Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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2019-01-08
CBS Control #: CBS6227
HPFB File #: C1892-100390
REF: H-1819-HO

Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

Re: Further to the Responses to Health Canada Inspection of Head Office 2018-07-09 to 2018-07-13

The following are the actions undertaken by Canadian Blood Services in response to the email dated 2018-10-02 requesting additional information for observations to the Exit Notice dated 2018-08-08.

Section 94 – Quality Management System

3. The Quality Event Management system is not followed consistently by staff to ensure errors and accidents are thoroughly investigated. For example,

a) The defined criteria for determining the scope of an investigation are not consistently followed:
i. To ensure all processes, equipment, supplies, personnel, etc. are identified, assessed and evaluated.
ii. To evaluate whether the issue applies locally or nationally.
iii. To ascertain whether the point of discovery (i.e. prior to release or after distribution) signifies potential risk to control of processes.

b) The criteria for assessing the categories used to perform the Risk Assessment of an issue were not sufficiently defined to ensure consistent assessment.

Combined Response for 3a and 3b:

An evaluation of quality event reports will be conducted to assess the extent of the inconsistency. Based upon the assessment, appropriate corrective actions will be identified by 2018-12-07.

In the interim, consistent application of the Quality Event Management (QEM) process will be reinforced by 2018-09-28 with the quality assurance management team as all quality events are reviewed by quality assurance for appropriateness of actions and completeness of documentation.

Health Canada Follow-up email dated 2018-09-11:

Comment:
The current process for performing risk assessment of a quality event is contingent on the thoroughness of the investigation and its documentation of the incident to include all processes, equipment, supplies, personnel, etc. This appears to be a weakness in your current system which may contribute to events being risk rated at a lower level. In addition, the process is highly subjective without clear criteria for performing the risk assessment to ensure consistency.

The comment has been acknowledged and will be considered in our efforts to continuously improve this process.

Health Canada Follow-up email dated 2018-10-02:

We request that CBS provide Health Canada with a summary of the evaluation of quality event reports including any corrective actions deemed appropriate and their proposed implementation timelines, as outlined in your combined response to 3a and 3b of the above response letter. The written summary must be submitted to the undersigned by December 31, 2018.

A subset of 157 past quality event reports generated over the period of 2018-01-01 to 2018-09-10 was randomly selected for review. This review confirmed the effectiveness of the process in the containment and dispositioning of products, the primary objectives of the quality event management process, in that all affected products, in all cases, were contained and dispositioned appropriately. The quality event reports were also reviewed to determine if the risk assessments were done correctly to trigger the CAPA process. It was identified that all quality events that should have triggered a CAPA did so. The review identified various documentation issues and a plan of action to address these issues with quality event management initiators, reviewers and approvers is being developed.

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: Shelley Smyth
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch