Direction of Audit and Risk, Plasma Supplier QA

Revised Questionnaire ***MARCH 2022***

ON-SITE AUDIT QUESTIONNAIRE OF EU COLLECTION SITES

GENERAL INFORMATION ABOUT THE EU COLLECTION SITE / HOME BASE FOR MOBILES

Organisation Name					
Country / State / City					
Site Address					
Organization Type	☐ Non-Profit	☐ Profit/Remunerated	☐ Compensated		
Audit Type	Qualification/Agreement ☐	Re-Qualification/Follow-up ☐	For cause/Post deviation ☐		
Site Activity (principal)	Collection ☐	Manufacturing ☐	Storage (Warehouse) ☐	Transport ☐	
Other Activities,(if exist)	Quality Assurance ☐	IT System (MIS) ☐	Mobile Drives ☐	Mobile Staging ☒	
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 ☐

BLOOD COLLECTION (WHOLE BLOOD / SOURCE PLASMA) (1/3) – GMP CHAPTER 6.1 & 6.2

Employee/Personnel Number of key personnel on site and per categories (including mobile team)	Physician: _____	Registered Nurse: _____	External driver _____
	Physician Substitute: _____	Technician: _____	Internal driver: _____
	Collection Staff: _____	Clerical: _____	Other (e.g. Volunteers): _____

Information regarding donors and donation

- Volunteer/Voluntary donor	Yes ☐	No ☐	SOP:_____
- Anonymous	Yes ☐	No ☐	SOP:_____
- Paid donor (Remunerated donor: cash, money card)	Yes ☐	No ☐	SOP:_____
- Non-paid donor (no cash money, no transfer…)	Yes ☐	No ☐	SOP:_____
- Compensated donor*** (if yes, please complete below)	Yes ☐	No ☐	SOP:_____
➥Nature of the compensation if applicable	- - - -		

Permanent Collection Site Is the blood collection area organized in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure? ***(2005/62/EC / Annex 3.3.3)***	Yes ☐ No ☐ **(observation on-site)**
1. Are the donor areas separated from all processing areas? ***(2005/62/EC / Annex 3.2: Blood donor area)***	1. Yes ☐ No ☐ **(observation on-site)**
2. Is there a confidentially/privacy area to fill up the DHQ and medical interview?	2. Yes ☐ No ☐ **(observation on-site)**
3. Are the janitorial items stored in a specific closet outside of the storage room? ***(EU)***	3. Yes ☐ No ☐ **(observation on-site)**
4. Are the biohazard waste bins stored in a secured and locked area outside of the storage room? ***(2005/62/EC / Article 3.6)***	4. Yes ☐ No ☐ **(observation on-site)**
5. Are donor's restrooms directly open to the storage areas or to the donor room?	5. Yes ☐ No ☐ **(observation on-site)**
6. Is the storage room properly arranged, cleaned and organized, permanently closed? Segregation of softgoods vs. goods?	6. Yes ☐ No ☐ **(observation on-site)**
Is there a floor plan available for the collection site?	Yes ☐..No ☐
Donor screening booths for donor selection How many Donor screening booths are in use in this permanent location?	Number of booths:_____ Booth # ID: Yes ☐ No ☐
What is the flooring installed in the donor screening booths? (type of floor: **observation on-site**)	Carpeted ☐ Hard floor ☐ Plastic covering ☐ Concrete screed ☐ Wood flooring ☐ Others ☐:_____

Critical Supply Storage Area

What is the temperature monitoring system used for the Critical Supply Storage Area (CSSA)?

1. Chart recorders ☐	Vendor:_____	Temperature reading: Once a day ☐ Twice a day ☐ Every 4hours ☐ Periodicity of the disk change: Weekly ☐ Bi-monthly ☐ Monthly ☐
2. C.A.M.S ☐	Vendor:_____	Temperature monitoring: Daily ☐ 24h/24h ☐ 7d/7d ☐ Number of Sensors/probes: _____
3. Thermometer Min/Max ☐	Vendor:_____	Temperature monitoring: Once a day ☐ Twice a day ☐ Weekly ☐ Periodicity of the battery change: Weekly ☐ Bi-monthly ☐ Monthly ☐

BLOOD COLLECTION (WHOLE BLOOD / SOURCE PLASMA) (2/3) – GMP CHAPTER 6.1 & 6.2

Acceptable temperature range in the Critical Supply Storage Area (CSSA)?	**15-25**°C ☐ **20-24**°C ☐ Others: _____
Date of the last mapping in the CSSA to determine the warmest spots and place the sensor on the right position?	Date: _____ Mapping reference: _____ ***Please provide this mapping***
Donor Selection / Eligibility Are the procedures for safe identification of donors, suitability interview, and eligibility assessment in place regularly updated?	Yes ☐ No ☐
1. Is there a SOP in place to verify the blood donor identity? *(Upon arrival at the blood establishment, donors must provide evidence of their identity: ID# with photo)*	1. Yes ☐ No ☐ SOP Ref:_____ Version:_____
2. Is there an Educational material given before donation? ***Provide current document in use***	2. Yes ☐ No ☐ Doc Ref:_____ Version:_____
3. Is there a Post-Donation form given after donation? ***Provide current document in use***	3. Yes ☐ No ☐ Doc Ref:_____ Version:_____
4. Is there a DHQ (Donor Medical Questionnaire) up-to-date? ***Provide current document in use (WB and SP if applicable)***	4. Yes ☐ No ☐ Doc Ref:_____ Version:_____
Do they take place before each donation and comply with the requirements set out in **FDA 21CFR** and Annex II/III to Directive **2004/33/EC** (**2005/62/EC/Annex 6.1.1**)?	Yes ☐ No ☐
Does donor suitability include? ▪ Measure of Hemoglobin ☐ or Hematocrit ☐ ▪ Blood pressure measure ▪ Temperature measure ▪ Donor weight ☐ / Donor height ☐ ▪ General aspect, arms	Yes ☐ No ☐ SOP:_____ Version:_____ Yes ☐ No ☐ SOP:_____ Version:_____ Yes ☐ No ☐ SOP:_____ Version:_____ Yes ☐ No ☐ SOP:_____ Version:_____ Yes ☐ No ☐ SOP:_____ Version:_____
"Reference Tables for Deferral Criteria": criteria, duration of deferral period, status: temporary, permanent)?	Yes ☐ No ☐ Table Reference:_____ ***Provide current document in use***
Number of donors deferred for the previous year and the current year (January to now)?	Year n-1: **2018** = Temporary deferral: _____ Permanent deferral:_____ Year n-1: **2019** = Temporary deferral: _____ Permanent deferral:_____
Is there a SOP in place to describe Whole blood collection? Donor identity must be confirmed before each critical step in the process but, at the very least, before donor selection and venipuncture?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a SOP in place to describe hand washing/disinfection for collection staff, gloves usage, and work clothes?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a SOP in place to describe the scrub process to disinfect skin before venipuncture (scrub duration, dry duration)?	Yes ☐ No ☐ Ref:_____ Version:_____
Nature of disinfecting/scrub solution	Name:_____ Scrub time:_____ Drying time:_____
Before venipuncture, a check should be made to ensure that the collection system to be used is not damaged or contaminated, and that it is appropriate for the intended collection? Abnormal moisture or discoloration could suggest a defect	
Is there a statement in place to list the devices used to collect whole blood and source plasma units?	Yes ☐ No ☐ ***Provide the list and package insert for each device***
Is there a statement in place regarding anticoagulants used to collect whole blood and source plasma units?	Yes ☐ No ☐ ***Provide the list and package insert for each solution***
Is there a SOP in place to implement action to be taken in case of adverse reactions spotted during the donation?	Yes ☐ No ☐ Ref:_____ Version:_____

BLOOD COLLECTION (WHOLE BLOOD / SOURCE PLASMA) (3/3) – GMP CHAPTER 6.1 & 6.2

Is there a SOP in place to label collection devices, sample tubes, DHQ form…?	Yes ☐ No ☐ Ref:_____ Version:_____
Type of DIN (Donor identification number) pre-printed labels A system of unique donation numbers should be used to identify each donor and the related donation and all of its associated components, samples and records, as well as to link each one to each of the others	ISBT128 ☐ Bleed no. ☐ Other ☐ ***Please provide a set of DIN labels***
Are the Blood bag and sample tube pre-printed labels maintained in a secure location when not in use and out of reach of the general public?	
Are the systems of sterile blood bags used for the collection of blood and blood components and their processing CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the bag must be traceable for each blood component? **(2005/62/EC/Annex 6.2.2)**	
Is there a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed? **(2005/62/EC/Annex 6.2.7)**	
Transport of the whole blood units and blood components from collection site to manufacturing site	Validated: Yes ☐ No ☐ - Dossier Controlled: Yes ☐ No ☐ - Dossier Number of pick-ups per day:
Acceptable temperature range Whole blood:	**1-6**°C ☐ **20-24**°C ☐ Others ☐ _____ Maximum time: _____
Plasma:	< **-18**°C ☐ < **-30**°C ☐ Others ☐ _____ Maximum time: _____
Weather protections for outgoing/incoming boxes available (protect transfer of shipping boxes from pick-up area to the truck).	Yes ☐ No ☐ Evidence (photo)_____
Is there a SOP in place in case of failure/breakdown of collection equipment and/or IT systems? Paperwork available in the bus?	Yes ☐ No ☐ Ref:_____ Version:_____

COLLECTION DEVICES INFORMATION (WHOLE BLOOD / SOURCE PLASMA DMD)

WHOLE BLOOD DISPOSABLE MEDICAL DEVICE (WB DMD)

		DMD no.1	DMD no.2	DMD no.3	DMD no.4
Device Reference (Disposable Medical Device = DMD)					
Plasma bag dimension *(in millimeters or inches with correspondence between the 2 measures)*	Length (mm)				
	Width (mm)				
Plasma bag thickness: empty before WB separation / filled with plasma after blood components separation *(maximum value in mL)*	Empty (mL)				
	Filled in (mL)				
Filling volume range *(value in mL)*	Minimum				
	Average				
	Maximum				
Presence of chimneys / fins		☐ YES / ☐ NO	☐ YES / ☐ NO	☐ YES / ☐ NO	☐ YES / ☐ NO
Pigtail / Tubing segment presence ☐ YES / ☐ NO *[If YES => size]*					
Sample tubes presence ☐ YES / ☐ NO *[If YES => how many?]*					

SOURCE PLASMA DISPOSABLE MEDICAL DEVICE (SP DMD)

		DMD no.1	DMD no.2	DMD no.3	DMD no.4
Device Reference (Disposable Medical Device = DMD)					
Plasma bag dimension *(in millimeters or inches with correspondence between the 2 measures)*	Length (mm)				
	Width (mm)				
Plasma bag thickness: empty before SP collection / filled with plasma after source plasma collection *(maximum value in mL)*	Empty (mL)				
	Filled in (mL)				
Filling volume range *(value in mL)*	Minimum				
	Average				
	Maximum				
Presence of chimneys / fins		☐ YES / ☐ NO	☐ YES / ☐ NO	☐ YES / ☐ NO	☐ YES / ☐ NO
Pigtail / Tubing segment presence ☐ YES / ☐ NO *[If YES => size]*					
Sample tubes presence ☐ YES / ☐ NO *[If YES => how many?]*					

COLLECTION EQUIPMENT & MATERIALS (1/4)	GMP CHAPTER 6.1 & 6.2
Is there a list of critical equipment used for the collection site?	Yes ☐ No ☐ ***Please provide the list***
Name of the electronic equipment management system in use (e.g. InforEAM, SAP…) ***(Description and overview)***	Name: _____ Version: _____
Are the equipment purchased from approved suppliers?	Yes ☐ No ☐ SOP: _____ Version: _____
Is equipment for measuring, weighing, recording and control calibrated at defined intervals using appropriate methods?	Yes ☐ No ☐ SOP: _____ Version: _____
Are calibration reports included the accuracy of any testing equipment and traceability to a national standard?	Yes ☐ No ☐ SOP: _____ Version: _____
Are reports and/or calibration certificates reviewed and signed to show acceptance of the document?	Yes ☐ No ☐ SOP: _____ Version: _____
Are the failed calibrations mentioned of non-conformance in order to investigate the potential impact?	Yes ☐ No ☐ SOP: _____ Version: _____
Are defective equipment labelled clearly as such and, if possible, removed from processing/testing areas?	Yes ☐ No ☐ SOP: _____ Version: _____

COLLECTION EQUIPMENT & MATERIALS			GMP CHAPTER 6.1 & 6.2	
Number of collection equipment for the site per type of use:				
1. Hemoglobin (Hb) or hematocrit (Ht) monitor	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
	Hemoglobin check ☐	Hematocrit check ☐	Hemoglobin check ☐	Hematocrit check ☐
2. Blood Pressure monitor	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
3. Temperature monitor	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
4. Whole blood collection mixer	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
5. Bag sealer	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____ Per site: _____	**Number**	Total: _____ Per site: _____
6. Source plasma collection machine	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____	**Number**	Total: _____

		Per site: _____		Per site: _____
7. Platelets/RBCs collection machine	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____	**Number**	Total: _____
		Per site: _____		Per site: _____
8. Blood Analyzer	**Name:**		**Name:**	_____
	Reference:		**Reference:**	_____
	Manufacturer:		**Manufacturer:**	_____
	Number	Total: _____	**Number**	Total: _____
		Per site: _____		Per site: _____
9. Refractometer (TP for SP donor)	**Name:**		**Name:**	
	Reference:		**Reference:**	
	Manufacturer:		**Manufacturer:**	
	Number	Total: _____	**Number**	Total: _____
		Per site: _____		Per site: _____

MOBILE COLLECTIONS (BLOOD DRIVES) – GMP CHAPTER 6.1 & 6.2

Is the suitability for mobile donor sessions assessed before using premises (for both vehicles/busses/coaches and inside set up)?	Yes ☐ No ☐ SOP Ref: _____ Version: _____
1. Sufficient size to allow proper operation;	1. Yes ☐ No ☐
2. Donor privacy/confidentiality;	2. Yes ☐ No ☐
3. Safety for staff and donors;	3. Yes ☐ No ☐
4. Presence of ventilation, electrical supply, lighting, toilet and hand-washing facilities;	4. Yes ☐ No ☐
5. Reliable communication, blood storage and transport;	5. Yes ☐ No ☐
6. Guarantee of adequate interim storage.	6. Yes ☐ No ☐
Is the arrangement of the donor room and procedures ensured that blood/plasma is collected in a safe and tidy environment, and to minimize the risk of errors and microbial contamination?	Yes ☐ No ☐ SOP Ref: _____ Version: _____
Number of coaches/vehicles and vans for inside set-up	Coaches/Vehicles/Busses: _____ Vans for Inside Set-up: _____
Number of bloodmobiles performed from this site, if applicable	Per day ☐ Per week ☐ Per month ☐
Is there a SOP in place to qualify, validate, set-up and maintain laptops used in mobile collections?	Yes ☐ No ☐ Ref:_____ Version:_____
Frequency of upload/download to secure donor eligibility verification and access to current SOPs	Daily ☐ Weekly ☐ Monthly ☐ SOP:_____
Number of units collected per month in blood drives (Average)?	Whole blood:_____ Source plasma: _____ DRBC:_____
Number of units collected per month in the permanent site (Average)?	Whole blood:_____ Source plasma: _____ DRBC:_____
Percentage of units collected in blood drives vs. permanent site	Whole blood:_____ Source plasma: _____ DRBC:_____

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? Frequency of routine maintenance? Frequency of Internal Quality control (QC)performed on truck(s)	Monthly ☐ Biannually ☐ Annually ☐ None ☐ - Justify:_____ Monthly ☐ Biannually ☐ Annually ☐ None ☐ - Justify:_____ 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:_____			
Date of the latest routine maintenance				
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:				

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**).