



SUPPLIER AUDIT CLOSURE MEMO

Audit Record Number	1540092
Audit Date(s)	15 March 2021
Company Name and Site Address	Fakultni nemocnice Olomouc I. P. Pavlova 185/6 Olomouc, 77900 Czech Republic
Host Contact Information	Dana.Galuszkova@fnol.cz Prim. MUDr. Dana Galuszková, Ph.D., MBA
Product(s) / Services	Source Plasma derived by Apheresis Recovered plasma derived from Whole Blood Donations
Audit Type	<input type="checkbox"/> On-Site <input checked="" type="checkbox"/> Questionnaire <input type="checkbox"/> Third Party <input type="checkbox"/> Other: A Questionnaire Audit was performed in accordance to COVID-19 Audit Risk Assessment G-TAK-000469
Audit Sub-Type	<input type="checkbox"/> Initial / Qualification <input checked="" type="checkbox"/> Routine / Maintenance <input type="checkbox"/> For Cause <input type="checkbox"/> Other: _____
Audit Scope	<p>The purpose of this questionnaire audit was to provide a systematic and independent assessment to verify the effectiveness of your quality systems and technical capabilities with reference to Takeda requirements, regulations and standards which include, but are not limited to:</p> <p>General</p> <ul style="list-style-type: none"> • Inspections by authority • Contracts • CE Certificates of materials, Declaration of Conformity (from bottles, bags, and anticoagulant) • Implementation of corrective actions from previous audits <p>Laboratory</p> <ul style="list-style-type: none"> • Check of the laboratory area, preparation and handling of samples and related data • Testing, Confirmation Tests, data transfer, participation in proficiency testing • Used kits, CE-Certificates, Declaration of Conformity and storage of kits • Temperature monitoring for reagents • Shipments applying to serology and PCR test samples <p>Process of manufacturing</p> <ul style="list-style-type: none"> • First Time Donor, Qualified Repeat Donor • Donor Selection, Exclusion Criteria, Temporary Exclusion • Tracing the way of an applicant / qualified donor through the donation facility • Tracing the way of a plasma donation from collection to release for pick up • Tracing the production of source plasma with sampling, freezing, release procedures and storage • Look Back and Post Donation



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	<p>Storage and Transport</p> <ul style="list-style-type: none"> • Validation of shock freezers, storage freezers or walk in cells and transport • Temperature monitoring of freezers, fridges storage rooms and transport • Calibration / Temperature Control / Deviations/ Alarm System/ Temperature Monitoring <p>Quality Manual (SOP's) Training (Qualification and Requalification) Cleaning and Maintenance Supplier Qualification Process Buildings and Facilities Change Control Corrective and Preventive Action Document and Record Controls Hygiene Regime incl. Pest Control Information Technology: Verification / Validation / Documentation, Archiving Internal Audits Management Responsibility / Quality Management System</p>
Audit General Information	<p>The questionnaire audit was conducted by Ludwig Semper</p> <p>Additionally, the systems and processes mentioned in the above section "Audit Scope" were also evaluated during the audit.</p> <p>The audit identified (1) major observation and (1) minor observation resulting in a satisfactory audit classification. The observations were related to:</p> <ul style="list-style-type: none"> • Validation (minor) • Takeda Requirements (major)
Closure Statement	<p><input type="checkbox"/> No observations were noted at the time of the audit. No response is required.</p> <p><input checked="" type="checkbox"/> Corrective actions completed and/or proposed corrective action and associated timelines are accepted and will be verified during the next audit Supplier response accepted and no further response is requested.</p> <p><input type="checkbox"/> Supplier has elected not to respond to audit observations.</p> <p>Note - The auditee is ultimately responsible for the execution of any uncompleted corrective actions.</p>
Final Audit Rating	<p><input checked="" type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory</p>

Issued By:



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Print Name:	Ludwig Semper
Signature:	<div>DocuSigned by: Ludwig Semper</div>
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