Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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Canada

2020-08-25
CBS Control #: CBS6427
HPFB File #: C1892-100390
REF: H-2021-CAL-W

Sandi Dube
Regional Regulatory Compliance and Enforcement Officer
Regulatory Operations and Enforcement Branch (ROEB)
Health Canada

Dear Sandi:

Re: Responses to Health Canada Inspection of Wholesale Activities at Calgary Operations 2020-07-14 to 2020-07-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-07-21.

C.02.014 – Quality Control

1. The assessment, documentation, and/or procedures for considering the resale of returned drugs were inadequate.

The procedure for the evaluation of returned goods was deficient as follows:

A. There was insufficient evidence that guidance was obtained from the supplier to make an informed decision pertaining the restock of the returned product.

Organization will undertake the assessment of current processes and procedures in consultation with the suppliers of plasma protein products, as they relate to obtaining the guidance from the supplier regarding the restocking of the returned products. The identified amendments to procedures or contracts will be revised by 2021-04-01.

C.02.015 - Quality control department

2. Investigations into deviations, reports, and/or follow-up actions were inadequate. Temperature excursions were not thoroughly investigated according to a written procedure, and there was insufficient follow-up action taken after evaluation of the excursion. For example:

A. QER# 56-18-136830 - Temperature monitoring device in alarm for 25 minutes on 2018-07-24, during shipment of the refrigerated product (2-8 degrees Celsius) Cuvitru 20% 5ml/ 1g, Lot# LE13S005AE. There was no documented investigation to determine the root cause of the temperature excursion; whether it was due to the shipping container or the conditions in the transportation vehicle.

B. QER# 20-19-140864 - Plasma Protein Product storage room 610 with High Threshold alarm, greater than 25 degrees Celsius for 4 hours 1 min, on 2019-07-23. The temperature

excursion was not recorded with all the original details, explaining the investigation into the root cause and the resolution. Note: This information was requested and provided during the inspection

Combined response to 2a and 2b:

With the implementation of the "Quality Event Management" module in the EtQ Reliance software on 2019-10-28, the Deviation/Minor Quality Event management process has been automated. The system has been configured to include several mandatory questions that prompt the user to provide a more detailed description of the quality event, as well as the impact assessment and immediate actions taken. All users of the Quality Event Management module underwent training and the documentation expectation were reiterated in the training provided.

The Quality Event Management process is being evaluated with respect to the current risk assessment and investigation of low risk events. In depth analysis is being conducted, and a strategy will be developed by 2020-10-30.

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
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