Direction of Audit and Risk, Plasma Supplier QA

Revised Questionnaire ***MARCH 2022***

ON-SITE AUDIT QUESTIONNAIRE OF EU. PLASMA SUPPLIER

GENERAL INFORMATION ABOUT THE EU ORGANISATION (LFB PLASMA SUPPLIER)

Organisation Name					
License Number (if applicable only relative to plasma production)	No:				
Country / State / City					
Site Address					
Organisation Type	☐ Non-Profit	☐ Profit/Remunerated	☐ Compensated		
Site Activity (principal)	Collection ☐	Manufacturing ☐	Storage(Warehouse) ☐	Collection ☐	
Other Activities,(if exist)	Quality Assurance ☐	IT System (MIS) ☐	Lookback ☐	Quality Assurance ☐	
Audit Type	Qualification/Agreement ☐	Re-Qualification/Follow-up ☐	For cause/Post deviation ☐		
Audit Scope (On-Site Audit)	QA/QMS ☐	IT System ☐	Collection ☐	Mobile Drives ☐	Mobile Staging ☐
	Lookback ☐	Manufacturing ☐	Plasma QC ☐	Plasma Storage ☐	Transport ☐
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					

Manufacturing of Plasma for LFB - **Type of Contain** - **Type of Sample**	Recovered Plasma 24h ☐ Bottle ☐ Bag ☐ Tube ☐ Segment ☐	Recovered Plasma 72h ☐ Bottle ☐ Bag ☐ Tube ☐ Segment ☐	Single/strict Source Plasma (Plasmapheresis) ☐ Bottle ☐ Bag ☐ Tube ☐ Segment ☐	Mixed/Combined Aphaeresis (e.g. Plasma/Platelets) ☐ Bottle ☐ Bag ☐ Tube ☐ Segment ☐
Number of unit collected / processed for the last year	RP24H:	RP72H:	SP24H:	Plasma units obtained from mixed aphaeresis

Donations are from voluntary	Non-Remunerated Donor ☐	Remunerated Donor ☐	Compensated Donor ☐
EU Certification Status	**EU** certified Yes ☐ No ☐	Date of last **EU** inspection + Outcome:	
	EU Agency:	EU Member State:	
	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)?	Yes ☐ No ☐ QM Ref:_____ Version:_____
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?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Does the Change control process comply with **FDA** and **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)?	Yes ☐ No ☐ ***Provide example of quality indicators***
1. Are thresholds and acceptable limits available for each sector of activity?	1. _____
2. How are Quality indicators managed and followed up (who is involved)?	2. _____
3. How would you rate their efficiency?	3. _____
4. How are they communicated to the staff?	4. _____
5. Do you have periodic reviews summing up achieved and non-achieved quality targets?	5. Yes ☐ No ☐ Frequency:_____
Are there systems in place to ensure that deviations, adverse events, adverse reactions and non-conformances are documented, carefully 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 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:_____

QUALITY MANAGEMENT SYSTEM (QMS) (2/2) – GMP CHAPTER 1	
Is there a SOP in place for CAPAs implementation? 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)***	Yes ☐ No ☐ SOP Ref:_____ Version:_____ 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 the corrective and preventive actions system ensured that existing component non-conformity or quality problems are corrected, and that recurrence of the problem is prevented?	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 – 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: _____
	Medical Director: _____	Physician: _____	Supervisor: _____
	Technician: _____	QA Specialist: _____	Clerical: _____
	Collection Staff: _____	Manufacturing Staff: _____	Internal driver: _____
	External driver: _____	Other: _____	Other: _____
Head of Processing/Testing independent from Quality Assurance?			
Key Personnel 1. Is there an organizational chart available?		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?		Yes ☐ No ☐ ***Provide example of job position per staff category***	
1. Do the employees in responsible positions have adequate authority to carry out their responsibilities? *(2005/62/EC/Annex 2.2)*		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) 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:_____ (SOP)	
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, testing, and storage areas?		Yes ☐ No ☐ NA ☐ SOP/Form: _____	
Are there any instructions to prohibit unhygienic practices in prepared areas or in any other area where blood or blood components could be affected?		Yes ☐ No ☐ NA ☐ SOP/Form: _____	

Clerical*: routine documentation and administrative tasks

PREMISES / FACILITIES IN GENERAL (1/2) – GPM CHAPTER 3

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 all planned changes to the facilities, 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, facility or system?	Yes ☐ No ☐
Are the premises including mobile sites located, constructed, adapted and maintained to suit the activities to be carried out? ***(2005/62/EC / Annex 3.3.1)***	Yes ☐..No ☐ ***(Observation during the tour on-site)***
1. Is the access to critical premises (manufacturing, server room, QC lab…) regulated and controlled? ***(2005/62/EC / Annex 3.4)***	1. Yes ☐..No ☐
2. Are there steps in place to prevent the entry of unauthorized people?	2. Yes ☐..No ☐
Are the preparation 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 locations?	Yes ☐ No ☐ ***Provide the floor plans***
Is sufficient space given to avoid mix-ups and cross-contamination?	Yes ☐..No ☐ ***(Observation during the tour on-site)***
Is there an adequate and suitable storage space for sample tubes before shipping to the testing labs and records?	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:_____
Are the facilities for changing clothes and washing/toilet purposes been readily accessible and appropriate for the number of users?	Yes ☐..No ☐
Janitorial / Cleaning	Yes ☐..No ☐ Contract No.:_____ Effective date:_____
Is there a planned Cleaning/Janitorial program (contract, frequency/periodicity, solutions/disinfecting, tasks, service…)? ***Please provide the "Janitorial" contract (name of the company)***	Frequency: Daily ☐ Twice a week ☐ Weekly ☐ Monthly ☐
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 ☐ Doc Ref:_____
	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:_____
Date of the latest Health and Safety audit conducted, If Applicable?	Audit date:_____ Auditor:_____
	Outcome: Satisfactory ☐ Unsatisfactory ☐
Number of major and minor concerns highlighted during this H&S audit? ***Please provide the last H&S audit report***	Number of major concerns:_____
	Number of minor concerns:_____

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

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: Weekly ☐ Monthly ☐ Quarterly ☐ Other ☐_____
Date of the latest pest control visit on site?	Latest pest control date:_____ Doc signed: Yes ☐..No ☐ ***Please provide the Pest control service tickets for the last 12 months***
Biomecial Waste (BMW) Is there a planned Biohazard waste program (contract, frequency, locations, licensed vendor…)? ***Please provide "BMW Service" contract***	Yes ☐..No ☐ Contract No._____ Effective date:_____ Frequency: Daily ☐ Weekly ☐ 2 x Week ☐ 3 x Week ☐ 2 x Month ☐
Date of the latest BMW pick-up on site?	Latest BMW pick-up date:_____ Doc signed: Yes ☐..No ☐ ***Please provide the Pest control service tickets for the last 12 months***
Are the Biohazard waste bins stored in a secured and locked area?	Yes ☐..No ☐ Area/room: _____
Is there specific/dedicated area designated for the safe disposal of waste, disposable items used during testing, and for reactive sample tubes? ***(2005/62/EC/Annex 3.6)***	Yes ☐..No ☐ Area/room: _____
Are the unsuitable units due to reactive viral marker test results quarantined in this designated area? ***(e.g. prison, cage with padlock, etc.)***	Yes ☐..No ☐
Temperature Monitoring Temperature monitoring system, Wireless (name, manufacturer, alarm temperature set point…)?	CAMS:_____
What is the Frequency of temperature monitoring?	Twice a day ☐ Daily ☐ Weekly ☐ Monthly ☐
What is the Frequency of calibration of the probes/sensors?	Monthly ☐ Quarterly ☐ Biannually ☐ Yearly ☐
What is the acceptable temperature range in storage area of critical supply (CSSA)?	**15-25**°C ☐ **20-24**°C ☐ Others: _____
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?	
Number of reoccurrences of temperature excursion in critical supply/product area(s) (previous year, 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:_____
In case of the CAMS 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:_____
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:_____

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

Is equipment properly selected to minimize any hazard to donors, personnel or blood components? ***(2005/62/EC/Annex 4.2)***	Yes ☐..No ☐
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?	Yes ☐..No ☐ SOP Ref:_____ Version:_____
6. New or modified facilities;	6. Yes ☐..No ☐_____
7. Equipment and materials, automats;	7. Yes ☐..No ☐_____
8. Automated systems;	8. Yes ☐..No ☐_____
9. After repair;	9. Yes ☐..No ☐_____
10. Prior the initial use.	10. 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.	1. Yes ☐..No ☐_____
2. Verification of the correct installation against pre-defined criteria.	2. Yes ☐..No ☐_____
3. Collection and collation of supplier operating and working instructions and maintenance requirements.	3. Yes ☐..No ☐_____
4. Calibration requirements.	4. Yes ☐..No ☐_____
5. Verification of construction materials.	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))*	*(Completion of a successful OQ allows finalization of calibration, operating and cleaning procedures, operator training and preventive maintenance requirements)*
1. Tests developed from knowledge of processes, systems and equipment to ensure the system is operating as designed.	1. Yes ☐..No ☐_____
2. Tests to confirm upper and lower operating limits, and /or "worst case" conditions.	2. Yes ☐..No ☐_____
Does Performance Qualification (PQ) include? *(PQ should follow successful completion of IQ and OQ)*	*(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. Tests, using production materials, qualified substitutes or simulated blood components proven to have equivalent behavior, under normal and worst case operating conditions.	1. Yes ☐..No ☐_____ *(frequency of sampling used to confirm process control should be justified)*
2. Tests should cover the operating range of the intended process, unless documented evidence from the development phases confirming the operational ranges is available.	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?	1. Yes ☐..No ☐
2. Are maintenance and calibration regularly scheduled, carried out and documented according to established procedures?	2. Yes ☐..No ☐
3. Are intervals of calibration and monitoring determined for each equipment to achieve/maintain a desired accuracy and quality level?	3. Yes ☐..No ☐ *(Trending and analyses of calibration and monitoring results are a continuous process)*
4. Is calibration and monitoring procedure based on a recognized international standard?	4. Yes ☐..No ☐
5. Is calibration status of all equipment that requires calibration readily available?	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?	1. Yes ☐..No ☐_____
2. Do the processes undergo a prospective validation program, wherever possible? *(retrospective validation no longer an acceptable approach)*	2. Yes ☐..No ☐_____
3. Does the process validation of new blood components cover all intended processes and sites of manufacture?	3. Yes ☐..No ☐_____
4. Does the design assume that the validation performed is representative for all process or product settings?	4. Yes ☐..No ☐_____
Documentation, Instructions? 1. Are operating instructions available and appropriate records kept?	1. Yes ☐..No ☐
2. Are instructions for use, maintenance, servicing, cleaning, and sanitation available and described?	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 ☐

DATA PROCESSING SYSTEM / INFORMATION SYSTEM – 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?	 1. Yes ☐ No ☐
2. Validated before use?	2. Yes ☐ No ☐
3. Maintained in a validated state?	3. Yes ☐ No ☐
Are hardware and software correctly protected against unauthorised use or unauthorised changes?	1. Yes ☐ No ☐
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 ☐
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?	Yes ☐ No ☐ SOP Ref:_____ Version:_____ 1. Yes ☐ No ☐
2. Are methods of preventing unauthorized entry in place?	2. Yes ☐ No ☐
3. Are personal identity codes/ passwords changed regularly?	3. Yes ☐ No ☐
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?	Yes ☐ No ☐ Plan Ref:_____ (version:_____) 1. Yes ☐ No ☐
2. Is applicable documentation revised accordingly?	2. Yes ☐ No ☐
3. Is relevant personnel trained appropriately before any change introduced into routine use?	3. Yes ☐ No ☐
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?	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:_____
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 to process and release tests results (UPS, generator…)? 1. Power generator periodically checked?	Yes ☐ No ☐ Plan Ref:_____ (version:_____) 1. Yes ☐ No ☐ By Who: _____ Periodicity:_____
2. Uninterruptible Power Supply) periodically checked?	2. Yes ☐ No ☐ By Who: _____ 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:_____
Is there a SOP to manage the introductions or corrections of data manually (a double entry, two different employees…?)	Yes ☐ No ☐ SOP Ref:_____ Version:_____

DOCUMENTATION / ADMINISTRATION (1/2) – GMP CHAPTER 5	
Name of Donor 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 ☐ Others ☐:_____ 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 SOP in place to describe notification management sent to the customers in case of positive results found?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
What are the information methods of the clients in the case of results found positive during donor testing?	
Is there a SOP or process in order to notify the customers whether a donor is found with a positive result?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Delay to inform the customer/fractionator in case of positive results?	
Is there a SOP in place to manage/review alerts notification relating to reagents/solutions, collection devices and/or equipment/material?	Yes ☐ No ☐ SOP Ref:_____ Version:_____

DOCUMENTATION / ADMINISTRATION (2/2) – GMP CHAPTER 5

Is there a SOP in place to describe lookback and notification management?	Yes ☐ No ☐ SOP Ref:_____ Version:_____ Is this SOP compliant with EU regulations regarding? – *A look back SOP consists of tracing previous donations and testing of any retained samples within a timeframe of at least 6 months prior to the last negative donation).* – *Data needed for full traceability must be stored for at least 30 years*
Are deferred donor files segregated in locked/secured closet?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is there a SOP or process in order to notify a donor with a positive result?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is there a SOP to block, recall and discard non-conforming blood products available?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Delay to inform the manufacturer in case of non-conformance of quality/safety of plasma for fractionation	Yes ☐ No ☐ SOP Ref:_____ Version:_____
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 Product quality reviews (PQR) available with the objective of verifying the consistency of the existing process and the appropriateness of current specifications in order to highlight trends and to identify improvements of components and process? *(A PQR may also be considered as an instrument for surveying the overall quality status of a blood component and its manufacturing processes, including the collection)*	Yes ☐ No ☐ Date for the latest PQR:_____ _____
Frequency/periodicity of the PQR?	Biannually ☐ Annually ☐ By who:_____
Is there a SOP in place to qualify suppliers / vendors? *(assessment process to purchase critical supplies)*	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Are the reagents and materials only purchased from approved suppliers and met the documented requirements and specifications of usage?	Yes ☐ No ☐ Suppliers List Ref:_____
1. Is there a SOP in place to release the critical materials? *(If relevant, materials, reagents and equipment must meet the requirements of Council Directive **93/42/EEC** for medical devices and Directive **98/79/EC** of the European Parliament and of the Council for in vitro diagnostic medical devices, or comply with equivalent standards in the case of collection in third countries)*	Yes ☐ No ☐ SOP Ref:_____ Version:_____
2. Who is in charge of the release (qualified person to perform this task)? ***(2005/62/EC/Annex 4.3)***	_____
Is there a certificate of release for each batch provided by the Manufacturers of sterile materials (e.g. blood bag systems, anticoagulant solutions)?	Yes ☐ No ☐
Are there acceptance criteria defined by the blood establishment (including at least: material name, manufacturer, compliance with relevant requirements? *(e.g. pharmacopoeias or regulations for medical devices) and confirmation that the materials are sterile and pyrogen-free)*	Yes ☐ No ☐ Doc Ref:_____
Suppliers/vendors/subcontractors re-qualified on an established and regular basis? ***Periodicity + Process***	On-site audit ☐ Periodicity:_____ Off-site audit ☐ Periodicity:_____

MANUFACTURING / PROCESSING / PRODUCTION (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: _____

Manufacturing facilities Is there a floor plan available for the manufacturing facility?	Yes ☐ No ☐ ***Please provide the floor plans***
Manufacturing 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 manufacturing	Name: _____ Manufacturer: _____ Ver.:_____
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 components and any critical materials and consumables?	7. Yes ☐ No ☐
Whole blood/Plasma Reception Is there a SOP to record at reception whole blood units and blood components in the processing area?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Are there receiving/dispatch bays in place to protect incoming/outgoing materials *(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 ☐
Minimal time for processing whole blood/plasma after collection ended?	
Maximal time for processing whole blood/plasma after collection ended?	
Weight of the raw material at reception in the processing area?	Whole blood: Yes ☐ No ☐ Acceptable range:_____ Source plasma: Yes ☐ No ☐ Acceptable range:_____
Back-up sample for fractionator (additional analyses, archive sample)?	Sample tube: Yes ☐ No ☐ Number of tubes + volume:_____ Segment/pigtail: Yes ☐ No ☐ Length of segment: _____
Centrifugation programs (number, parameters…)	Program n°:_____ Speed:_____ Temperature:_____ Time:_____ Program n°:_____ Speed:_____ Temperature:_____ Time:_____

MANUFACTURING / PROCESSING / PRODUCTION (2/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Plasma Freezing Plasma freezing (parameters, freezing cycle, maximum loading, validation of the core temperature…)	For Recovered: Last validation:_____/_____/_____ Max Loading:_____ For Source: Last validation:_____/_____/_____ Max Loading:_____ Revalidation: Annually ☐ Every 2 years ☐ After repair ☐
Freezing time / temperature	**-25**°C in < **1**h ☐ **-25**°C in **2-6**h ☐ **-25**°C in < **12**h ☐ Others ☐ _____
Does the validation of freezing processes consider worst-case scenarios that take into account minimum and maximum loads and positions in the freezer?	Yes ☐ No ☐
Plasma Storage *(2005/62/EC/Annex 3.3.5.1)*	
1. Are the storage areas provided for appropriately secure and segregated storage of distinct categories of blood and blood components, including quarantine, and released materials (recovered/source plasma)?	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 recovered and source plasma storage?	3. Yes ☐ No ☐_____
4. Is the capacity of the cold warehouse sufficient for recovered and source 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 ☐
Storage room: Recovered plasma **#ID (S/N)**_____	Capacity: _____ Temperature range: _____
Storage room: Source plasma **#ID (S/N)**_____	Capacity: _____ Temperature range: _____
Storage room: Transfusable plasma **#ID (S/N)**_____	Capacity: _____ Temperature range: _____
Storage room: Red Cells **#ID (S/N)**_____	Capacity: _____ Temperature range: _____
Plasma storage 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 ☐ CAMS Name _____
Is there a scheduled program to control alarms regularly (who performs the test, periodicity, record….?	Yes ☐ No ☐ Vendor_____ Periodicity_____
Plasma storage parameters:	
1. Mapping/remapping (sensors);	1. Last mapping:_____ Number of sensors:_____
2. Identification of cold and warm spots,	2. Cold spots:_____ Warm spots:_____ Alarms:_____
3. Calibration of the sensors in the cold warehouse	3. Calibration: Annually ☐ Every 2 years ☐ After repair ☐
Have provisions (alternatives) been made in the event of equipment failure or power failure in the main storage facility? ***(2005/62 / EC / Annex 3.3.5.2)*** *(e.g. transfer of products in another cold warehouse, alternate solution)*	Yes ☐ No ☐
Is there a SOP in place to label and release the compliant plasma units?	Yes ☐ No ☐ SOP Ref: _____ Version:_____
Does the release of the plasma/box initiate a computer recording?	
1. Conformity check of labelling and plasma appearance	Yes ☐ No ☐
2. Concordance between units physically present in the box and those indicated on the listings	Yes ☐ No ☐

MANUFACTURING / PROCESSING / PRODUCTION (3/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Do you check whether the packaging well maintains the integrity and storage temperature of blood and blood components during distribution and transportation? ***(2005/62/EC/Annex 7.5).***	Yes ☐ No ☐
Is there a SOP in place to process/manage non-compliant units?	Yes ☐ No ☐ SOP Ref: _____ Version: _____
Is the computer systems designed to control decisions related to inventories and release of blood components able to prevent the release of all blood or blood components considered not acceptable for release?	Yes ☐ No ☐
Is there a preventing release of any components from a future donation from a deferred donor should be possible?	Yes ☐ No ☐
In the event that a final component fails release due to a potential impact on patient safety, does the donor record immediately update to ensure, where appropriate, that the donor(s) cannot make a further donation?	Yes ☐ No ☐
Number of units processed / collected for the year?	Previous Year:_____ Current year:_____
Summary/Inventory of discarded units	
1. Percentage of Donor deferred	Previous year: Current year:
2. Percentage of wasted units due to units mislabeling	Previous year: Current year:
3. Percentage of wasted units due underweight	Previous year: Current year:
4. Percentage of wasted units due to overweight	Previous year: Current year:
5. Percentage of units broken or loss of integrity	Previous year: Current year:
6. Percentage of units not released due to visual aspect	Previous year: Current year:
Color: milky plasma (lipaemia), pink/red plasma (hemolysis), purple/brown plasma (bacterial contamination), visible clots, icteric, etc.	
7. Percentage of units not released due to testing	Previous year: Current year:
8. Percentage of units not released due to expiration date	Previous year: Current year:
(outdated components (expired date))	
Are there **OOs** and **OOT** results procedures available?	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_____
Do you monitor blood component quality using statistical process control to ensure that a state of control is maintained throughout the blood component lifecycle with the relevant process trends evaluated?	Yes ☐ No ☐
Is the maintenance of the validated status of the blood components documented in the Product Quality Review?	Yes ☐ No ☐
Are Incremental changes over time and the need for any additional actions (e.g. enhanced sampling) considered?	Yes ☐ No ☐

OOS = Out-of-Specification Results: *A result that falls outside established acceptance criteria which have been established in official compendia and/or by company docs*
OOT = Out of Trend Results: *A time dependent result which falls outside a prediction interval or fails a statistical process control criterion*

MANUFACTURING / PROCESSING / PRODUCTION (4/4) – GMP CHAPTER 6.6, 6.7, 6.8 & 7

Is there a list of critical equipment for the manufacturing 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:_____
Centrifugation programs (number, parameters…)	Program Red Cells Speed:_____ Temperature:_____ Time: _____ Program VM Speed:_____ Temperature:_____ Time: _____ Program NAT Speed:_____ Temperature:_____ Time: _____

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

1. Centrifuges	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
2. Separator/Extractors/Expressors	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
3. Balances/scales/weights	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
4. Sealers / thermal welders	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
5. Freezer/Walk-In-Freezer	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
6. Refrigerator/Walk-In-Refrigerator	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
7. Storage room for final products (Cold room/ Storage Walk-In-Freezer)	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____

OUTSOURCED ACTIVITIES MANAGEMENT – GMP CHAPTER 8

Do you outsource certain activities?	Transport (samples) ☐ Metrology ☐ Pest Control ☐ Cleaning/Janitorial ☐ BMW Management ☐ Others ☐ Activity:_____ Others ☐ Activity:_____
Is there a SOP in place to outline how outsourcing activities must be managed?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Provide the List of main outsourced activities	
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_____ QC Yes ☐ No ☐ No. contract:_____ Date_____ Cleaning Yes ☐ No ☐ No. contract:_____ Date_____ Pest control Yes ☐ No ☐ No. contract:_____ Date_____ Testing 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 ☐
Are all arrangements for blood collection, processing and testing in compliance with the requirements of Good Practice and regulatory requirements and agreed by both parties?	Yes ☐ No ☐
Does the contract clearly describe who is responsible for purchasing materials, testing and releasing materials, undertaking blood collection, and for processing and testing (including in-process controls)?	Yes ☐ No ☐
In the case of sub-contracted analyses, does the contract state the arrangements for the collection of samples and the contract acceptor understands that they may be subject to inspections by the Competent Authorities?	Yes ☐ No ☐
Are the preparation and distribution records, including reference samples kept by, or be available to, the contract giver?	
Are any records relevant to assessment of the quality of the blood or a blood component in the event of complaints or a suspected defect accessible and specified in the defect/recall procedures of the contract giver?	
Do you perform external audit of your sub-contractors on a regular basis (scheduled)?	On-site audit ☐ Frequency:_____ SOP Ref:_____ Off-site audit ☐ Frequency:_____ SOP Ref:_____
What are the standards/referential used for the audit of the outsourced activities?	**ISO** ☐ **GMP** ☐ **AABB** ☐ **FDA** ☐ 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

Are complaints and other information, including serious adverse reactions and events correctly documented and investigated for causative factors?	Yes ☐ No ☐
Is there a SOP in place to handle complaints and claims of internal/external clients/customers, donors (litigation, unsatisfied customers, fractionators...)?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Does the procedure in place ensure that the Competent Authorities are notified, as appropriate, of serious adverse reactions or serious adverse events in accordance with regulatory requirements? ***(2005/62/EC/Annex 9.2)***	Yes ☐ No ☐
Is there an effective recall procedure in place, including a description of the responsibilities, notification of the Competent Authority, and actions to be taken? ***(2005/62/EC / Annex 9.3.2)***	Yes ☐ No ☐ Ref:_____ Version:_____ *(Purpose of the investigation: identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk **(2005/62/EC / Annex 9.3.3)**)*
1. Are actions taken within pre-defined periods of time?	1.Yes ☐ No ☐
2. Are actions included tracing all relevant blood components and, where applicable, must include trace-back?	2.Yes ☐ No ☐
Are recalled blood components or products 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 defect:_____ Year n:_____ Percentage of quality defect:_____
Ways of communication with suppliers / vendors / manufacturers…..	Mailbox ☐ Phone ☐ Fax ☐ Email ☐ Others ☐ _____
Ways of communication with clients/customers (internal/external), hospitals, fractionators….	Mailbox ☐ Phone ☐ Fax ☐ Email ☐ Others ☐ _____

SELF-INSPECTION, AUDITS AND IMPROVEMENTS – 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***	Yes ☐ No ☐ Date of last audit:_____
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?	Nb 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?	Nb: _____ Reason for deferred audits_____
Number of unscheduled audits performed?	Nb: _____ Reason for unscheduled audits_____
Number of critical non-conformities per activity?	Nb: _____ Level of gravity_____
Number of major non-conformities per activity?	Nb: _____ Type of MD_____

TRANSPORT OF SAMPLE TUBES AND BLOOD COMPONENTS	
Is the transport of sample tubes from the customers facilities to the labs an outsourced activity?	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, blood component susceptibility and any other relevant factors)?	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 ☐
Who is in charge of the transport of sample tubes from the customers' facilities to the testing labs?	
Name of transporter company	Name:_____ _____
Number of trucks dedicated for sample tubes?	
Name of the electronic transport equipment management system in use (if applicable)	Name:_____ Ref:_____ Version:_____
Is the traceability of the supply chain managed electronically (equipment)?	Yes ☐ No ☐ IT System used:_____
Trucks purchased from approved suppliers?	Yes ☐ No ☐ _____
Frequency of the performance qualification?	Monthly ☐ Biannually ☐ Annually ☐ None ☐ - Justify:_____
Frequency of routine maintenance?	Monthly ☐ Biannually ☐ Annually ☐ None ☐ - Justify:_____
Frequency of Internal Quality control (QC)performed on truck(s)	Daily ☐ Weekly ☐ Monthly ☐ None ☐ - Justify:_____
TRANSPORT BOXES USED	
Frequency of the performance qualification?	Monthly ☐ Biannually ☐ Annually ☐ None ☐ Justify:_____
Does performance qualification perform with extreme weather conditions (winter / summer)?	
Is there a SOP in place to define the cleaning/disinfecting of the transport boxes?	
Frequency of the cleaning/disinfecting of the transport boxes?	Daily ☐ Twice a week ☐ Weekly ☐ None ☐ Justify:_____
Date of the latest routine maintenance	

TRANSPORT OF SAMPLE TUBES AND BLOOD COMPONENTS

REFRIGERATED VEHICLES/TRAILS/TRUCKS USED (TRANSPORT OF UNITS/SAMPLE TUBES)

Number of trucks per type	Whole blood:_____/Red cells_____/Plasma_____
Trucks purchased from approved suppliers?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Frequency of the performance qualification?	Monthly ☐ Biannually ☐ Annually ☐ None ☐ Justify:_____
Does performance qualification conduct with extreme weather conditions (winter / summer, longest distance, longest duration of transport)?	
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:	
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:	

QUALITY MONITORING AND CONTROL (RECOVERED ANS SOURCE PLASMA) –GMP CHAPTER 11

Does Plasma QC activity perform on-site?	Yes ☐ No ☐ By whom:_____
Is there a list of critical equipment for the QC activity?	Yes ☐ No ☐ ***Please provide the list***
Equipment purchased from approved suppliers?	Yes ☐ No ☐ SOP: _____ Version: _____
Is there a sampling program in place to perform plasma QC up-to-date?	Yes ☐ No ☐ Ref:_____ Version:_____
Does Plasma QC activity outsource?	Yes ☐ No ☐ Vendor:_____
Are acceptance criteria based on a defined specification for each blood donation and blood component?	Yes ☐ No ☐ *(Specifications set out in the Standards section of Chapter 5 - Component monographs contained in the Guide to the preparation, use and quality assurance of blood components - Council of Europe may be used).*
Plasma QC contract (frequency, tests to be done, sampling, method, reagents…)?	Yes ☐ No ☐ Ref:_____
Transport of the plasma samples to be controlled from organization to the outsource services	Validated: Yes ☐ No ☐ Ref:_____ Controlled: Yes ☐ No ☐ Ref:_____
Factor VIII quality control ***(Provide Package inserts)***	Method:_____ Reagent:_____ Vendor:_____ Single ☐ On pool ☐ Pool size: _____ Instrument:_____
Total Protein quality control ***(Provide Package inserts)***	Method:_____ Reagent:_____ Vendor:_____ Single ☐ On pool ☐ Pool size: _____ Instrument:
Residual leucocytes, red cells and platelets measures in the plasma ***(Provide Package inserts)***	Method:_____ Reagent:_____ Vendor:_____ Single ☐ On pool ☐ Pool size: _____ Single ☐

QUALITY MONITORING AND CONTROL (RECOVERED ANS SOURCE PLASMA) –GMP CHAPTER 11

Equipment/Instrument for Plasma quality control:

1. Instrument for FVIII measure	**Name:**	_____	**Name:**	_____
	Reference:	_____	**Reference:**	_____
	Manufacturer:	_____	**Manufacturer:**	_____
	Number	_____	**Number**	_____
2. Instrument for Total Protein measure	**Name:**	_____	**Name:**	_____
	Reference:	_____	**Reference:**	_____
	Manufacturer:	_____	**Manufacturer:**	_____
	Number	_____	**Number**	_____
3. Instruments for residual cells counting	**Name:**	_____	**Name:**	_____
	Reference:	_____	**Reference:**	_____
	Manufacturer:	_____	**Manufacturer:**	_____
	Number	_____	**Number**	_____
4. Instrument for Bacteria control	**Name:**	_____	**Name:**	_____
	Reference:	_____	**Reference:**	_____
	Manufacturer:	_____	**Manufacturer:**	_____
	Number	_____	**Number**	_____

Are there **OOS** (out-of-specifications) and **OOT** (out-of-trend) results procedures available? **	Yes ☐ No ☐ Ref: _____ Version:_____

References, regulations used for LFB assessment

European regulations:

- Council Recommendation **98/463/EC** of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community.
- Commission Directive **2001/83/EC** on the Community Code relating to medicinal products for human use.
- Commission Directive **2002/98/EC** setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.
- Commission Directive **2003/94/EC** of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medical products for human use and investigational products for human use.
- Commission Directive **2004/33/EC** implementing Directive **2002/98/EC** as regards certain technical requirements for blood and blood components.
- Commission Directive **2005/61/EC** implementing Directive **2002/98/EC** of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.
- Commission Directive **2005/62/EC** implementing Directive **2002/98/EC** of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.
- Good Practice Guidelines for Blood Establishment Required to Comply with Directive **2005/62/EC** (This text in force by 15/02/2018 / Per Commission Directive (EU) **2016/1214**)).
- **C**ommission directive **2016/1214** of the **25th July 2016** amending Commission Directive **2005/62/EC** as regards to quality standards and specifications for blood establishments.
- Recommendation **95(15)** of the Council of Europe entitled "Guide to the preparation, use and quality assurance of blood components".
- **Annex 14 & Annex 15 -** EU Guidelines for GPM for Medicinal Products for Human & Veterinary Use**.**
- European Pharmacopeia Monograph: Human plasma for fractionation (**0853**).