 Training Management – Training Developer states that training may be required for compendia at the discretion of the process owner. Both the National Training Matrix and the Training plan identified that no training was required for CO-00037 Production Manual: Component Handling Guidelines Revision 4.

Work instruction WI-00541 Training Management – Training Developer will be revised no later than 2024-09-30 to clarify that compendia, if not trained to directly, is expected to be covered as part of the training to the associated work instructions.

In this case, CO-00037 Production Manual: Component Handling Guidelines Revision 4 was included as part of the training to the change for Apheresis Pathogen Inactivation Technology (PIT) implementation. A Confirmation of Employee Training (CET) (dated 2023-06-02) and associated training plan and Change Communication Memo supporting this was shared with the inspectors at the time of the inspection.

DEV-23-009901 was initiated on 2023-11-21 for the discrepancy between the Local and National Training Matrix. Investigation identified that the Local Training matrix was incorrect for CO-00037 Production Manual: Component Handling Guidelines. It was documented as "A" Awareness and should have been documented as "N"- No Training required, as per the Training Plan and the National Matrix. The local matrix was updated to reflect "N" as per the training plan and national matrix and approved on 2023-11-23.

Section 100 - Equipment

3. The validation, calibration, cleaning, or maintenance of critical equipment were not always sufficient.

a) The preventative maintenance (PM) of some biosafety cabinets (BSC) were not completed by their due date. For example, the BSC in Room 363, R000003943 was due for PM on 2023-11-03 and was observed to be available for use on 2023-11-06.

DEV-23-009428 was initiated on 2023-11-07.

Out of Service tags were affixed to the affected equipment on 2023-11-06 and the vendor was called in to complete the preventive maintenance (PM) on 2023-11-07. The PM passed without any deficiencies. A review of the work instruction WI-00534 Management of Equipment by Owners was done on 2023-11-22 with applicable Facilities staff and clarity provided that the responsibility of monitoring for PM for the biosafety cabinets resides with Facilities staff.

b) PM records for multiple walk-in-coolers, such as the Walk-in-refrigerator Room 172, R00021305, were not reviewed by the due date of 2023-11-03 as required by WI-00534 - Management of Equipment by Owners (rev 7) and WI-00669 - Refrigeration Inspection and Maintenance (rev 1).

DEV-23-009879 was initiated on 2023-11-20.

An investigation as part of the deviation was undertaken to determine root cause. The individual who performed the review believed that their signature indicated completion of the review and forwarding of the documents to Equipment Services for upload into RAM. Clarification of the signature and date requirement for review was provided to the individual on 2023-11-22. A review of the Walk-in Cooler PM records for the past 3 quarters for all units was undertaken and all records found to be reviewed on PM due date which was the same date that the PM was performed.

Section 117 - Records

4. Records were not always accurate, complete, legible, indelible and/or readily retrievable.

a) The Quality Inspection of Critical Supplies form 1000105559 for SSP+ Platelet Additive Solution (PAS) 500mL, lot #22091355F1, Section 1: Supply was incomplete (ie. Initials and date missing).

MQE-23-003901 was initiated on 2023-11-09.

Details of this error and requirements per WI-00773 Inspection of Critical Supplies were reviewed by Brampton Logistics Shipper/Receivers on 2023-11-14 and Brampton QA Associates on 2024-01-11.

b) The Quality Inspection of Critical Supplies form 1000105559 for CERUS Intercept lot #CE22L16L71, Section 3: Document Verification was incomplete (i.e. checkmark missing to indicate that the supply corresponds to Product Certificate).

MQE-23-003901 was initiated on 2023-11-09.

Details of this error and requirements per WI-00773 Inspection of Critical Supplies were reviewed by Brampton Logistics Shipper/Receivers on 2023-11-14 and Brampton QA Associates on 2024-01-11.

c) **The date for completion of production on form F800910, Batching Record - B2-FP/1st Stage Cryo was recorded as 2021-03-19 while the collection date was 2021-03-08. There were no other dates on the form to determine when component production occurred.**

MQE-23-003911 was initiated on 2023-11-10.

Production records were reviewed and staff was able to verify the correct date of 2021-03-09 from the test pending report.

Production staff were made aware of this observation at the time of Health Canada Inspection.

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