ON-SITE AUDIT QUESTIONNAIRE OF EU TESTING LABS

Testing/Screening Lab / Supplier Name	
Country / City	
Site Address	
Organisation Type	Non-Profit ☐ Profit/Remunerated ☐ Compensated ☐ **501(c)(3))** (US) ☐
Audit Type	Qualification/Agreement ☐ Re-Qualification/Follow-up ☒ For cause/Post deviation ☐
Audit Scope (field audit)	Viral Marker testing ☐ NAT Testing ☐ Donor IH ☐ Confirmatory Tests ☐

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					

CD: Critical Deviation, MD: Major Deviation, OD: Other Deviation, R: Remark

QUALITY MANAGEMENT SYSTEM (QMS) – GMP CHAPTER 1

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 ☐

Is there a Quality Manual/or equivalent available?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a Site Master file available (SMF)?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a Change control (CC) procedure available?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a SOP in place to manage deviations, deficiencies and errors system?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there a SOP in place for CAPAs implementation?	Yes ☐ No ☐ Ref:_____ Version:_____
Are there quality indicators in order to follow quality targets set (example per sector)?	Yes ☐ No ☐ Date of last review + example:_____
Are there scheduled meetings to review & follow quality targets (frequency, who does what)?	Yes ☐ No ☐ Date of last review + example:_____
Name of software system in use to trace and follow deviations/gaps (notification, CAPA, closure…)	
Did your organisation updated their QMS to reflect current EU- GMP guidelines regarding?	
- Involvement of top Management?	Yes ☐ No ☐ Ref:_____ Version:_____
- Root cause analysis?	Yes ☐ No ☐ Ref:_____ Version:_____
- Continual Quality Improvement (CQI)?	Yes ☐ No ☐ Ref:_____ Version:_____
Are there scheduled meetings to review & follow quality targets (frequency, who does what)?	Yes ☐ No ☐ Frequency:_____

PERSONNEL AND ORGANISATION – GMP CHAPTER 2

General Organization List the personnel participating in the management review by categories only (no name)?	

Number of employees / personnel (staff/key personnel)	Total: _____	Part-time: _____	Half time: _____
	Medical Director: _____	Physician: _____	Supervisor: _____
	Technician: _____	QA Specialist: _____	Clerical*: _____
	Internal driver: _____	Other: _____	Other: _____

Number of shifts per day	365-days: _____	7-days/week: _____	24-hours: _____
	Shift 1 (hours): _____	Shift 2 (hours): _____	Shift 3 (hours): _____

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? *(All personnel must have up-to-date job descriptions, which clearly set out their tasks and responsibilities. Responsibility for processing management and quality assurance must be assigned to different individuals, and who function independently (2005/62/EC/Annex 2.2))*	Yes ☐ No ☐ *Provide example of job position per staff category*
Are the job descriptions regularly reviewed and updated? *Provide example of job position per staff category*	Yes ☐ No ☐ Frequency: _____
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: _____

Competency / Training 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*
Are the contents of training programs periodically assessed and the competence of personnel evaluated regularly? *(2005/62/EC/Annex 2.4)*	Yes ☐ No ☐ Frequency: _____
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*

LABORATORIES / FACILITIES IN GENERAL (1/2) – GMP CHAPTER 3

Is there a general policy in place for the qualification of facilities and equipment, automated systems?	Yes ☐..No ☐ SOP Ref:_____ Version:_____
Are all planned changes to the laboratories, equipment, utilities and processes formally documented?	Yes ☐ No ☐ Doc provided:_____
Are the premises/laboratories located, constructed, adapted and maintained to suit the activities to be carried out? *(2005/62/EC /Annex 3.3.1)*	Yes ☐..No ☐
Is the dedicated laboratory area for testing separated from the blood-donor and blood-component processing area, with access restricted to authorized personnel? *(2005/62/EC/Annex 3.3.4)*	Yes ☐..No ☐ *(Observation during the tour on-site)*
1. Is the access to critical premises (testing labs, 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 laboratories 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)*
Do you have floor plans for the laboratories?	Yes ☐..No ☐
Are the laboratories designed to suit the operations of samples receiving, samples testing, and release of the results to be carried out in them?	Yes ☐..No ☐ *(Observation during the tour on-site)*
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 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 for washing/toilet purposes been readily accessible and appropriate for the number of users?	Yes ☐..No ☐
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:_____ 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 the 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 during the previous year, and since the beginning of this year 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:_____
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*

LABORATORIES / FACILITIES IN GENERAL (1/2) – GMP CHAPTER 3

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?	Yes ☐..No ☐
Temperature Monitoring Temperature monitoring system, Wireless (name, manufacturer, alarm temperature set point…)?	CAMS:_____

Storage room: for sample tubes	**#ID (S/N)**_____	Capacity: _____	Temperature range: _____
Storage room: for VMT reagents	**#ID (S/N)**_____	Capacity: _____	Temperature range: _____
Storage room: for NAT reagents	**#ID (S/N)**_____	Capacity: _____	Temperature range: _____
Storage room: for Donor IH	**#ID (S/N)**_____	Capacity: _____	Temperature range: _____

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 specify the maximum length of time the temperature stayed out of range before intervention of operator or engineer in the case 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 system:_____
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 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:_____
1. New or modified facilities;	**1.** Yes ☐..No ☐_____
2. Equipment and materials, automats;	**2.** Yes ☐..No ☐_____
3. Automated systems;	**3.** Yes ☐..No ☐_____
4. After repair;	**4.** Yes ☐..No ☐_____
5. Prior the initial use.	**5.** Yes ☐..No ☐_____
Are all planned changes to the equipment, utilities and processes formally documented and assessed?	Yes ☐ No ☐ Doc provided:_____
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)* **1.** Tests, using production materials, qualified substitutes or simulated blood components proven to have equivalent behavior, under normal and worst case operating conditions.	*(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. 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 ☐
Are equipment for measuring, weighing, recording and control calibrated and checked at defined intervals using appropriate methods?	Yes ☐..No ☐
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:_____

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

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 ☐
1. Are the software, hardware and back-up procedures checked regularly to ensure reliability?	**1.** Yes ☐ No ☐
2. Are hardware and software correctly protected against unauthorised use or unauthorised changes?	**2.** 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 ☐ Base tests:_____
Is there a SOP in place to describe management, monitoring and traceability of passwords and user profiles?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is there a validations process in place to monitor upgrade, update or modification of data processing software?	Yes ☐ No ☐ Plan Ref:_____ (version:_____)
Is the servers' room safe and secured, protected against fire, flooding and non-authorized people?	Yes ☐ No ☐ Protection deployed:_____
Is the computer and server area sufficiently big enough to avoid clutter or cramping (ground and space)?	Yes ☐ No ☐
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 – GMP CHAPTER 5

Are documents setting out specifications, procedures and records covering each activity undertaken by your company in place and kept up-to-date? *(2005/62/EC/Annex 5.1).*	
Name of the electronic documents management system in use?	
Authorization of written procedures done by? (Job position)	
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?	
Escalation process procedure to raise quality issues?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
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 of the records / documents? *(Records must be retained for a period according to local, national or EU requirements, as appropriate: 2002/98 Article 14.3)*	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is traceability data (that allow tracing from donor to recipient and vice versa) retained for a minimum of **30** years (**2002/98 Article 14.3**)?	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:_____
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:_____
Delay to inform the customer/fractionator in case of positive results?	
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:_____
Suppliers/vendors/subcontractors re-qualified on an established and	On-site audit ☐ Periodicity:_____

regular basis? *Periodicity + Process* | Off-site audit ☐   Periodicity:_____

TESTING LABORATORY (1/2) – GMP CHAPTER 6.3, 6.4 & 6.5

Is there a floor plan available for the testing/screening labs?	
Laboratory areas under temperature monitoring?	**15-25**°C ☐ **20-24**°C ☐ Others ☐ Range: _____ Low alarm set: _____ High alarm set:_____
Name of the electronic equipment management system in use	Name_____ Version_____
Operational days of the testing/screening labs	24h/24h ☐ 7d/7d ☐ Other ☐ Operational days:_____ Shift number per day: _____ Time slot: _____
Is there a back-up laboratory in case of emergency situation (unexpected event stopping partially or completely activities)	Yes ☐ No ☐ Vendor:_____
Do the transport conditions of the samples from collection site to testing labs periodically evaluate? *(Stress conditions, extreme conditions of warm and cold weather)*	Yes ☐ No ☐ *Provide last validation*
Samples management Is there a SOP in place to define the samples collected for testing? **1.** Number of samples according its nature **2.** Color cap of samples according its nature **3.** Volume of samples according its nature **4.** Testing performed according the samples nature	Yes ☐ No ☐ Ref:_____ Version:_____ EDTA:_____ Serum:_____ Others:_____
Number of tested samples processed per day (average)?	Normal day: _____ Higher day: _____
Is there a SOP to manage and check the samples at reception/accessioning area of the testing labs?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
1. Monitoring of the transport conditions	**1.** Yes ☐ No ☐ Method:_____
2. Non-conformities due to temperature excursion during transport	**2.** Yes ☐ No ☐ Management NC:_____
3. Samples receipt and documents check *(announced quantity vs. actual quantity received according)*	**3.** Yes ☐ No ☐ _____
4. Criteria for acceptance or rejection of samples *(sample quality, lipaemia, icterus, haemolysis, fibrin, right labelling)*	**4.** Yes ☐ No ☐ _____
5. Insufficient sample volume to perform the required test(s)	**5.** Yes ☐ No ☐ _____
6. Non-conformities linked to sample labelling	**6.** Yes ☐ No ☐ _____
7. Management of the non-conformant samples	**7.** Yes ☐ No ☐ _____
Samples storage before and after testing (temperature/storage time according tests performed)	Walk-In-refrigerator ☐ Walk-In-freezer ☐ S/N# _____ Storage temperature: **2-8**°C ☐ Frozen ☐:_____ Other ☐:_____ Low alarm set:_____ High alarm set:_____ Storage time for: ABO-Rh:_____ VM:_____ NAT: _____ Remapping: Annually ☐ Every 2 years ☐ After repair ☐
Reagents / Kits management Is there a SOP to manage and monitor reagents used for testing/screening and confirmatory test? **1.** Transport conditions monitoring for incoming reagents? **2.** Assessment of the reagents upon receipt and accompanying documents (purchase order, damage, package insert)? **3.** Storage conditions, inventory levels (stock alert), labeling and	Yes ☐ No ☐ SOP Ref:_____ Version:_____ **1.** Yes ☐ No ☐ Method:_____ **2.** Yes ☐ No ☐ _____ **3.** Yes ☐ No ☐ _____

| expiry date management, defective reagent report? | |

TESTING LABORATORY (2/2) – GMP CHAPTER 6.3, 6.4 & 6.5

Do you manage the storage and use of materials/reagents taking into account the expiry date of materials in respect of the 'first-in first-out' (**FIFO**) or 'first-expired first-out' (**FEFO**) principle?	Yes ☐ No ☐ **FIFO** ☐ **FEFO** ☐
Storage of reagents used for testing/screening (temperature/storage time according tests performed)	Walk-In-refrigerator ☐ Walk-In-freezer ☐ S/N# _____ Storage temperature: **2-8**°C ☐ Frozen ☐:_____ Other ☐:_____ Low alarm set:_____ High alarm set:_____ Storage time: ABO-Rh:_____ VM:_____ NAT: _____ Remapping: Annually ☐ Every 2 years ☐ After repair ☐
Are there SOPs in place to qualify/validate new reagents (new batches) used in the labs?	Yes ☐ No ☐ Ref:_____ Version:_____
Is there SOP in place to perform the pooling of samples prepared for NAT testing?	Yes ☐ No ☐ Ref:_____ Version:_____
What is the size of the pool prepared to the NAT testing (primary pool and master pool) and NAT reagents used?	HIV/HCV/HBV Reagents: _____ Pool size:_____ WNV Reagents: _____ Pool size:_____ HAV/B19 Reagents: _____ Pool size:_____
Does the quality of the laboratory testing assess regularly by participation in a formal system of proficiency testing, such as an external quality-assurance program *(2005/62/EC/Annex 6.3.5)*	Organism:_____ Periodicity:_____ Results:_____ Organism:_____ Periodicity:_____ Results:_____ Organism:_____ Periodicity:_____ Results:_____
Are screening algorithms defined precisely in writing to deal with initially reactive specimens, and to resolve discrepancies in results after re-testing?	Yes ☐ No ☐ Doc Ref:_____ Version:_____
Is there SOP in place to manage the questionable and/or positive results, the discrepancies with previous results?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is there a SOP in place to describe how to disassemble the primary pool to single donation to find the reactive sample?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Does blood group serology testing include procedures for testing specific groups of donors (e.g. first-time donors, donors with a history of transfusion)? *(2005/62/EC/Annex 6.3.6)*	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is each donation tested for ABO and Rh D blood typing?	Yes ☐ No ☐ SOP Ref:_____ Version:_____
Is each donation tested for clinically-significant irregular red-cell antibodies?*	Yes ☐ No ☐ SOP Ref:_____ Version:_____
If not*: Are at least all first-time donors tested?	Yes ☐ No ☐
Are there OOS (out-of-specifications) and OOT (out-of-trend) results procedures available?	Yes ☐ No ☐ SOP Ref:_____ Version:_____

TESTING/SCREENING EQUIPMENT (1/2) — GMP CHAPTER 6.3, 6.4 & 6.5

Question	Response
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 the pre-analytical activity automated?	Yes ☐ No ☐ Instrument: _____ SOP: _____
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: _____

Equipment for Testing/screening/confirmatory tests:

Equipment	Field	Value	Field	Value
1. Labs centrifuges (+ Type)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
2. Pre-analytical automate for pooling of sample tubes	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
3. Automated equipment for Viral Marker Testing (VMT)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
4. Automated equipment for NAT Testing (PCR)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
5. Equipment for the confirmatory tests for the Viral Marker (serology)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
6. Equipment for the confirmatory tests for the Viral Marker (NAT)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
7. Automated equipment for the determination of the blood typing of the blood donor (ABO/Rhesus D)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____
8. Automated equipment for the screening of the Red Blood Cells antibodies (RBC Ab screening)	Name:	_____	Name:	_____
	Reference:	_____	Reference:	_____
	Manufacturer:	_____	Manufacturer:	_____
	Number	_____	Number	_____

TESTING/SCREENING EQUIPMENT (2/2)		**GMP CHAPTER 6.3, 6.4 & 6.5**	
9. Refrigerator used for the storage of reagents/kits	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	
10. Freezer used for the storage of reagents/kits	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	
11. Refrigerator/Freezer used for the storage of the sample tubes	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	**Name:** _____ **Reference:** _____ **Manufacturer:** _____ **Number** _____	

Is there an emergency plan in place in case of electrical failure, computer shutdown or equipment breakdown

Yes ☐ No ☐   Plan Ref:_____   Version:_____

- Plug into secure power lines: inverters and connected on **UPS**

Yes ☐ No ☐   _____

- Power generator reset to relaunch the process

Yes ☐ No ☐   _____

Confirmatory tests

- If outsourced

Tests Outsourced: Yes ☐ No ☐   Tests In house: Yes ☐ No ☐

Name of the outsourced laboratory:_____

- Tests de confirmatory outsourced

HIV 1/2 Ab	Yes ☐ No ☐	HBsAg	Yes ☐ No ☐	HCV	Yes ☐ No ☐
HBcore	Yes ☐ No ☐	HTLV I/II	Yes ☐ No ☐	Syphilis	Yes ☐ No ☐
HTLV I/II	Yes ☐ No ☐	Syphilis	Yes ☐ No ☐	HIV NAT	Yes ☐ No ☐
HCV NAT	Yes ☐ No ☐	HBV NAT	Yes ☐ No ☐	HAV NAT	Yes ☐ No ☐
B19 NAT	Yes ☐ No ☐	WNV NAT	Yes ☐ No ☐	Others:_____	

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

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 ☐
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 ☐ _____

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 sampling program in place to perform plasma QC up-to-date?	Yes ☐ No ☐ Ref:_____ Version:_____
Does Plasma QC activity outsource?	Yes ☐ No ☐ Vendor:_____
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 ☐
Are there **OOS** (out-of-specifications) and **OOT** (out-of-trend) results procedures available? **	Yes ☐ No ☐ Ref: _____ Version:_____
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:_____

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**	_____

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**)).

- Commission 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**).