Shire

Supplier Audit Report

Supplier Name & Site Location:	**F.N. Olomouc Transfuzni oddeleni** **I.P. Pavlova 6** **CZ-775 20 Olomouc** Subcontractor Prerov and Hranice see separate Audit Report
Trackwise ID:	**#1279077**
Audit Date(s):	**12. & 15.03.2018**
Supplier Contact Personnel:	**Prim. MUDr. Dana Galuszkova** Dana.Galuszkova @fnol.cz
Supplied Products / Services:	**Plasma obtained by whole blood collection** **Plasma obtained by Apheresis (Olomouc only)**
Lead Auditor:	**Heinz Krausz**
Co-Auditor:	**Eva Brosenbauer**
Translator:	**Lenka Musilova** (CZ Translator Shire) **Adela Horakova** (CZ Translator FN Olomouc)
Type of Audit:	☐ Initial / Qualification ☒ Maintenance ☒ For-cause audit ☐ Other:
Audit Classification:	☒ Satisfactory ☐ Unsatisfactory

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Scope / Objectives of the Audit:	The purpose of this visit was to provide a systematic and independent assessment to verify the effectiveness of your quality systems and technical capabilities with reference to Shire BioLife requirements, regulations and standards which include, but are not limited to: • **Buildings and Facilities** • **Change Control** • **Corrective and Preventive Action / Nonconformity Management** • **Follow up of the previous BioLife Audit** • **Document and Record Controls** • **Equipment Maintenance, Calibration, Cleaning** • **Hygiene Regime incl. Pest Control** • **Identification and Traceability / Donor Selection / Donation Process** • **Plasma processing / Plasma freezing / Plasma storage/** • **Transport** • **Information Technology: Verification / Validation / Documentation** • **Internal Audits** • **Laboratory Controls** • **Management Responsibility / Quality Management** • **Materials Management** • **Look Back Process** • **Supplier Quality Management** • **Training Plans, Documentation and Qualification** • **Validation**
Applicable Regulation, Standard and Guidance:	• **Regulatory Standards** • **GMP Standards** • **Shire BioLife Requirements**
Distribution:	• **Dana Galuszkova** (Prim. Olomouc) • **Lenka Musilova** (Shire CZ Translator) • **Robert Weiss** (Shire QA BioLife Europe) • **Rene Büchel** (Shire Plasma Procurement Europe)

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Lead Auditor	
Lead Auditor Print Name:	**Heinz Krausz**
Lead Auditor Signature:	i.A. Eva Brosenbauer
Date (DD-MM-YYYY):	20.03.2018
Management Approval	
Lead Auditor Management Print Name:	**Monika Käfer**
Lead Auditor Management Signature:	
Date (DD-MM-YYYY):	20.03.2018

Executive Summary			
	Quantity	**Quality System Element / Process**	**Applicable Regulation, Standard and / or Guidance**
Critical Observations	**N/A**	**N/A**	**N/A**
Major Observations	**N/A**	**N/A**	**N/A**
Minor Observations	**3**	**Document and Record Controls** **Materials Management** **Supplier Quality Management**	**EU GMP , Vol. 4** **Shire Min. Requ.**
Recommendations / Comments	**N/A**	**N/A**	**N/A**

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History of Company / Organization

The blood bank of F.N. Olomouc TO supplies plasma (SP, RP) to Shire. They have 5 contract partners for RP: Prerov, Hranice, Vsetin and Jesenik (Prostejov for Autotransfusion). Recoverd Plasma supplied to Shire only from the subcontractors Prerov, Hranice and Vsetin.

IT System: TIS Stapro s.r.o. Version 5.34.13 from 31.10.2016
Central Temperature Monitoring: Condata
eSOP Management: ENVIS LIMS
Equipment: 7x Haemonetics PCS2, 3x Haemonetics MCS+, 2x MABG shock freezeer, 1x Dometic MBF21shock freezer, 2x Haier DW-401508 Mracici box (unreleased plasma storage), 2x walk in freezing cell (released plasma storage), 4x Biomixer 330, 3x JMS Dual Press, 4x Cryofuge 6000i, 1x Eppendorf centrifuge for tubes.
Staff: 7 MD, 25 nurses, 23 lab technicians, 14 paramedic, 4 helper, 5 admin, 3 university degree

Laboratory SE: 2x Architect Plus i2000 SR (screening infection serology), Sysmex KX21N (blood count), Techno DiaMed (AB screening)
Laboratory NAT: Shire BioLife Vienna

Source Plasma Set: Haemonetics SC 692 und SC 627
Whole Blood Set: JMS- 1JM8318307, Macopharma LQT 6280LU

The subcontractors are supplied by Olomouc with released blood sets, vials and barcodes labels.
LB / PD to Shire is done central from Olomouc.

Quality / Regulatory Status of Company	
Audits from regulatory authorities: (Examples, dates & results)	**National Health Authority:** 13.-16.09.2016 **BioLife Audit:** 20.-21.07.2016 (Routine Audit), 23.03.2017 (IT Audit) **All Satisfactory**

Status of Corrective Actions from Previous Audits

All observations from the previous Audits are closed satisfactory.

Major Changes since the last Shire Audit and planned Changes

- New sets for Whole Blood collection: Macopharma LQT 6280 LU (08/2017)
- New freezing box Haier DW-401508 Mracici box (unreleased plasma S20 and S21)

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FACILITY TOUR OVERVIEW

- Donation: follow the way of the donor and product during collection, storage of soft goods, preparation of transport (whole blood collection, blood samples)
- Production: follow the way of the product from arrival to final packaging, centrifugation, separation, plasma freezing, plasma storage
- Laboratory: follow the way of blood samples until data transfer of the test results to the donor management system.

DOCUMENT / SYSTEM / PROCESS REVIEW SUMMARY

Buildings and Facilities: Donation Area Production Area Laboratory Area Storage Areas	Chapter 3	
Change Control: CC 16/2017 (New sets for whole blood collection) SOP-TO-02	Chapter 1	
Corrective and Preventive Action / Nonconformity Management: Deviation N 03/2018 (Shire Complaint) Deviation N 01/2018 (Laboratory Olomouc) Complaint to Hranice 13/2017 SOP-TO-13	Chapter 1	
Document and Record Controls: SOPs Protocols	Chapter 4	X
Equipment Maintenance, Calibration, and Cleaning: Maintenance and cleaning of donation and production equipment Calibration of temperature devices / sensors incl. alarm test Check of alarm limits Logbooks (incl. service protocols) Temperature trends and alarm limits SOP for ZM EXP-04	Chapter 3, Annex 15	

<12.&15.03.2018> Audit of: <Olomouc>

Hygiene Regime incl. Pest Control: Cleaning Protocols Hygiene Plan Microbiological Monitoring (donation and production) Pest Control (hospital contract) SOP-TO-03 SOP-PI-ODB-01	Chapter 3	
Identification and Traceability / Donor Selection (iQPP): Way of the donor Donor registration and selection Donor questionnaire, donor register card Donation process	Chapter 4	
Information Technology – Verification / Validation / Documentation: Barcode labels for the donation (blood / plasma bags, sample vials, …) IT documentation of the donation (donor number, donation number, lot number, …)	Annex 11	
Internal Audits: Audit Schedule 2014, 2015, 2016, 2017, 2018 (Internal Audits Olomouc and subcontractor audits)	Chapter 9	
Laboratory Controls: Pre-analytics (storage of blood samples) Blood Count, Infection Serology, Antibody Screening Laboratory data transfer Laboratory equipment maintenance Logbooks (incl. service protocols) Storage of reagents Lot-Number documentation and release of reagents Proficiency testing SOP-PI-LIM-18	Chapter 6	
Management Responsibility / Quality Management: Site Master File, Organization Chart	Chapter 1, 2	

Materials Management: Storage of soft goods Lot-Number documentation and release of sets Alarm limits storage temperature SOP-ODB	Chapter 1, 3, 7	X
Release & Look Back / Post Donation Process: LB HCV, HIV, HBsAg (2014-2018) from Olomouc and subcontractors PD VN02305-18-01 (02/2018) Liquidation protocols IT documentation (perm. / temp. deferral) Results of confirmation laboratory SOP-VYR-03, SOP-VYS-01	Chapter 4, Annex 14	
Supplier Quality Management: Audit contract partners, Audit Plan (2014-2018) Tracking list and assessment of suppliers / partners (yearly trending) SOP for Shire Plasma SOP-VYR-09 V1 01.02.2018	Chapter 1, 3, Annex 14	X
Training Plans, Documentation and Qualification: Qualification and Re-qualification of employees SOP training Signatures and initials of staff members Job description SOP-TO-04	Chapter 2	
Transport – Validation / Temperature Control / Deviations: Documentation of whole blood and sample transport from the subcontractors to Olomouc 12.03.2018 Calibration of temperature sensor in the car (5M327-93) Calibration of temperature loggers for the transport (subcontractors) Transport validation 2014, 2015, 2016, 2017, 2018 (summer, winter) SOP-VYR-02	Annex 14, 15 GDP (good distribution practice)	

Validation: Validation Mabag Freezer #1 05.09.2017 Validation Mabag Freezer #2 02.01.2018 Validation Dometic MBF21 Freezer 28.-31.12.2017 Validation Plasma Storage S2-II, S14, S15, S20, S21 SOP for SF and Plasma Storage PI-VYR-09 SOP for SF Dometic PI-VYR-2 SOP for SF MABAG PI-VYR-22	Chapter 3, Annex 14, 15	
Topics not covered (to be reviewed during next Audit): N/A		

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List of Observations

Observation #1:
Regulation/Standard/Guidance/Quality Agreement Requirement/Company Procedure or Policy not being met: ***Document and Record Controls***
Category: ☐ Critical ☐ Major ☒ Minor
Observation Description:

1. There was no SNC (supplier notice of change) to Shire submitted for the Freezer S20 and S21 (Haier DW-401508 Mracici box unreleased plasma)
2. The Liquidation protocols are signed without date (2nd signature).
3. New or revised SOPs (since 2018) require signatures for SOP created, evaluated and approved. These signatures are done without date.
4. In the PCS2 cleaning protocol 02/2018 Tipp Ex is used.

Observation #2:
Regulation/Standard/Guidance/Quality Agreement Requirement/Company Procedure or Policy not being met: ***Materials Management***
Category: ☐ Critical ☐ Major ☒ Minor
Observation Description:

1. For the storage room "Sklad Materialu" building "N", the temperature specification is 15°C – 29°C.
   The specification is not in accordance to the manufactures requirements, as 0.9% sodium chloride solution (Baxter) should be stored at max. 25°C.

Observation #3:
Regulation/Standard/Guidance/Quality Agreement Requirement/Company Procedure or Policy not being met: ***Supplier Quality Management***
Category: ☐ Critical ☐ Major ☒ Minor
Observation Description:

1. The current Shire Minimum Requirements 10/2017 are not submitted to the contract partners from Olomouc (Hranice, Prerov and Vsetin). This is why documents from the subcontractors are not updated acc. to the current Shire Minimum Requirements (e.g in respect to LB/PD, MSM permanent deferral).

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List of Recommendations / Comments

Recommendation / Comment #1: N/A

For each CRITICAL, MAJOR or MINOR nonconformity, please provide a response within **30 days** from receipt of this report that includes the following:

- Immediate correction(s) made
- Root Cause(s)
- Corrective action plan with expected completion date(s)

Once actions have been documented in the response as completed/performed, please provide all documentation necessary to demonstrate the action has been implemented.

Parent Document(s): VV-00674637 / TO SOP-0067, Supplier Quality Audit Procedure