ON-SITE AUDIT QUESTIONNAIRE OF EU PLASMA INTERMEDIATE STORAGE BEFORE SHIPPING TO LFB

GENERAL INFORMATION ABOUT THE EUROPEAN PLASMA STORAGE SERVICES

Company Name					
Country / State / City					
Site Address					
Organisation Type	☐ Non-Profit ☐ Profit/Remunerated ☐ Compensated				
Site Activity	☐ Plasma Storage ☐ Supplies storage ☐ Manufacturing ☐ Transport				
	☐ Quality Assurance ☐ Data Processing ☐ Other:				
Audit Type	☐ Qualification/Agreement ☐ Re-Qualification/Follow-up ☐ For cause/Post deviation				
Audit Scope (On-Site Audit)	☐ QA/QMS ☐ Data Processing ☐ Vehicles Staging ☐ Manufacturing ☐ Supplies transportation ☐ Supplies Storage ☐ Plasma Storage ☐ Plasma Transportation				
Date of the present audit		Critical issue:	Major issue:	Other issue:	Remark:
Previous audit date		Critical issue:	Major issue:	Other issue:	Remark:
Major changes applied since the previous audit					
EU Certification Status	**EU** certified Yes ☐ No ☐ Date of last **EU** inspection + Outcome: **Member state:** EU Agency name: **Final Outcome (Observation):** Pending ☐ On going ☐ GMP certificate ☐				

QUALITY MANAGEMENT SYSTEM (QMS) (1/2) – GMP CHAPTER 1

Is the **Quality System** based on **EU** Good Manufacturing Practices (**2003/94/EC**) and meets the requirements identified in the Directive **2005/62/EC**?	
1. Is there a Quality **Manual** or equivalent available? **2.** Whether yes, does this document contain a description of the QMS (including management responsibilities)?	**1.** ☐ Yes ☐ No QM Ref: Version: **2.**
Is there a **Site Master file** available (SMF)?	Yes ☐ No ☐ SMF Ref: Version:
1. Is there a **Change control** (CC) procedure available? **2.** If yes, does this SOP define an impact assessment regarding the quality of the manufactured blood products?	**1.** ☐ Yes ☐ No SOP Ref: Version: **2.**
Does the Change control process comply with **EU 2005/62/EC** *(**TS066-§1.1.12**: assignment of a change classification = "Major Impact/Minor Impact/No Impact", based on the impact of the change to product safety, purity, or potency…? to be compliant)*?	☐ Yes ☐ No ☐ NA
In case of a change to an existing process, do you systematically initiate a risk-based approach to prospective validation, as part of the change control procedure?	☐ Yes ☐ No ☐ NA
Do you systematically perform qualification and/or validation prior to implementation of new processes, facilities, systems, equipment, or tests?	☐ Yes ☐ No ☐ NA
Are effects of each change to the system or equipment, as well as its impact on quality and safety, determined to identify the extent of re-validation required?	☐ Yes ☐ No ☐ NA
Are all procedures, premises and equipment that have an influence on the quality and safety of blood and blood components validated before introduction and re-validated at regular intervals ***(2005/62/EC/Annex 1.2.2)***?	☐ Yes ☐ No ☐ NA
Are there **quality indicators** in place, in order to follow quality targets set (SOP to describe the process)? **1.** Are thresholds and acceptable limits available for each sector of activity? **2.** How are Quality indicators managed and followed up (who is involved)? **3.** How would you rate their efficiency? **4.** How are they communicated to the staff? **5.** Do you have periodic reviews summing up achieved and non-achieved quality targets?	☐ Yes ☐ No ***Provide example of quality indicators*** **1.** **2.** **3.** **4.** **5.** ☐ Yes ☐ No Frequency:

QUALITY MANAGEMENT SYSTEM (QMS) (2/2) – GMP CHAPTER 1

Are there systems in place to ensure that deviations and non-conformances are documented, investigated for causative factors of any defect and, where necessary, followed up by the implementation of corrective actions to prevent recurrence?	☐ Yes ☐ No		
Name of software system in use to trace and follow deviations/gaps (notification, CAPAs, closure…)			
Is there a SOP in place to manage and follow deviations, deficiencies and errors system? *(An appropriate level of root-cause analysis should be applied during the investigation of deviations, suspected product defects, and other problems: EDQM Ed 19-§**1.2.13**)*	☐ Yes ☐ No	SOP Ref:	Version:
Did your organization update the QMS to reflect current EU- GMP guidelines **2005/62/EC (directive 2016/1214)** regarding?			
1. Involvement of the top Management?	**1.** ☐ Yes ☐ No	Ref:	Version:
2. Root cause analysis?	**2.** ☐ Yes ☐ No	Ref:	Version:
3. Continual Quality Improvement (CQI)?	**3.** ☐ Yes ☐ No	Ref:	Version:
Is there a SOP in place for **CAPAs** implementation?	☐ Yes ☐ No	SOP Ref:	Version
1. Data are routinely analyzed to identify quality problems that may require corrective action or to identify unfavorable trends that may require preventive action. ***(2005/62/EC/Annex 9.4.2)***	**1.** ☐ Yes ☐ No		
2. All errors and accidents must be documented and investigated in order to identify problems for correction. ***(2005/62/EC/Annex 9.4.3)***	**2.** ☐ Yes ☐ No		
3. Are the CAPAs system ensured that existing component non-conformity or quality problems are corrected, and that recurrence of the problem is prevented?	**3.** ☐ Yes ☐ No		
Are there **scheduled meetings** to review & follow quality targets (frequency, who does what)?	☐ Yes ☐ No	Frequency:	
What is the date for the latest Management review meeting? ***Could you provide this document to review on-site***			

PERSONNEL AND ORGANIZATION (1/2) – GMP CHAPTER 2

General Organization List the personnel participating in the management review by categories only (no name)?			
Number of employees / personnel (staff)	Total:	Part-time:	Half-time:
	Number of managers		
	Name and job position of Key people		
	Quality Department		
	Warehouse Department		
	Drivers		
	Others:		
Key Personnel 1. Is there an organizational chart available? ***Provide the organizational chart***		1. ☐ Yes ☐ No Ref:	Version
2. Are the relationships between key personnel clearly shown in the managerial hierarchy?		2. ☐ Yes ☐ No	
Job Position Are there job descriptions available for all employees/managers? 1. Do the employees in responsible positions have adequate authority to carry out their responsibilities? *(2005/62/EC/Annex 2.2)*		☐ Yes ☐ No ***Provide example of job position per staff category*** 1. ☐ Yes ☐ No	
2. May their duties be delegated to designated deputies of a satisfactory qualification level in case of their absence?		2. ☐ Yes ☐ No	
Are the job descriptions regularly reviewed and updated? ***Provide example of job position per staff category***		☐ Yes ☐ No Frequency:	
Competency / Training Is there a SOP in place to qualify personnel before they start a job *(tutor system, working with qualified personnel, qualification table...)*?		☐ Yes ☐ No SOP/Form:	
Is there a training program (initial and continued plan) in place for each employee? ***(2005/62/EC/Annex 2.3)***		☐ Yes ☐ No ***Provide training program for the current year***	
Does training program include Good Manufacturing Practice? ***(2005/62/EC/Annex 2.3)***		☐ Yes ☐ No ☐ NA	
Are the contents of training programs periodically assessed and the competence of personnel evaluated regularly? ***(2005/62/EC/Annex 2.4)***		☐ Yes ☐ No Frequency:	

PERSONNEL AND ORGANIZATION (2/2) – GMP CHAPTER 2		
Did the training program for the year achieve (percentage)?	Year:	Achievement percentage:
Did the evaluation of competence for the year achieve (percentage)?	Year:	Achievement percentage:
Did the Quality objective(s) from previous management review meeting achieve (percentage)?	Year:	Achievement percentage:
Are there instructions available to ensure as far as is practicable that no person affected by an infectious disease or having open wounds or lesions is engaged in the testing operations?	☐ Yes ☐ No ☐ NA	SOP/Form:
Are there instructions to prohibit eating, drinking, chewing or smoking, or storing food, beverages, or personal-use medications in treatment, in the storage areas?	☐ Yes ☐ No ☐ NA	SOP/Form:
Are there any instructions to prohibit unhygienic practices in prepared areas or in any other area where recovered/source plasma or blood components could be affected?	☐ Yes ☐ No ☐ NA	SOP/Form:
Is there the presence of designated personnel during shipment/reception?	☐ Yes ☐ No ☐ NA	
Who is responsible to sign the transit sheet when loading / unloading completed?		

PREMISES / FACILITIES IN GENERAL (1/3) – GPM CHAPTER 3	
Is there a security system in place to monitor and ensure the integrity of the site and all premises and equipment? ***[Surveillance system for site security with 24-hour video surveillance (7-days a week)]***	☐ Yes ☐ No System Name: Vendor/Security Company:
If an automated security system is in place, is it equipped with interior and exterior surveillance cameras?	☐ Yes ☐ No Number of cameras for the entire location: Number of ''indoor/interior'' cameras: Number of ''outdoor/exterior'' cameras: Number of cameras in the storage areas (cooler room, freezer…)
Is there a procedure in place to manage the surveillance and the security of the facilities?	☐ Yes ☐ No SOP Ref: Version:
Is there a general policy regarding qualification/validation of facilities, equipment, and automated systems in place to ensure compliance with the intended use and regulatory requirement?	☐ Yes ☐ No SOP Ref: Version:
Are the qualification activities considered at all stages from initial development of the user requirements specification through to the end of use of the equipment, facility or system?	☐ Yes ☐ No
1. Is the access to critical premises (storage, server room, …) regulated and controlled? ***(2005/62/EC / Annex 3.4)*** 2. Are there steps in place to prevent the entry of unauthorized people?	1. ☐ Yes ☐ No 2. ☐ Yes ☐ No
Are the storage areas ventilated effectively, with air-control facilities (including temperature and, if necessary, humidity and filtration) appropriate to the operations undertaken?	☐ Yes ☐ No ***(Observation during the tour on-site)***
Are there floor plans for the warehouse?	☐ Yes ☐ No ***Provide the floor plans***
What is the surface of each storage area? How many pallets position of storage are available in each storage?	
Is sufficient space given to avoid mix-ups and cross-contamination?	☐ Yes ☐ No ***(Observation during the tour on-site)***
Do you have special provisions to protect sensitive instruments from vibration, electrical interference, humidity, and extreme temperatures?	☐ Yes ☐ No Doc Ref

PREMISES / FACILITIES IN GENERAL (2/3) – GPM CHAPTER 3

Janitorial / Cleaning Is there a planned Cleaning/Janitorial program (contract, frequency/periodicity, solutions/disinfecting, tasks, service…)? ***Please provide the "Janitorial" contract (name of the company)***	☐ Yes ☐ No Contract No.: Effective date:
Is there a recorded review of the cleaning performed by the labs' employees to check the service provided by the vendor? ***If yes, Please Provide form used for cleaning log for the last 12months***	☐ Yes ☐ No Document Reference: Frequency: ☐ Daily ☐ Twice a week ☐ Weekly ☐ Monthly
Achievement of the planned cleaning program in percentage (previous year and current year: January to now)?	Year n-1: Achievement percentage: Year n: Achievement percentage:
Number of occasion when cleaning was not properly performed (previous year and current year: January to now)?	Year n-1: Number of gaps: Year n: Number of gaps:
Pest Control Is there a planned Pest control program (contract, frequency, solutions, tasks, locations…)? ***Please provide the "Pest control" contract***	☐ Yes ☐ No Contract No.: Effective date: Frequency: ☐ Monthly ☐ Quarterly ☐ 2 × Year ☐ Yearly ☐ Other:
Date of the latest pest control visit on site? ***Please provide the Pest control service tickets for the last 12 months***	Latest pest control date: Document signed: 1. By the Pest control Company ☐ Yes ☐ No 2. By the Customer ☐ Yes ☐ No
Biomedical Waste (BMW) Is there a planned Biohazard waste program (contract, frequency, locations, licensed vendor…)? ***Please provide "BMW Service" contract***	☐ Yes ☐ No Contract No.: Frequency: ☐ Daily ☐ Weekly ☐ 2 × Week ☐ 3 × Week ☐ 2 × Month ☐ Other:
Date of the latest BMW pick-up on site? ***Please provide the Pest control service tickets for the last 6 months***	Latest BMW pick-up date: Document signed: 1. By the BMW Company ☐ Yes ☐ No 2. By the Customer ☐ Yes ☐ No
Are the Biohazard waste bins stored in a secured and locked area?	☐ Yes ☐ No Area/room: What is the system for securing the waste areas (key, padlock…)?
Temperature Monitoring Temperature monitoring system, Wireless/CATMS (name, manufacturer, alarm temperature set point…)? ***[CATMS: Centralized Alarm & Temperature Monitoring System]***	CATMS 01: ☐ Yes ☐ No Name: CATMS 02: ☐ Yes ☐ No Name: Thermometers 01: ☐ Yes ☐ No Manufacturer: Thermometers 02: ☐ Yes ☐ No Manufacturer:
What is the Frequency of temperature monitoring? ***(For each system used)***	☐ 2 × Day ☐ Daily 2 × Week ☐ Weekly ☐ Monthly ☐ Other (in particular for manual thermometer):

PREMISES / FACILITIES IN GENERAL (3/3) – GPM CHAPTER 3	
CATMS: What is the Frequency of calibration of the probes/sensors?	☐ Weekly ☐ Monthly ☐ Quarterly ☐ Biannually ☐ Yearly
Thermometers: What is the Frequency of the battery change?	☐ Monthly ☐ Quarterly ☐ Biannually ☐ Other:
In case of the CATMS is unable to record temperature electronically, is there a back-up system (manual or other, power generator, Min/Max thermometer…)?	☐ Yes ☐ No Type of back-up:
In case of the thermometers are unusable or damaged to record temperature manually, is there another system to check the temperature?	☐ Yes ☐ No Type of back-up:
What is the acceptable temperature range in storage area of critical supply (CSSA)?	☐ **15-25**°C ☐ **20-24°**C ☐ Others: Alarm temperature set point: Low level: High level:
Number of temperature excursions observed in the critical supply storage area (previous year and current year: January to now)? ***Please provide the temperature excursions dossiers for the last 6 months and the CAPAs implemented***	Year n-1: Number of temperature excursions: Year n: Number of temperature excursions:
Please indicate the maximum duration during which the temperature remained out of range before the intervention of the operator or engineer in the cases above?	
Is there a procedure in place to manage temperature excursions and to define the conduct to be taken to preserve critical supplies/reagents?	☐ Yes ☐ No SOP Ref: Version:
In case of recurrent temperature excursions, is there a SOP or a protocol in place to relocate the critical supply in an alternate storage?	☐ Yes ☐ No SOP Ref: Version:
Is there an existing protocol/back-up process to provide power following a power interruption? ***(e.g.: back-up power generator…)***	☐ Yes ☐ No Type of back-up system

EQUIPMENT AND MATERIALS (1/2) – GMP CHAPTER 4

Is all equipment qualified, calibrated and maintained to suit its intended purpose? *(2005/62/EC/Annex 4.1)*	☐ Yes ☐ No
Is there a general policy as regards of qualification/validation in place to ensure compliance with the intended use and regulatory requirement for items below? **1.** New or modified facilities; **2.** Equipment and materials, automats; **3.** Automated systems; **4.** After repair; **5.** Prior the initial use.	☐ Yes ☐ No SOP Ref: Version: **1.** ☐ Yes ☐ No **2.** ☐ Yes ☐ No **3.** ☐ Yes ☐ No **4.** ☐ Yes ☐ No **5.** ☐ Yes ☐ No
Are all planned changes to the equipment, utilities and processes formally documented and the impact on the quality on blood components assessed?	☐ Yes ☐ No Doc provided:
Are the qualification activities considered at all stages from initial development of the user requirements specification through to the end of use of the equipment or automated system?	☐ Yes ☐ No
Does Installation Qualification (IQ) include? **1.** Installations of components, equipment, piping, instrumentation, and services, checked against up-to-date engineering drawings and specs. **2.** Verification of the correct installation against pre-defined criteria. **3.** Collection and collation of supplier operating and working instructions and maintenance requirements. **4.** Calibration requirements. **5.** Verification of construction materials.	**1.** ☐ Yes ☐ No **2.** ☐ Yes ☐ No **3.** ☐ Yes ☐ No **4.** ☐ Yes ☐ No **5.** ☐ Yes ☐ No
Does Operational Qualification (OQ) include? *(OQ normally follows IQ but depending on the complexity of the equipment, it may be performed as a combined Installation/Operation Qualification (IOQ))* **1.** Tests developed from knowledge of processes, systems and equipment to ensure the system is operating as designed. **2.** Tests to confirm upper and lower operating limits, and /or "worst case" conditions.	*(Completion of a successful OQ allows finalization of calibration, operating and cleaning procedures, operator training and preventive maintenance requirements)* **1.** ☐ Yes ☐ No **2.** ☐ Yes ☐ No
Does Performance Qualification (PQ) include? *(PQ should follow successful completion of IQ and OQ)* **1.** Tests, using production materials, qualified substitutes or simulated blood components proven to have equivalent behavior, under normal and worst case operating conditions. **2.** Tests should cover the operating range of the intended process, unless documented evidence from the development phases confirming the operational ranges is available.	*(PQ is described as a separate activity, nevertheless in some cases it may be appropriate to perform it in conjunction with OQ or Process Validation.)* **1.** ☐ Yes ☐ No *(frequency of sampling used to confirm process control should be justified)* **2.** ☐ Yes ☐ No
Maintenance, Calibration management **1.** Is there regular & planned maintenance to detect/prevent avoidable errors and keep the equipment in its optimum functional state? **2.** Are maintenance and calibration regularly scheduled, carried out and documented according to established procedures? **3.** Is the calibration and monitoring interval determined for each equipment to achieve/maintain a desired accuracy and quality level? **4.** Is calibration and monitoring procedure based on a recognized international standard? **5.** Is calibration status of all equipment that requires calibration readily available?	**1.** ☐ Yes ☐ No **2.** ☐ Yes ☐ No **3.** ☐ Yes ☐ No *(Trending and analyses of calibration and monitoring results are a continuous process)* **4.** ☐ Yes ☐ No **5.** ☐ Yes ☐ No

EQUIPMENT AND MATERIALS (2/2) – GMP CHAPTER 4

Are equipment for measuring, weighing, recording and control calibrated and checked at defined intervals using appropriate methods?	☐ Yes ☐ No
Are critical processes constantly monitored and periodically evaluated to confirm that they remain valid?	☐ Yes ☐ No Periodicity: Doc:
Cleaning / Decontamination Is equipment designed/selected so that it can be thoroughly cleaned (and decontaminated) and stored only in a clean and dry condition?	☐ Yes ☐ No
Are cleaning and decontamination performed according to detailed and written procedures?	☐ Yes ☐ No SOP Ref: Version:
Process Validation *(2005/62/EC/Annex 4.4)* 1. Does the validation show the processes are robust and ensure consistent blood component quality prior to their distribution and routine clinical use? 2. Do the processes undergo a prospective validation program, wherever possible? *(retrospective validation no longer an acceptable approach)* 3. Does the process validation of new blood components cover all intended processes and sites of manufacture? 4. Does the design assume that the validation performed is representative for all process or product settings?	1. ☐ Yes ☐ No 2. ☐ Yes ☐ No 3. ☐ Yes ☐ No 4. ☐ Yes ☐ No
Documentation, Instructions? 1. Are operating instructions available and appropriate records kept? 2. Are instructions for use, maintenance, servicing, cleaning, and sanitation available and adequately described?	1. ☐ Yes ☐ No 2. ☐ Yes ☐ No
Are the adequate records of such tests maintained, including the values obtained prior to any adjustment?	☐ Yes ☐ No
Are calibration reports included the accuracy of any testing equipment and traceability to a national standard?	☐ Yes ☐ No
Are reports and/or calibration certificates reviewed and signed to show acceptance of the document?	☐ Yes ☐ No
Is there a procedure available for each type of equipment that detailing the action to be taken if malfunctions or failures occur?	☐ Yes ☐ No SOP Ref: Version:
Are the failed calibrations mentioned of non-conformance in order to investigate the potential impact?	☐ Yes ☐ No
Are defective equipment labelled clearly as such and, if possible, removed from processing/testing areas?	☐ Yes ☐ No
How are you informed when products are ready for dispatching and picking-up? Contract, periodicity, frequency, point of picking-up, route? **Vitalant** **LifeServe** **Gulf Coast** **Carter BloodCare**	

DATA PROCESSING SYSTEM / INFORMATION SYSTEM (1/2) – CHAPTER 4.2

Data processing software (name, manufacturer, version…)?	Name: Version:
Are the computerized systems, software, hardware, and back-up procedures used by the company? 1. Checked regularly to ensure reliability? 2. Validated before use? 3. Maintained in a validated state?	1. ☐ Yes ☐ No Periodicity: 2. ☐ Yes ☐ No ***Please provide the last validation dossier & associates Change Control*** 3. ☐ Yes ☐ No
Are hardware and software correctly protected against unauthorised use or unauthorised changes?	☐ Yes ☐ No Security audit? ☐ Yes ☐ No (Date / Report?)
Is there a SOP in place to describe the structure and architecture of the IT system (interactions, interfaces, links)	☐ Yes ☐ No SOP Ref: Version:
Is there a system in place to prevent unauthorized access to computers and laptops?	☐ Yes ☐ No Description:
Is there a back-up procedure in place to prevent loss of or damage to data at expected and unexpected down-times or function failures? ***(2005/62/EC/Annex 4.5)***	☐ Yes ☐ No SOP Ref: Version: Periodicity: Record media:
Is there a SOP in place to restore data in order to ensure they are still usable and readable (crash tests)?	☐ Yes ☐ No SOP Ref: Version:
Frequency/periodicity of the restoration of the computerized data to ensure that they are still effective?	☐ Weekly ☐ Monthly ☐ Quarterly ☐ Biannually ☐ Annually ☐ Other:
Is there a SOP in place to describe management, monitoring and traceability of passwords & user profiles? 1. Is there a hierarchy of permitted user access to enter, amend, read or print data? 2. Are methods of preventing unauthorized entry in place? 3. Are personal identity codes/ passwords changed regularly?	☐ Yes ☐ No SOP Ref: Version: 1. ☐ Yes ☐ No Number of levels 2. ☐ Yes ☐ No 3. ☐ Yes ☐ No Periodicity
Is there a validations process in place to monitor upgrade, update or modification of data processing software? 1. Are all changes in computerized systems validated? 2. Is applicable documentation revised accordingly? 3. Is relevant personnel trained appropriately before any change introduced into routine use? 4. Is user-testing included to demonstrate that the system is correctly performing all specified functions both at initial installation and after any system modifications?	☐ Yes ☐ No Plan Ref: Version: 1. ☐ Yes ☐ No 2. ☐ Yes ☐ No 3. ☐ Yes ☐ No 4. ☐ Yes ☐ No
Is the servers' room safe and secured, protected against fire, flooding and non-authorized people?	☐ Yes ☐ No Protection deployed:
Is there an emergency plan in case of failure or breakdown of the IT system to process and release blood products?	☐ Yes ☐ No SOP Ref: Version:

DATA PROCESSING SYSTEM / INFORMATION SYSTEM (2/2) – CHAPTER 4.2	
Is there quality audit performed on the IT system and servers to verify their inviolability and security, and to control if the systems are maintained at all times?	☐ Yes ☐ No By whom: Date of last audit:
Is there an emergency plan available in case of failure or breakdown of the Data Processing System? 1. Power generator periodically checked?	☐ Yes ☐ No Plan Ref: Version: 1. ☐ Yes ☐ No By Whom: Periodicity:
2. Uninterruptible Power Supply) periodically checked?	2. ☐ Yes ☐ No By Whom: Periodicity:
In case of failure or breakdown of the IT system, do you have SOPs for operating in degraded mode?	☐ Yes ☐ No SOP Ref: Version:

DOCUMENTATION / ADMINISTRATION (1/1) – GMP CHAPTER 5	
Name of data management system in use (software name, manufacturer, version, installation date…)	
Authorization of written procedures done by? (Job position)	
Escalation process procedure to raise quality issues?	☐ Yes ☐ No SOP Ref: Version:
Frequency of review/update the SOPs used?	☐ Annually ☐ Every 2 years ☐ Other: By whom: Job position:
Number of procedures in date (up-to-date)?	
Number of procedures with overdue review date?	
% of non-conformities due to transcription error logged for the year?	
Regarding records/reports: percentage of non-conformities due to transcription error logged? (previous year, current year: Jan. to now)?	Year n-1: Number of NC: Year n: Number of NC:
Are electronic data integrity checked periodically?	☐ Yes ☐ No ☐ Monthly ☐ Biannually ☐ Annually Others ☐:
Is Hard copy data integrity checked periodically?	☐ Yes ☐ No ☐ Monthly ☐ Biannually ☐ Annually ☐ Others:
Is the data integrity check periodically performed on traceability data ***(date of the latest evaluation)***	☐ Yes ☐ No Frequency: Last check:
Is there a SOP in place to manage the retention (archiving) of the records / documents?	☐ Yes ☐ No SOP Ref: Version:
Is the storage of archives/retention performed on-site or off-site (outsourcing?)?	☐ On-site ☐Off-site SOP Ref: Version: Vendor name: Contract No:
Is there a temperature and humidity monitoring in place in the retention/archives room?	Acceptable range for temperature monitoring: Acceptable range for humidity surveillance:
Are the archiving facilities restricted to authorized employee?	☐ Yes ☐ No
Is there a disaster plan available and activated to respond to the effects of disasters (fire, flooding, natural disasters, intrusions of unauthorized people…)?	☐ Yes ☐ No SOP Ref: Version:
Is there a SOP in place to qualify suppliers / vendors? *(assessment process to purchase critical supplies)*	☐ Yes ☐ No SOP Ref: Version:
Are the materials and instruments (e.g.: palletizer, dry ice, palletizing film, scales) only purchased from approved suppliers and met the documented requirements and specifications of usage?	☐ Yes ☐ No Suppliers List Ref:
Suppliers/vendors/subcontractors re-qualified on an established and regular basis? ***Periodicity + Process***	☐ On-site audit Periodicity: ☐ Off-site audit Periodicity:

PLASMA STORAGE ACTIVITY (1/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Employee/Personnel Number of key personnel and per categories	Total:	Part-time:	Half-time:
	Director:	Manager:	Supervisor:
	Technician:	QA Specialist:	Clerical:
	Driver:	Other:	Other:

Are there facilities for changing clothes easily accessible, and appropriate for the number of users?	☐ Yes ☐ No
Are restrooms/bathrooms directly open to the storage areas?	☐ Yes ☐ No
Is there a quarantine area/ segregation?	☐ Yes ☐ No
Is there a computerised locking system to prevent quarantine product to be released?	☐ Yes ☐ No
Is there a storage of rejected recalled or returned materials or products?	☐ Yes ☐ No
Storage facilities Is there a floor plan available for the entire cold warehouse?	☐ Yes ☐ No ***Please provide the floor plans***
Are the storage areas under temperature monitoring?	Acceptable range ☐ **15-25**°C ☐ **20-24**°C ☐ Other: Low alarm set: High alarm set:
Name of the Electronic software management for products/plasmas storage	Name: Manufacturer: Version:
1. Are approved, written instructions for preparation existed for each type of component that is produced?	**1.** ☐ Yes ☐ No
2. Is there a process flow for each stage in the manufacturing, including where it is undertaken, and any critical equipment used?	**2.** ☐ Yes ☐ No
3. Are there methods to be used in place for starting up and maintaining critical equipment *(e.g. cleaning, assembly, calibration)*?	**3.** ☐ Yes ☐ No
4. Are there requirements to check that equipment and workstation are clean and suitable for use?	**4.** ☐ Yes ☐ No
5. Are there detailed stepwise processing instructions *(e.g. checks on materials, pre-treatments, critical process parameters such as time and temperature…)*?	**5.** ☐ Yes ☐ No
6. Are there instructions for any in-process controls with their limits?	**6.** ☐ Yes ☐ No
7. Are there requirements for storage of the plasma products and any critical materials and consumables?	**7.** ☐ Yes ☐ No

PLASMA STORAGE ACTIVITY (2/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Plasma Consignments Reception Is there a SOP to record and inspect the plasma consignments and containers upon reception?	☐ Yes ☐ No SOP Ref: Version:
Are there dispatch bays in place to protect incoming/outgoing materials and plasma products *(e.g. items transfer from the truck to the reception area)* and products from the weather? ***(2005/62/EC Article 3.1. / EU-GMP §3.20)***	☐ Yes ☐ No Evidence (photo):
Is the reception area designed and equipped to allow containers of incoming materials to be cleaned?	☐ Yes ☐ No
What is the process used for incoming materials and/or plasma containers? ***(EU GMP 5.2/4.19)***	
Who are the designated personnel overseen the products reception? Who is in charge of the final review of the incoming plasma shipments?	
Plasma Storage *(2005/62/EC/Annex 3.3.5.1)* 1. Are the storage areas provided for appropriately secure and segregated storage of different customers, including quarantine, and released materials and plasma products?	1. ☐ Yes ☐ No
2. Is environment of work area adapted to ensure the work to proceed in a logical sequence?	2. ☐ Yes ☐ No
3. Are lighting and ventilation appropriate and does not adversely affect storage of plasma?	3. ☐ Yes ☐ No
4. Is the capacity of the cold warehouse sufficient for plasma storage?	4. ☐ Yes ☐ No
Is access to storage areas restricted/limited and only accessible to authorized persons? ***(2005/62/EC/Annex 3.3.5.1)***	☐ Yes ☐ No
How are storage locations assigned?	☐ Yes ☐ No
Do you perform regular inventory of the existing stock?	☐ Yes ☐ No
Are there storage areas under temperature monitoring (cold warehouse) *(alarm set point temperature)?*	☐ **-18**°C ☒ **-20**°C or colder ☐ **25**°C or colder ☐ Other: Low alarm set: High alarm set:
Is there an alarm system alerting users in a timely manner to any excursion outside predefined limits?	☐ Yes ☐ No CATMS Name :

PLASMA STORAGE ACTIVITY (3/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Is there a scheduled program to control alarms regularly (who performs the test, periodicity, record….?	☐ Yes ☐ No Vendor: Periodicity:
Who is responsible to check the monitoring of the equipment?	☐ Yes ☐ No Vendor: Periodicity:
Plasma storage parameters: 1. Mapping/remapping (sensors); 2. Identification of cold and warm spots, 3. Calibration of the sensors in the cold warehouse	1. Last mapping: Number of sensors: 2. Cold spots: Warm spots: Alarms: 3. ☐ Semi-annually ☐ Annually ☐ Every 2 years ☐ After repair
Is there an existing protocol in the event of equipment or power failure in the main storage facility?	☐ Yes ☐ No
In the event of failure or of breakdown of the cold warehouses, do you have an emergency plan (transfer of the products to other cold warehouses, operation in downgraded mode, alternative storage…) ***(2005/62 / EC / Annex 3.3.5.2)***	☐ Yes ☐ No
Do you check whether the containers well maintain the integrity and storage temperature of plasma products during storage? ***(2005/62/EC/Annex 7.5).***	☐ Yes ☐ No
Are there procedures in place in case of incoming materials is out of specification (OOS) / Damaged / Broken…?	☐ Yes ☐ No SOP Ref: Version:
Percentage of Non-conformities due to temperature excursion during transport to production?	Year n-1: Number of NC: CAPAs: Year n: Number of NC: CAPAs:
Is there a list of critical equipment for the storage and transportation activity?	☐ Yes ☐ No ***Please provide the list***
Name of the electronic equipment management system in use (e.g. **Infor EAM**, **SAP**…) ***(Description and overview)***	Name: Version:
Are the equipment purchased from approved suppliers?	☐ Yes ☐ No SOP: Version:

PLASMA STORAGE ACTIVITY (4/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Number of manufacturing/processing/production equipment per type of use:

1. Freezer/Walk-In-Freezer	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total:	**Number**	Total:
		Per site:		Per site:
2. Refrigerator/Walk-In-Refrigerator	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total:	**Number**	Total:
		Per site:		Per site:
3. Storage room for final products (Cold room/ Storage Walk-In-Freezer)	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total:	**Number**	Total:
		Per site:		Per site:

TRANSPORT OF PLASMA [VEHICLES / TRUCKS] (1/2)	
LFB auditors would like to visit one or to qualified trucks/trailers in use	
Information about transporter company	Company Name: Number of Drivers:
Are Trucks/Trailers purchased from approved suppliers? *(Supplier qualification)*	☐ Yes ☐ No SOP Ref: Version:
Number of trucks/trailers dedicated for plasma transportation? Is there an up-to-date list of validated vehicles for the transport of plasma from US blood/plasma banks to your storage facilities?	
What is the transport capacity of the trailers dedicated to the transport of the plasma shipments (dimensions: width x height x depth)? How are these trailers equipped *(motor rated Hp, motor rated rpm, rated refrigeration capacity, refrigeration type)* and what materials are used for insulation? What is the payload capacity?	
What is the frequency/periodicity of the Trucks' maintenances? ***(mechanical revision, technical control, engine, brake, tyres…)*** Who is in charge of the truck's maintenances? Are the maintenances recorded and followed-up? (SOP/Form)	
What is the frequency/periodicity of the Trucks' cleaning/hygiene? Who is in charge of the cleaning/hygiene of the trucks? Are the cleaning/disinfecting recorded and followed-up? (SOP/Form)	***Please provide the "Cleaning/Hygiene" contract***
What is the frequency/periodicity of the Trucks' pest control & hygienic? Who is the service provider to whom you entrust the pest control for the trucks/trailers? ***Please provide the Pest control service tickets for the last 12 months***	***Please provide the "Pest control" contract***

TRANSPORT OF PLASMA [VEHICLES / TRUCKS] (2/2)

Is there a system for monitoring and ensuring the security and tampering of trucks and trailers	
Is there a back-up system in place in case of damage, accident, or incident occurring during the transportation?	
Frequency of the performance qualification? Frequency of routine maintenance? Frequency of Internal Quality control (QC)performed on truck/trailer(s)	☒ Monthly ☐ Biannually ☐ Annually ☐ None – Justify: ☐ Monthly ☐ Biannually ☐ Annually ☐ None – Justify: ☐ Daily ☐ Weekly ☐ Monthly ☐ None – Justify:
Latest transport qualification and Validation reports	☐ Yes ☐ No
Do the transportation routes clearly define? Are seasonal and other variations considered during verification of transport?	☐ Yes ☐ No
Does a risk assessment perform to consider the impact of variables in the transportation process other than those conditions which are continuously controlled or monitored? ***(e.g. delays during transportation, failure of cooling and/or monitoring devices, and any other relevant factors)?***	☐ Yes ☐ No
Does performance qualification conduct with extreme weather conditions ***(winter / summer, longest distance, longest duration of transport)***?	☐ Yes ☐ No
Due to the variable conditions expected during transportation, do you perform a continuous monitoring and recording of any critical environmental conditions?	☐ Yes ☐ No
Frequency of the performance qualification?	☐ Monthly ☐ Biannually ☐ Annually ☐ None Justify:
Number of performance qualification not conducted on schedule:	
Frequency of routine maintenance?	☐ Monthly ☐ Biannually ☐ Annually ☐ None Justify:
Number of planned maintenances performed in the previous year:	

TRANSPORT OF PLASMA [VEHICLES / TRUCKS] (3/3)	
Number of curative interventions performed in the previous year:	
Maximum number of reoccurring curative intervention performed on the same vehicle	Type/SN#/ID# Number:
Frequency of Internal Quality control (IQC) per vehicle:	☐ Daily ☐ Weekly ☐ Monthly ☐ None – Justify:
Maximum number of unsatisfactory Internal Quality control per vehicle:	
Access to temperature monitoring system (probes calibration, identification…)	
Is there a complete description of the alarms system in place in the trucks? ***(position/location in the truck, in the trailer)***	
How are alarms handled during plasma transport? When are the alarms triggered, threshold?	

OUTSOURCED ACTIVITIES MANAGEMENT (1/1) – GMP CHAPTER 8

Do you outsource certain activities? ***Provide the List of main outsourced activities***	☐ Transport ☐ Metrology ☐ Pest Control ☐ Cleaning/Janitorial ☐ BMW Management ☐ Others Activity:
Is there a SOP in place to outline how outsourcing activities must be managed?	☐ Yes ☐ No SOP Ref: Version:
Are outsourced activities covered by written contracts covering these activities, the products or operations to which they are related, and any technical arrangements made in connection with? *(Written contract between the **contract giver**: establishment or institution that sub-contracts particular work or services to a different institution and **given acceptor**: establishment or institution that performs particular work or services under a contract for a different institution)*	Transport ☐ Yes ☐ No No. contract: Date Metrology ☐ Yes ☐ No No. contract: Date Pest control ☐ Yes ☐ No No. contract: Date Cleaning ☐ Yes ☐ No No. contract: Date ☐ Others No. contract: Date
Does the contract drawn up between the contract giver and the contract acceptor specify their respective responsibilities relating to the contracted operations?	☐ Yes ☐ No
Does the contract clearly describe who is responsible for purchasing materials, controls and releasing materials/equipment?	☐ Yes ☐ No
Are the preparation and distribution records, including reference samples kept by, or be available to, the contract giver?	☐ Yes ☐ No
Are any records relevant to assessment of the quality of the services (transportation/storage) in the event of complaints or a suspected defect accessible and specified in the defect/recall procedures of the contract giver?	☐ Yes ☐ No
Do you perform external audit of your sub-contractors on a regular basis (scheduled)?	☐ On-site audit: Frequency: SOP Reference: ☐ Off-site audit Frequency: SOP Reference:
What are the standards/referential used for the audit of the outsourced activities?	☐ISO ☐GMP ☐Local Regulations ☐ Other:
Percentage of audit conducted for outsourced activity meet?	Year n-1: Percentage of external audits: Year n: Percentage of external audits:
Number of "For cause audit" for the outsourced activities (non-scheduled)?	Year n-1: Number of "For cause audit": Year n: Number of "For cause audit":

COMPLAINTS/CLAIMS - QUALITY DEFECTS AND PRODUCT RECALLS –GMP CHAPTER 9	
Is there a SOP in place to handle complaints and claims of internal/external clients/customers (litigation, unsatisfied customers, fractionators...)?	☐ Yes ☐ No SOP Ref: Version:
Are complaints and other information, correctly documented and investigated for causative factors?	☐ Yes ☐ No
Are recalled of products or supplies systematically identified and stored separately in a secure area while awaiting a decision on their fate?	☐ Yes ☐ No
What is the number of complaints?	Year n-1: Number of complaints: Year n: Number of complaints:
What is the percentage of quality defect?	Year n-1: Percentage of quality defects: Year n: Percentage of quality defects:
Ways of communication/information escalation with suppliers / vendors / manufacturers…	☐ Mailbox ☐ Phone ☐ Fax/Telecopy ☐ Email ☐ Others:
Ways of communication/information escalation with clients / customers, fractionators…	☐ Mailbox ☐ Phone ☐ Fax/Telecopy ☐ Email ☐ Others:

SELF-INSPECTION, AUDITS AND IMPROVEMENTS (1/1)– GMP CHAPTER 10	
Name of software system in use to trace and follow self-inspection and internal audits (agenda, report, CAPA…)	Name: Version:
Is there a SOP in place to perform self-inspections and/or internal audits? ***(2005/62/EC / Annex 10.1)***	☐ Yes ☐ No SOP Ref: Version:
Is there a program in place for self-inspection and internal audits *(who prepares this planning, what is the frequency)?*	☐ Yes ☐ No SOP Ref: Version:
Self-inspection/internal audits performed according to scheduled plan? ***Provide last audit date for the site and audit report***	☐ Yes ☐ No Date of last audit: Audit Report No.:
Are there documented records for self-inspections & internal audits/ that lead to the implementation of relevant CAPAs?	☐ Yes ☐ No ***Please provide audit reports for example***
Self-inspections/internal audits performed by? (Position / sector of activity)?	
How many internal auditors / trainings of auditor?	Number of auditors: Qualification/training:
What are the standards/referential used?	**ISO** ☐ **GMP** ☐ **JOCE** ☐ **Ph. EU** ☐ Others ☐**:**
Degree of achievement in percentage according to planned schedule (audit performed vs. audit scheduled)?	Previous year: Current year:
Number of deferred planned self-inspection/internal audit?	Number: Reason for deferred audits
Number of unscheduled audits performed?	Number: Reason for unscheduled audits
Number of critical non-conformities per activity?	Number: Level of gravity - - - - -
Number of major non-conformities per activity?	Number: Type of major deviations - - - - -

APPLICABLE REFERENCES [cGMP/NORMS/STANDARDS]

European Pharmacopoeia & Recommendation

Recommendation 95(15) of the Council of Europe entitled "Guide to the preparation, use and quality assurance of blood components" (current version).
European Pharmacopoeia Monograph n°0853 (Human plasma for fractionation).

European Directives/Guidelines:

2001/83/EC on the Community Code relating to medicinal products for human use.
2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, and amending 2001/83/EC.
2004/33/EC implementing 2002/98/EC as regards certain technical requirements for blood and blood components.
2005/61/EC implementing 2002/98/EC of the EU Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions/events.
2005/62/EC implementing 2002/98/EC of the EU Parliament/Council as regards Community standards and specifications relating to a Quality System for blood establishments.
2003/94/EC laying down the principles and guidelines of cGMP in respect of medicinal products for human use and investigational medicinal products for human use.
2016/1214 amending 2005/62/EC as regards to quality standards and specifications for blood establishments.

EU-cGMP for Medicinal Products for Human and Veterinary Use

Annex 01	Manufacture of sterile medicinal products.
Annex 11	Computerized Systems.
Annex 14	Manufacture of MPD from human blood or human plasma.
Annex 15	Qualification and Validation.

EMA Q&A Data Integrity (current version).

Guidelines of EMA Committees: Committee for Medicinal Products for Human (CHMP)

EMA/CHMP/BWP/706271/2010 (February 1, 2012), Guideline on plasma-derived medicinal products.

EMA/CHMP/BWP/548524/2008, rev.1 (08-2016), Guideline on Epidemiological Data on Blood Transmissible Infections.