



**Canadian  
Blood  
Services**

BLOOD  
PLASMA  
STEM CELLS  
ORGANS  
& TISSUES

1800 Alta Vista Drive  
Ottawa ON  
K1G 4J5  
Canada

2021-11-22

CBS Control #: CBS6602

HPFB File #: C1892-100390

REF: H-2122-EDM-W

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

Dear Ms. Vandendyck:

**Re: Responses to Health Canada Inspection of Wholesale Activities at Edmonton Operations  
from 2021-10-12 to 2021-10-15**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-10-22.

**C.02.024 - Records**

1. **The firm was unwilling and/or unable to provide sufficient information to verify compliance on their self-inspection program.**
  1. **Records for the self-inspection program were incomplete or missing. The first and third pages of the 2018 self-inspection report were reviewed. At the time of the inspection, the 2021 self-inspection report was still in progress. The records for the results of their self-inspection program, evaluation and conclusions, and corrective measures implemented were not available.**

*During the audit of the wholesale activities in Edmonton the following documents relating to the 2018 self-inspection were requested and reviewed:*

- *the standard operating procedures,*
- *the audit plan,*
- *the audit checklist,*
- *the executive summary,*
- *the audit report signature page, and*
- *a listing of the number of observations and their criticality.*

*In addition to these documents, the process was explained using examples from the 2018 self-inspection, where an observation was tracked from response to corrective action, and finally through to CAPA.*

*Canadian Blood Services believes that the information provided and reviewed to date is sufficient to verify compliance. If there are any specific elements of the program that could not be provided, Canadian Blood Services is certainly open to discussing this matter.*

Canadian Blood Services acknowledges that the 2021 self-inspection while still in progress, is on schedule. Once completed, the additional audit documentation, as listed above, will be forwarded to your attention no later than November 26, 2021.

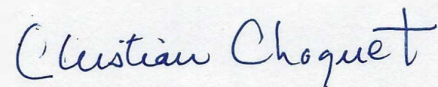
- 2. Pertaining to the 2018 self-inspection, there was no evidence that corrective actions, their implementations and effectiveness were reviewed by senior company management in a timely manner.**

*As per SOP 08 031, Quality Audits, the quality audits group are responsible for tracking promised actions for observations until closure and ensuring they are completed in a timely manner. All Quality Audit reports, including corrective actions are reviewed and approved by senior management.*

*In addition to the documents provided as referenced in response to observation 1.1, an example from the 2018 self-inspection was provided to demonstrate how observations are tracked from response to corrective action, and finally through to CAPA and closure.*

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,



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