octapharma

Corporate Quality Plasma

No.: 017SOP125/05 Appendix 6 (Version 00)	**Report of Findings** (CAPA Response Template, & Evaluation Form)
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Official Name & Facility Addresses:

1.) University Hospital Olomouc
Department of Transfusion Medicine
I.P. Pavlova 185/6
CZ- 779 00 Olomouc

2.) Hospital Hranice
Zborovska 1245
CZ- 753 22 Hranice

Audit Date(s): **13./ 14. 06.2018**

A written response (CAPA) is requested **within 21 days** upon receipt.

Please confirm receipt of this report per email.

Please send your CAPA response per email 1) signed, in PDF format, and 2) as corresponding WORD document to the email address provided.

Your CAPA response is to be directed to the attention of Octapharma CQP:

doris.reisinger@octapharma.com

Report Date: 27.06.2018

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*Categories: Critical=**C** / Major=**M** /Other=**O***

HRANICE:

Finding Nr.: 1-5
Category: O

Findings:

- SOPs are not updated in regular intervals.
- Changes are documented manually in the original document.
- Documented training is only performed in case of serious changes.
- The new update of the donor questionnaire did not result in a training for the physician.
- No system for the requalification of personnel in place.

Remark/Reference: *PIC/S GMP Guide*

Corrective Actions (to be completed by audited facility)
SOPs will be update in regular intervals.All changes in SOPs will lead to edition new version of SOP. Documented training will be done after all changes.The new update od the donor questrionnaire was done on June. Requalification of personnel will be done every 2 years.
Target Date: 31.12.2018

Comments to CAPA Response (to be completed by Octapharma)

Finding Nr.: 6
Category: O

Finding:

No clipboards are provided for donors to fill out their questionnaires in privacy.

Remark/Reference: *PIC/S GMP Guide*

Corrective Actions (to be completed by audited facility)
Clipboards will be procured.

Target Date: 31.8.2018

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Comments to CAPA Response (to be completed by Octapharma)

Finding Nr.: 7
Category: O

Finding:

The calibration of the loggers used for the monitoring of transport temperature is performed every third year. Thermometers recording the temperature of the rooms and the fridge (sample storage) are calibrated biannual.

Remark/Reference: *All thermometers and loggers should be calibrated annually.*

Corrective Actions (to be completed by audited facility)
Loggers will be calibrated annualy.
All thermometers will be calibrated annualy.

Target Date: 31.1.2019

Comments to CAPA Response (to be completed by Octapharma)

OLOMOUC

Finding Nr.: 1
Category: O

Finding:

During the review of the results of factor VIII testing it was discovered that several results showed activated factor VIII. No investigations were performed to find the reason for this great number of high factor VIII yield (e. g. equipment error, testing error).

Remark/Reference: *PIC/S GMP Guide*

Corrective Actions (to be completed by audited facility)
Analysis of each and individual steps shall be conducted during control of factor VIII (defrost steps, sample collection, transportation to lab, testing steps). Employees that is preparing samples for testing has been trained. After analysis will be collected new control samples for testing. In the future we plan to evaluate and analyse higher values of factor VIII.

Target Date: 31.8.2018

Comments to CAPA Response (to be completed by Octapharma)

Finding Nr.: 2
Category: O

Finding:

The area around the external freezing chamber, where plasma for Octapharma is stored, is not included in the current Pest Control system (no regular controls, no traps outside the chamber).

Remark/Reference: *PIC/S GMP Guide*

Corrective Actions (to be completed by audited facility)
The pest control at FH Olomouc is done by external company with which is closed contract for that. Requirement to include into control check also place around external freezing chamber has been presented to the company. Monitoring and traps have been required.

Target Date: December 2018

Comments to CAPA Response (to be completed by Octapharma)

Finding Nr.: 3
Category: O

Finding:

Some information given in the hygiene plan and in the attachments to the hygiene plan do not correspond.

Remark/Reference: *All thermometers and loggers should be calibrated annually.*

Corrective Actions (to be completed by audited facility)
The plan of hygiene and their attachments shall be unified.

Target Date: 30.9.2018

Comments to CAPA Response (to be completed by Octapharma)

Recommendations and remarks:

1. Calibration of reference thermometers should ideally be performed in yearly intervals.

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Actions (to be completed by audited facility)

The calibration intervals are determined for each department of FH Olomouc by operating deputy person. The department will propose a change in the calibration interval, and at the same time will propose for the tender purpose an external company that will perform at FH Olomouc validations, in order to request an annual calibration interval.

2. The regular control of the emergency kit in the collection area should be documented as it was done in the past.

Actions (to be completed by audited facility)

This list does not claim to be an all-inclusive list of the deficiencies/improvements that may exist for this center. It only reflects the observations made in the scope of this specific visit for the areas and procedures observed.

References:

- Current Octapharma QA Agreement including annual updates
- Applicable national and international guidelines, directives and laws
- PIC/S GMP Guides PI 008-03, PI 023-2
- Current Pharm. Eur.: Human Plasma for Fractionation
- Current Pharm. Eur. Monograph "Human Plasma (Pooled and treated for Virus Inactivation)", current version
- Octapharma SOP 017SOP125: Audit of plasma suppliers

⇨ **Supportive materials should be submitted with your response (e.g. digital photos, SOPs, training records) where applicable.**

List of attachments (please indicate related finding number):

1.
2.
3.

CAPA RESPONSE DATE:

octapharma

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Submitted by *(Name & Position)* / **Signature:** _____

MUDr. Dana Galuszková, Ph.D., MBA
Head of Department

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(to be completed by Octapharma)

Auditor(s): Doris Reisinger

Facility Type: ☐ Plasma Supplier ☐ Testing Laboratory ☐ Other:_____

Audit Type: ☐ Qualification ☒ Routine ☐ Follow-Up ☐ Focused

Audit date(s): 13./14.06.2018

CAPA HISTORY

Date of initial response:

1° _____ ☐ acceptable ☐ not acceptable

Follow-up response dates: ☐ not applicable

2° _____ ☐ acceptable ☐ not acceptable

3° _____ ☐ Acceptable ☐ not acceptable

Follow up audit necessary? ☐ not applicable

☐ yes: Comments /Reason _____

Audit Outcome:

Audit Closure:

☐ passed

☐ failed

For qualification audits or critical findings only:

Auditor _____
(Date & Signature -stamp)

Head of CQP _____
(Date & Signature -stamp)