HÉMA-QUÉBEC

BERD INSPECTION OF HQM FROM MARCH 10–14, 2003

OBSERVATIONS AND RESPONSES

WHOLE BLOOD—Manufacturing Control—C.02.011

1. Contrary to GMP CFA-INS-003, numerous procedures had not been updated in several years.

Response: At present, the GMP review process is in progress. All of the departments have identified writers and trained them to write GMPs. All of the GMPs to be revised have been identified.

Each department must finalize its writing schedule for mid-April.

In mid-May, an overall schedule will be prepared, specifying the priorities for the departments. The *Service de la conformité et de l'agrément* (Compliance and Certification Department) will process requests for changes.

Compliance: May 2003

WHOLE BLOOD—Raw Materials Testing—C.02.009

2. The information provided in the blood donation file prepared following a positive response to Question 9b cannot be used to verify that the donor was asked the secondary questions provided in Directives D-CFA-2002-049 and D-CFA-2002-090.

Response: A training module covering the selection interview process as well as a manual explaining BDF documentation for malaria will be developed and implemented in June 2003.

Compliance: June 2003

WHOLE BLOOD—Equipment—C.02.005

3. The collection equipment indicated in the monthly sampling list was not systematically returned to the *Service des équipements biomédicaux* (Biomedical Equipment Department).

Response:

a) An exhaustive audit of the equipment inventory at Héma-Québec is in progress and will be completed by June 30, 2003.

b) A sampling date control and follow-up process will be implemented and harmonized with GMP SEB-INS-015, Sampling Recall Process, now being revised.

Compliance: June 2003

WHOLE BLOOD—Testing of raw materials—C.02.010

4. There was no analysis certificate for the injectable sodium chlorine solution, lot No. W3B26A1, used to wash red blood cells. Corrected during the inspection.

Response: The analysis certificate was received on March 14. A directive concerning the quality control of critical materials, indicating that an analysis certificate is required for the critical material to be released, has been in effect since 03-21-2003: D-CFA-2003-003.

Compliance: March 2003

WHOLE BLOOD—Files—C.02.021

5. The microfilm reconciliation process could not be used to document and verify the traceability of all of the documents received from the sub-contractor.

Response: A new procedure is being drafted. In keeping with this procedure, all Blood Donation File (BDF) forms microfilmed by the supplier will be counted. The supplier will provide a written report comparing the number of BDFs microfilmed with the number of BDFs listed on the control sheet for each blood donor clinic.

A new count will be made by the supplier following any discrepancy. If there is still a discrepancy, the box in question will be verified by Héma-Québec's *Service de la gestion des dossiers donneurs* (Donor File Management (DFM) Department).

Compliance: June 2003

WHOLE BLOOD—Manufacturing Control—C.02.011

6. Qualification of Technical Facilities for Mobile Blood Donor Clinics Form INF-ENR-093.2 was not signed as required.

Response: The technicians who check the equipment before it is sent out for a mobile blood donor clinic were confused with respect to the signatures required at the bottom of Form INF-ENR-093.2.

We requested a modification to Form INF-ENR-093.2 Version 1.0, namely the removal of the blood donor clinic supervisor. Therefore, the signatures of the "checker," namely the person who checks the equipment, and an inspector will be required.

When the new INF-ENR-093.2 Version 2 form is implemented, the technicians will be required to read and sign Directive D-CFA-20002-020, which refers to this new form.

Compliance: April 2003

WHOLE BLOOD—Personnel—C.02.006

7. The following shortcomings were observed with respect to employee training programs:

a) The training files did not always refer to the version of the GMPs in effect (Blood Bank).

b) The training grid occasionally included errors (*Service des equipments biomédicaux* (Biomedical Equipment Department)), although the appropriate training had been given.

Response: In order to prevent documentation errors on qualification certificates, a refresher session was held for the operations training agents. The qualification certificates will be systematically compared to the training grid, documents in effect and new documents to be put into effect. This refresher session was held during the team meeting of Monday, March 24, 2003.

In order to prevent errors in the training grid, Distribution of Draft Procedures Form CFA-ENR-011 will be modified to include the names of all of the departments. The person who issues a draft version of a GMP will identify the departments concerned on Form CFA-ENR-011 and will distribute the GMP. Each department will assess the pertinence of the GMP for their purposes. If the GMP is pertinent, the training personnel for the department will be notified. The training grid will be updated by the individual responsible for the training when the GMP is put into effect.

Compliance: May 2003

WHOLE BLOOD—Equipment—C.02.005

8. There was no signature on some of the intervention request and follow-up forms to document whether the verification was made (COBAS, Cell-Dyn 1200, Sorvall RC3 BP …).

Response: All of the documentation concerning an action taken on the part of an external or internal department will be verified, initialled and dated by a manager of the *Service des equipments biomédicaux* (Biomedical Equipment Department) before the equipment in question is put back into use. GMP SEB INS-013 Controlled Equipment—Documentation Required will go into effect 07-05-2003.

Compliance: May 2003