PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 019–3
25 September 2007

PIC/S GUIDANCE DOCUMENT FOR INSPECTORS

SITE MASTER FILE FOR SOURCE PLASMA ESTABLISHMENTS

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1. DOCUMENT HISTORY

Adoption by the PIC/S Committee	3 June 2003
Entry into force	15 July 2003

2. INTRODUCTION

2.1 The Site Master File for Source Plasma Establishments (SMF – SPE) refers to the PIC/S Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (PI 008) and should be read in close conjunction to it; relevant terminology can be found there. It is based on the information as given in the PIC/S document PE 008.

2.2 The SMF – SPE should be completed by the manufacturer. In case of more than on choice the correct boxes should be marked and missing entries should be filled in. Hand-written entries must be easily legible (use printed / block letters). Numerical data should refer to a calendar year.

2.3 In order to provide actual information the SMF – SPE should be completed not earlier than approximately six (6) weeks prior to the inspection.

2.4 The SMF – SPE should be sent back to the authority not later than four (4) weeks prior to the inspection. In exceptional cases it may be handed over to the inspector immediately prior to the inspection at the latest.

2.5 When submitted to a regulatory authority, the SMF – SPE provides information on the manufacturer's operations and procedures that can be useful in the efficient planning and undertaking of an inspection. The SMF – SPE will also be part of the inspection report.

2.6 Copies of the following documents should be added to the SMF-SPE *(the inspector may request additional copies of other documents)*:

a) Manufacturing license (in the U.S.A.: Biologics License)

b) All amendments / supplements (e.g. immunisation program) to the Manufacturing License, if applicable (in the U.S.A.: Official letters to the Biologics License)

c) Annual Registration (in the U.S.A. only)

d) Additional State Licenses (if applicable)

e) QPP (Quality Plasma Program) and CLIA (Clinical Laboratory Improvement) certificate (in the U.S.A. only)

f) Last inspection report (including any observation) issued by the National Authority (in the U.S.A.: Form 483 or Warning Letter) and response of the source plasma establishment

g) Organisation chart for the overall company and for the source plasma establishment
(also showing the *names of responsible persons)*

h) Actual floor plan with *indication of at least the following areas*

- Donor waiting area
- Donor interview
- Processing area
- Freezer(s)
- Storage of files for active donors, inactive donors and rejected donors
- Softgoods storage area
- Biohazard room (including the way for biohazard *into* the storage room and *out of* this room for shipment)

2.7 The following documents should be available for the inspection:

a) Quality Assurance (QA) handbook (procedures)

b) Self inspections (program and documentation of execution)

c) Documentation about proficiency testing (results for at least 1 year)

d) Job descriptions of persons in responsible positions [e.g. Manager, Production Manager, QA Specialist, Physician, in the U.S.A. additionally: Physician Substitute]

e) Training program (and documentation)

f) Sanitation and pest control program (and documentation)

g) Incidents, accidents, errors, complaints, recalls (SOP and documentation of execution)

h) Look back procedures (SOP and complete documentation)

i) Deferral systems [national and / or company own deferral registry (SOP and documentation)]

j) Release and distribution of plasma (SOP and documentation of distribution)

3. PURPOSE

3.1 The purpose of this document is to provide guidance for companies on how to create basic information about their activities that can be useful for them and to the regulatory authority in planning and conducting inspections. The completed SMF – SPE should be part of the inspection report.

3.2 This document should also be a source for training purposes for inspectors.

4. SCOPE

4.1 This documents applies to source plasma establishments.

4.2 At the time of issue, this document reflected the current state of the art. It is not intended to be a barrier to technical innovations or the pursuit of excellence. The advice in this document is not mandatory for industry. However, industry should consider this recommendations as appropriate.

4.3 The SMF – SPE will be regularly adapted to current facts, if necessary.

5. SITE MASTER FILE

Refer to Annex for the format to be used.

6. REVISION HISTORY

Date	Version Number	Reasons for revision
1 July 2004	PI 019-2	Change in the Editor's co-ordinates
25 September 2007	PI 019-3	Change in the Editor's co-ordinates

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Annex: Site Master File for Source Plasma Establishments

Annex

Site Master File for Source Plasma Establishments (SMF – SPE)

Source Plasma Establishment (Plasmapheresis Centre): (Name, address, company, phone and fax-No., Email)	

Signature and title:

(Responsible person from the Corporate Office / Management)

Date of preparation:

Signature and title:

(Manager / Production Manager/ Responsible Person from the Plasmapheresis centre)

1. General information				
				Remarks (not to be filled in by the company)
1.1. Contact Person for the Health Authority *(Name, title, address, Phone No., Fax-No., Email)*				
1.2. Hours of opening	Day:	Opening hours (donor acceptance)		
		From (a.m.):	Till (p.m.):	
	Mo.			
	Tu.			
	We.			
	Th.			
	Fr.			
	Sa.			
	Su.			
	Total opening hours per week: hours			
1.3. Date of opening in the actual location (by the current owner / company)	(Month, day, year)			
1.4. Previous owner and previous name of the centre (if applicable)	Previous owner (company):		Previous name (centre):	

1. General information *– continuation -*					Remarks (not to be filled in by the company)
1.5. City of Location: Number of inhabitants	< 20 000: ☐	< 50 000: ☐	more:		
1.6. Neighbourhood: missions, homeless shelters etc.		Distance (Approximately)			
• located within a radius of about 10 miles / 16 km	Yes: ☐	Less than 5 miles / 8 km ☐	More than 5 miles / 8 km ☐	No: ☐	
• List of such locations	available (names, addresses):			Not available ☐	
	handling defined in SOP No.:			Not defined ☐	
1.7. Other plasmapheresis centres	available in the same area, up to about 40 miles / 60 km: ☐			Not available ☐	
If yes: • centres and distance (approximately)	Company name		Distance		
			< 20 miles / 30 km)	more	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
• exchange of information with these centres mentioned above, with	Yes			No exchange: ☐	
	all of these centres: ☐	some of these centres: ☐			
	Information covers:				
	cross donating: ☐	rejected donors: ☐	reactive test results:☐	others: ☐	
	Frequency of information exchange:				
	daily: ☐	weekly: ☐	other:		

2. Licenses from the competent authority / authorities					
					Remarks (not to be filled in by the company)
2.1. Manufacturing License by the national authority (in the U.S.A. Biologics License)	*License available* Yes: ☐ No: ☐	*Date of issue*:	N/A: ☐		
	License Number:	Expiry date:	N/A: ☐		
	Last amendment (date)		None: ☐		
	includes the centre: ☐	*centre not (yet) included:* ☐			
• Centre is still running under the license of another company (e.g. former owner)	Yes (time of role over): ☐	No: ☐			
	License No.:				
2.2. Other State License(s)	Available: ☐	Not available: ☐	Not required: ☐		
• if applicable: which State License(s)					
	Date of issue:	Expiration date:			
		N / A ☐			
2.3. Current Annual Registration *(U.S.A. only)*	Date of issue:	Registration No.:			
• includes: *(more than one tick possible)*	Source plasma ☐	Whole blood ☐	Blood products for diagnostic use (non injectable products) ☐		

3. Official Inspections						Remarks (not to be filled in by the company)
3.1. Last inspection performed by the competent National Authority - date and result -	Date:					
	No observation ☐	Inspection report with observations (U.S.A.: Form 483) ☐	Warning letter (U.S.A.) ☐			
	Number of observations: (if applicable)					
3.2. Previous inspection (s) performed by another authority (e.g. European or PIC/S Health Authority)	Yes: ☐		No, first inspection ☐			
	Health Authority	date	accepted			
			yes	no		
			☐	☐		
			☐	☐		
			☐	☐		
			☐	☐		
			☐	☐		
3.3. Relevant changes since last inspection (if applicable)	*Only in case of repeat inspection*					
• new owner	Yes: ☐	Date of change:			No: ☐	
	Former owner:					
• change of National license	Yes: ☐	Date of change:			No: ☐	
	Kind of change:					
• closure (especially for GMP related problems)	Yes: ☐	*Date of closure*:			No: ☐	
	Reason					
• relocation	Yes: ☐	Date of change:			No: ☐	
	Previous address:					
• major remodelling	Yes: ☐	Date of change:			No: ☐	
	Kind of change:					
• new SOP Manual	Yes: ☐	Date of change:			No: ☐	
	Kind of change:					

3. Official Inspections *– continuation -*			
			Remarks (not to be filled in by the company)
• change of persons in responsible positions (e.g. Manager, production manager, QA person)	Yes: ☐ Date of change: Kind of change:	No: ☐	
• computer system (e.g. new software / version)	Yes: ☐ Date of change: Kind of change:	No: ☐	
• new (type of) plasmapheresis machines	Yes: ☐ Date of change: Kind of change:	No: ☐	
• new / additional freezer	Yes: ☐ Date of change: Kind of change:	No: ☐	
• new / additional test lab	Yes: ☐ Date of change: Kind of change:	No: ☐	
• other relevant change (s)	Yes: ☐ Date of change: Kind of change:	No: ☐	
3.4. Relevant future planned changes (if applicable) –examples see 3.3.-	Yes: ☐ Date of change: Kind of change:	No: ☐	

4. Manufacturing activities

						Remarks (not to be filled in by the company)
4.1. Number of Source Plasma active donors (donors donating *more than one time* during the last 6 months)	Non-immunised donors only (last year)					
	< 200 ☐	200 to 500: ☐	500 to 1000 ☐	About 2000 ☐	More: ☐	
4.2. Number of Source plasma donations / units	Donations from non-immunised donors only					
• from repeat donors (= qualified donors)	Last year:		Current year *(up to the preparation date of the* SMF)			
• from new / applicant new donors	Last year:		Current year *(up to the preparation date of the* SMF)			
4.3. Immunisation program	In use: ☐		Not in use: ☐			
4.4. Kind of immunisation	*Licensed since:*	Not licensed	*In use since:*	Program discontinued since:		
• Hepatitis B		☐				
• Tetanus		☐				
• Anti-D		☐				
• Rabies		☐				
• Small Pox		☐				
• Rubella		☐				
• Others	Yes: ☐			No: ☐		
4.5. Vaccine for immunisation of	Vaccine: brand name, manufacturer				Not in use	
• Hepatitis					☐	
• Tetanus					☐	
• Rabies					☐	
• Anti-D	*(please add details as attachment)*				☐	
• other (which?)					☐	

4. Manufacturing activities *- continuation -*				
				Remarks (not to be filled in by the company)
4.6. Number of immunised active donors ** till preparation of the SMF*	*(Donors donating more than one time during the last 6 months)*			
		last year	current year *	
	Hepatitis			
	Tetanus			
	Rabies			
	Anti-D			
	other immunisation (summarised)			
4.7. Number of source plasma donations / units ** till preparation of the SMF*	*-Donations from immunised donors only-*			
		last year	current year *	
	Hepatitis			
	Tetanus			
	Rabies			
	Anti-D			
	others (summarised)			
4.8. Immunisation program in use for donors with pre-existing antibodies	Yes: ☐	Immunisation program(s):	No: ☐	
4.9. Number of donations from • disease state donors • disease associated antibody donors • for infectious disease marker positive tested donors ** till preparation of the SMF*	*-Donations from "Special donors"-*			
		last year	current year *	
	HIV			
	HBsAg			
	HCV			
	CMV			
	RSV			
	others (summarised)			

4. Manufacturing activities - *continuation* -					
					Remarks (not to be filled in by the company)
4.10. Program for plasma collection from	licensed since / letter of approval from:	not licensed:	In use since:	not in use:	
• disease state donors		☐		☐	
• donors with disease associated antibodies		☐		☐	
• donors tested positive for infectious disease marker		☐		☐	
If in use: • which disease / infectious disease marker (s)	Hepatitis B ☐	Hepatitis C ☐	HIV ☐	Other ☐	
• donations drawn at other time periods than for "normal plasma donations"	Yes: ☐	On which days / times:		No: ☐	
• donations taken only in special rooms and with designated equipment	Yes: ☐	Room:		No: ☐	
• additional or special cleaning / sanitation procedures and documentation required	Yes: ☐	SOP-No.:		No: ☐	
4.11. Other special programs	In use since: (month, year)	Not in use:	Program discontinued since (if applicable)		
• Infrequent program (first donation without any physical examination)		☐			
• Re-entry program (after elevated ALT test results)		☐			
• Re-entry program (after repeat reactive test results for infectious disease markers)		☐			
• Applicant donor program (use of the first donation when the test results for the 2nd donation are available)	In use since:		Not in use: ☐		

5. Testing Laboratories						
						Remarks (not to be filled in by the company)
5.1. Testing Laboratory in use for viral marker testing	Screening / Repeat Tests only					
• Viral marker testing performed in the *company own laboratory* (belonging to the same company)	Anti-HIV 1 / 2 ☐	HIV-1 p24 Antigen: ☐	Anti-HCV: ☐	HBsAg: ☐		
• Viral Marker testing may be performed in *another test lab* (e.g., as back up lab)	Anti-HIV 1 / 2 ☐	HIV-1 p24 Antigen: ☐	Anti-HCV: ☐	HBsAg: ☐		
• If so, in which laboratory? (company name, address)						
5.2. Testing Laboratory in use for other kind of testing	*- not viral marker related -*					
• Testing performed in the *company own laboratory*	ALT: ☐	RPR: ☐	Drug test: ☐	SPE: ☐	Other: ☐	
• Testing may be performed *in another test laboratory*	ALT: ☐	RPR: ☐	Drug test: ☐	SPE: ☐	Other: ☐	
• If so, in which laboratory? (company name, address)						

5. Testing Laboratories *- continuation -*				
				Remarks (not to be filled in by the company)
5.3. Testing Laboratory in use for viral marker testing	*Confirmatory tests only*			
• Viral marker testing performed in the ***company own laboratory*** (belonging to the same company / group)	HIV-1 Western Blot: ☐	HIV-2 ELISA: ☐	HIV-1 p24 Neutralisation: ☐	
	PCR (HIV, HBV, HCV): ☐	RIBA: ☐	HBsAg Neutralisation: ☐	
• Viral Marker testing may be performed in ***another test laboratory*** (e.g., as back up lab)	HIV-1 Western Blot: ☐	HIV-2 ELISA: ☐	HIV-1 p24 Neutralisation: ☐	
	PCR (HIV, HBV, HCV): ☐	RIBA: ☐	HBsAg Neutralisation: ☐	
• If so, in which laboratory? (company name, address)				

6. Quality Assurance (QA)				
				Remarks (not to be filled in by the company)
6.1. Quality Assurance Person / QA Specialist of the centre	Name:			
• Education of the QA specialist (prior to become QA specialist)				
• Training / certification * as QA specialist ** certification according to the company's own procedure*	Training completed (date):		Not completed: ☐	
	Date of certification:		No certification: ☐	
• Availability for QA affairs in the centre per working day	(hours, approximately):			
• QA person / specialist with additional responsibilities	Yes: ☐	No: ☐		
If yes: • additional responsibilities *in the centre*	Yes: ☐	Kind of responsibilities / position:	No: ☐	
• additional responsibilities *in another centre / facility*	Yes: ☐	Kind of responsibilities / position:	No: ☐	
		Distance to the other working place (Miles / km, approx.):		
• Requirements for certification defined in writing	Yes: ☐	SOP-No.:	No: ☐	
• Reporting line for the QA Specialist to	QA of the Corporate office: ☐	Manager of the Centre: ☐	Regional QA Manager: ☐	
	Other person? *(please specify name and position):*			

6. Quality Assurance (QA) *- continuation -*									
									Remarks (not to be filled in by the company)
6.2. "back-up" QA Person / QA Specialist	Name:							Not ☐ available:	
• Education of QA backup person / specialist (prior to become QA specialist)									
• Training / Certification as (Back up) QA specialist in the current company	Training completed (date):							Not completed: ☐	
	Date of certification:							No certification: ☐	
• Availability for QA affairs in the centre per working day	(hours per working day, approx.):								
• Routine responsibility in the centre:									
6.3. Duties of QA persons defined in writing?	Yes: ☐	SOP-No.:						No: ☐	
6.4. Regular checks of documentation performed by QA specialist (s)	Frequency								
	Daily	Weekly	Monthly	Quarterly	Semi-annually	Yearly	Other (which?)		
• review of Sop's / Training Manual	☐	☐	☐	☐	☐	☐			
• review of maintenance log books	☐	☐	☐	☐	☐	☐			
• review of calibration log books	☐	☐	☐	☐	☐	☐			
• review of donor files	☐	☐	☐	☐	☐	☐			
• review of look back information	☐	☐	☐	☐	☐	☐			
6.5. Self inspections (audits of performance) routinely performed according to a pre-arranged program	Yes: ☐	SOP-No.:						No: ☐	
	Routinely performed but not according to a program: ☐							Sporadically performed: ☐	
• Program defines (at least)	Areas to be audited ☐		Frequency per year ☐			Auditor ☐		No ☐ program	

6. Quality Assurance (QA) *- continuation -*						Remarks (not to be filled in by the company)
6.5.1. Audits performed by						
• Members from the Corporate Office	Yes: ☐	No: ☐	Frequency per year (at least)			
			Once: ☐	Other (which?)		
	Date of last Audit:		Last Audit			
			Closure date:	Not closed: ☐		
• Regional QA Manager	Yes: ☐	No: ☐	Frequency per year (at least)			
			Once: ☐	Other (which?)		
	Date of last Audit:		Last Audit			
			Closure date:	Not closed: ☐		
• QA Person / Specialist of the centre	Yes: ☐	No: ☐	Frequency per year (at least)			
			Once: ☐	Other (which?)		
	Date of last Audit:		Last Audit			
			Closure date:	Not closed: ☐		
6.6. Proficiency Testing						
• Requirement to take part in proficiency testing defined in writing	Yes: ☐	SOP-No.:			No ☐	
• Organisation for test samples / evaluation of test results						
• Kind of testing:	Total Protein ☐	Other (specify):				
• Results satisfactory (according to the definition of the organisation mentioned above) for the last and the current year	Yes: ☐	No, percentage: in year:				

7. Personnel					
					Remarks (not to be filled in by the company)
7.1. Centre Physician	Name:				
• Centre Physician	Employed since:	Retired: ☐	No: ☐		
		Additional employment as:		No: ☐	
• Presence during opening hours	On a regular basis: ☐	Not regularly (specify):			
- if on a regular basis:	Day	From	Till		
	Mo.				
	Tu.				
	We.				
	Th.				
	Fr.				
	Sa.				
	Su.				
	Total hours per week:				
7.2. Additional physician in the centre	Name (Physician b):				
• Presence during opening hours	On a regular basis: ☐	Not regularly (specify):			
- if on a regular basis:	Day	From	Till		
	Mo.				
	Tu.				
	We.				
	Th.				
	Fr.				
	Sa.				
	Su.				
	Total hours per week:				

7. Personnel *- continuation -*						
						Remarks (not to be filled in by the company)
7.3. Other additional physician (s) in the centre (summarised)	Number:		Hours of availability in the centre per week:			
7.4. Physician Substitute (s) *(U.S.A. only)*	a) Name:					
	b) Name:					
	c) Name:					
	d) Name:					
	e) Name:					
	f) Name:					
7.4.1. Education	RN:	LPN / LVN:	EMT:	Other (specify):		
Physician substitute a)	☐	☐	☐			
Physician substitute b)	☐	☐	☐			
Physician substitute c)	☐	☐	☐			
Physician substitute d)	☐	☐	☐			
Physician substitute e)	☐	☐	☐			
Physician substitute f)	☐	☐	☐			
7.4.2. Presence of physician substitutes during opening hours (from - till)	Day	*Sub a)*		*Sub b)*	*Sub c)*	
	Mo.					
	Tu.					
	We.					
	Th.					
	Fr.					
	Sa.					
	Su.					
Total hours per week:						

7. Personnel *- continuation -*					
					Remarks (not to be filled in by the company)
7.4.3. Presence of physician substitutes during opening hours (from - till)	Day	*Sub d)*	*Sub e)*	*Sub f)*	
	Mo.				
	Tu.				
	We.				
	Th.				
	Fr.				
	Sa.				
	Su.				
Total hours per week:					
7.5. Interaction (medical staff)	between the responsible physician and other physician(s) and / or physician substitute(s) / nurses				
• defined in writing	Yes: ☐	SOP-No.:		No: ☐	
• documentation available	Yes: ☐		No: ☐		
7.6. Number of staff (Physicians excluded)	Total number:	Number of staff, employed			
		Full-time:	Part-time:		
7.7. Training of the staff					
• performed according to a pre-arranged written program	Yes: ☐	SOP-No.:		No: ☐	
• check of competency after completion of training	Yes: ☐	SOP-No.:		No: ☐	
	Written test: ☐	Performance check: ☐			
• frequency of re-training per year (at least)	Once: ☐	Twice: ☐	Other (which?):		
7.8. Personnel hygiene requirements					
• defined in writing	Yes: ☐	SOP-No.:		No: ☐	
	Medical examinations prior to / after hiring ☐	Medical questionnaire prior to / after hiring: ☐	Hepatitis vacci-nation: ☐	Others: ☐	

8. Rooms and Equipment (plasma collection)				
				Remarks (not to be filled in by the company)
8.1. Floor plan includes all areas which are in use for collection and storage activities	Yes: ☐	No, (additional) external storage / warehouse in use ☐		
8.2. Storage of documents in the plasmapheresis centre	*Documents related to plasma collection, testing and / or shipment*			
• storage time for documents in the centre at least (years)	One (1): ☐	Two (2): ☐	Three (3) and / or more: ☐	
• storage conditions defined in writing (e.g. restricted access, protection against loss, fire, theft etc.)	Yes: ☐	SOP/ document -No.:	No: ☐	
8.3. Outside (external) storage of documents (if applicable)	Yes: ☐	Address:	No: ☐	
• unchanged since last inspection	Yes: ☐	*No, changed since*:		
• kind of location	Public warehouse: ☐	Rented building: ☐	company owned ☐	
• external location defined in writing (address, company, kind of location)	Yes: ☐	SOP/ document -No.:	No: ☐	
• storage conditions for the external location defined in writing (e.g. restricted access, protection against loss, fire, theft etc.)	Yes: ☐	SOP/ document -No.:	No: ☐	
• responsibilities for the external storage defined in writing	Yes: ☐	SOP/ document -No.:	No: ☐	
8.4. Total storage time defined in writing	Yes: ☐	SOP- No.:	No: ☐	
	Minimum storage time (years):			

8. Rooms and Equipment (Plasma collection) – *continuation* -												Remarks (not to be filled in by the company)
8.5. Outside (external) storage of softgoods (if applicable)	Yes: ☐	Address:									No: ☐	
• unchanged since last inspection	Yes: ☐	*No, changed since*:										
• kind of location	Public ware-house: ☐		Rented building: ☐			Company owned: ☐						
8.5.1. external location for softgoods • defined in writing (address, company, kind of location)	Yes: ☐	SOP/ document -No.:									No: ☐	
• storage conditions defined in writing (e.g. restricted access, protection against loss, fire, theft etc.)	Yes: ☐	SOP/ document -No.:									No: ☐	
• responsibilities for the external storage defined in writing	Yes: ☐	SOP/ document -No.:									No: ☐	
8.6. Plasmapheresis centre	*Arrangement of rooms*											
• Areas for donor interview / screening area / donor floor	On one (1) floor: ☐					On two (2) floors: ☐						
• Back doors	Number:	*used*										
		for personnel and / or material: ☐			as emergency exit only: ☐			N / A ☐				
• Booths for the donor interview	Number:	Totally enclosed (rooms): ☐			Partially enclosed (open to the staff area only): ☐			N / A ☐				
• Processing area	Totally enclosed:		Floor to ceiling wall			Closable window						
	Yes ☐	No ☐	Yes ☐		No ☐	Yes ☐		No ☐				

8. Rooms and Equipment (Plasma collection) – *continuation -*							Remarks (not to be filled in by the company)
8.7. Microhematocrit centrifuge (s)	Manufacturer:			Number	N / A ☐		
• calibration frequency	Daily: ☐	Monthly: ☐	Every 3 months: ☐	Other period (specify):			
• use of controls	Low: ☐	Normal: ☐		High: ☐			
8.8. Refractometer (optic part)	Manufacturer:			Number	N / A ☐		
• calibration frequency	Daily: ☐	Other period (specify):					
• use of controls	Low: ☐	Normal: ☐	High: ☐				
8.9. Donor beds	Number:						
8.10. Plasmapheresis machines	Manufacturer:		Number:				
8.11. Softgood area							
• temperature defined	Yes: ☐	SOP-No.:		No: ☐			
	Temperature (°C) :						
• temperature monitored	Yes: ☐	SOP-No.:		No: ☐			
	Frequency of monitoring:						
• pallets in use for softgoods	Wooden pallets ☐	Plastic pallets ☐	Pallets of other material:				
8.12. Urine test strips defined in writing	Yes: ☐	SOP-No.:		No: ☐			
8.13. other reagents (e.g. for blood typing, calibration) defined in writing	Yes: ☐	SOP-No.:		No: ☐			
• date for usage after opening defined	Yes: ☐	SOP-No.:		No: ☐			

9. Rooms and Equipment (Plasma freezing / storage)					
					Remarks (not to be filled in by the company)
9.1. Freezing of plasma *(procedure)*					
• freezing method	Flash freezing: ☐		Slow freezing (in the freezer): ☐		
• procedure defined in writing	Yes: ☐	SOP-No.:		No: ☐	
• max. time period between *end of collection* and *start of plasma freezing* defined in writing	Yes: ☐	SOP-No.:		No: ☐	
	Max. time period (minutes):				
• temperature for plasma freezing defined	Yes: ☐	SOP-No.:		No: ☐	
	Temperature (at least):				
	–30° C or colder ☐	–20° C or colder: ☐	Other:		
9.2. Flash freezing equipment (if applicable)	Number:			N / A ☐	
• flash freezing *start temperature* defined	Yes: ☐	SOP-No.:		No: ☐	
	Temperature (°C):				
• flash freezing *start temperature* regularly documented	Daily: ☐	Per run: ☐	Not documented: ☐		
9.3. Freezer (s)	Number:				
• separate freezers available for	tested / released units: ☐		untested / unreleased units: ☐		
• reactive units stored	Under lock and key: ☐		Not under lock and key: ☐		
	In the freezer: ☐	In the biohazard room: ☐	In an other place (specify):		

9. Rooms and Equipment (Plasma freezing / storage) – *continuation* -						
						Remarks (not to be filled in by the company)
9.3.1. Freezer temperature						
• defined in writing	Yes: ☐	SOP-No.:			No: ☐	
	colder than					
	-20° C ☐	-30° C ☐	Other			
• continuously monitored (temperature recorder)	Yes: ☐		No: ☐			
• frequency of (additional) manual temperature reading (per day)	once: ☐	twice: ☐	3 times ☐	Other (specify):	not per-formed: ☐	
• manual reading also during holidays and at weekends	Yes: ☐		No: ☐			
• maximum acceptable difference between manual temperature reading and automatic temperature recording defined	yes: ☐	SOP-No.:			Not defined ☐	
	Maximum temperature difference (°C):					

9. Rooms and Equipment (Plasma freezing / storage) *- continuation -*					
					Remarks (not to be filled in by the company)
9.3.2. Alarm device and alarms					
• Alarm start / Alarm set	Temperature (°C):		Difference to minimum temperature defined as (°C):		
• Documentation of (real) alarms defined in writing	Yes: ☐	SOP-No.:		No: ☐	
	SOP requires also remarks / explanations for possible alarm reasons: ☐		No: ☐	N / A ☐	
• Number of (real) alarms ** till preparation of the SMF*	current year * :		Previous year:		
9.3.3. Alarm checks					
• procedure defined in writing	Yes: ☐	SOP-No.:		No: ☐	
• procedure includes at least	Frequency of performance ☐	Documentation of temperature causing the alarm (starting from the probe) ☐	Max. acceptable response time of the alarm company : ☐		
• frequency	Monthly: ☐	Other (specify):			
• alarm checks additionally to "real alarms" (caused by accident)	Regularly performed		and documented		
	Yes: ☐	No: ☐	Yes: ☐	No: ☐	

9. Rooms and Equipment (Plasma freezing / storage) *- continuation -*						
						Remarks (not to be filled in by the company)
9.3.4. Validation of freezer • completed	Yes:	Date of completion:		N / A	Not performed:	
• Freezer No. 1	☐				☐	
• Freezer No. 2	☐			☐	☐	
• Freezer No. 3	☐			☐	☐	
• includes requirement for freezing temperature of at least –30°C or colder	*Only if plasma freezing is performed in the freezer*					
	Yes: ☐	Freezer is authorised for freezing: Yes: ☐	No: ☐		No: ☐	
	Coldest area (at least –30°C) in the freezer defined: ☐	Plasma freezing is performed in this area: ☐			Not defined ☐	
9.3.5. Freezer failures						
• Procedure of handling freezer failures defined in writing	Yes: ☐	SOP-No.:			No: ☐	
9.3.5.1. Number of freezer failures	Current year * ** till preparation of the SMF*		Previous year			
• causing use of dry ice						
• causing plasma reclassification						
• other freezer failures						
9.3.6. Information given to the customer if the plasma storage temperature (-20°C or colder) is inadvertently exceeded	Yes: ☐	No: ☐	Defined in SOP-No.		Not defined ☐	

10. Hygiene program (sanitation)					
					Remarks (not to be filled in by the company)
10.1. External cleaning company	Same company used since: (month, year)			No external company: ☐	
10.1.1. Contract available	Yes: ☐		No: ☐		
10.2. Sanitation program (written procedure) available	Yes: ☐		No: ☐		
• includes at least	• schedules		Yes: ☐	No: ☐	
	• substances		Yes: ☐	No: ☐	
	• kind of cleaning		Yes: ☐	No: ☐	
10.3. Documentation about cleaning / sanitation available for	Manufacturing areas / rooms: ☐	Equipment: ☐		Others: ☐	
• performed by	Janitorial staff: ☐		Centre staff: ☐		
10.4. Pest control					
• performed according to a written procedure	Yes: ☐	SOP-No.:		No: ☐	
• frequency (routinely)	Once per month: ☐	Other frequency (specify):			
• documentation available, showing at least	Date of performance: ☐	Areas ☐	Measures ☐	Not available ☐	
• contract / written agreement with the external company	available: ☐		not available: ☐	N / A ☐	
	Date:				

11. Blood / Plasma Samples					
					Remarks (not to be filled in by the company)
11.1. Labelling of samples	For virus marker testing only				
• sample tubes fixed to the plasma bottles	Yes: ☐		No: ☐		
• labelling of sample tubes at the beginning of the plasmapheresis	Yes: ☐	No, in the processing area: ☐	Other (specify):		
11.2. Storage of plasma samples prior to shipment	For virus marker testing only				
• defined in writing	Yes: ☐	SOP-No.:		No: ☐	
• storage in the cooler	Yes: ☐		No: ☐		
	Temperature in the cooler				
	Defined: ☐	Temperature (°C):	Not defined: ☐		
• storage in the freezer	For all samples: ☐		No: ☐		
	For back up samples only: ☐		For re-tests / confirmatory tests only: ☐		
11.3. Frequency of sample send off to the test lab	For virus marker testing only				
• Plasma units collected during the week (Mo, Tu, We, Th)	Next day after collection: ☐		Others:		
• Plasma units collected on Fr, Sa, Su	Maximum number of days after collection:				
11.4. Carrier for plasma samples:					
11.5. Duration of sample transport to the lab	On average (hours):			Max. time:	
	Less than 24 ☐	24 till 48 ☐	More than 48 ☐		
11.6. Conditions during sample transport					
• Use of cool packs (number, arrangement) defined	Yes: ☐	SOP-No.:		No: ☐	
• Use of dry ice (amount) defined in writing	Yes: ☐	SOP-No.:		No: ☐	

12. Test results (Availability in the centre)				
				Remarks (not to be filled in by the company)
12.1. Virus marker test results	Repeat reactive test results in the centre			
12.1.1. Centre information • Negative test results sent	Via modem or on-line: ☐	By hard copies: ☐	By other measures: ☐	
• Reactive test results sent	on-line: ☐	By Fax: ☐	By hard copies: ☐	
• Maximum time period between bleed date and availability of repeat reactive test results in the centre defined in writing	Yes: ☐	SOP-No.:	No: ☐	
	Time period (which):		N/ A ☐	
• Time period between bleed date and availability of repeat reactive test results	Last year			
	On average (days):	Maximum time (days):		
	Current year (till preparation of the SMF)			
	On average (days):	Maximum time (days):		
12.2. Confirmatory test results	Confirmatory test results in the centre			
• Maximum time period between bleed date and availability of confirmatory test results in the centre defined in writing	Yes: ☐	SOP-No.:	No: ☐	
	Time period (which):		N/ A ☐	
• Time period between bleed date and availability of confirmatory test results	Last year			
	On average (days):	Maximum time (days):		
	Current year *(till preparation of the SMF)*			
	On average (days):	Maximum time (days):		

13. Release of plasma units and shipment, rejection of units						Remarks (not to be filled in by the company)
13.1. Release of plasma units						
• Procedure defined in writing	Yes: ☐	SOP-No.:			No: ☐	
• Performed by	The centre: ☐	Corporate office: ☐	Others:			
• Double check prior release (2 different persons involved in the procedure)	*If release is performed by the centre:*					
	Of all units: ☐	No double check: ☐	N/ A ☐			
13.2. Rejection of reactive units	Performed by					
• in the centre	Management / Production manager: ☐	QA person: ☐	QC person: ☐	Other:		
• Double check prior to rejection (2 different persons involved in the procedure)	Yes: ☐	No double check: ☐	Other precautions: ☐			
• Handling of reactive units prior to shipment (if applicable) defined in writing	Yes: ☐	SOP.-No.:		No: ☐		
	Barcode crossing out: ☐	Re-labelling: ☐	Other precautions ☐			
13.3. Shipment of plasma units	Frequency					
13.3.1. Frequency of shipment	Weekly	Bi-weekly	Every 4 weeks	Other period (which?)		
• Negative (non reactive) plasma units only	☐	☐	☐			
• also untested units (test results pending)	☐	☐	☐	Other period ☐	Not shipped ☐	
• also units tested reactive / positive *(not included shipment to a waste company)*	☐	☐	☐	Other period ☐	Not shipped ☐	
13.3.2. Carrier (plasma shipment)	Company (name, address):					

14. Rejection of donors / Deferral System (s)					
					Remarks (not to be filled in by the company)
14.1. Donor Deferral System (in the U.S.A.: NDDR System)	Implementation (month / year):			Not available: ☐	
14.1.1. Possibility to remove donors from the NDDR list	On the centre level: ☐	Not on the centre level: ☐		Not in use: ☐	
If yes:	Donors from this centre only				
• number of donors, removed from the list	Number:			Not in use: ☐	
• does the donor in question get a new donor number	Yes: ☐	No: ☐		N / A ☐	
14.2. Additional deferral list in use, *related to the centre*	ROLODEX / DDR / Card File: ☐	Other (which):			
• If yes, required entries	Defined in writing: ☐			Not defined: ☐	
14.3. Additional deferral list in use, *related to the company* (contains also data from other centres)	Central Test Lab listed: ☐	Other lists (which):		No additional list: ☐	
14.4. Number of rejected repeat / qualified donors (new donors not included)	(Hepatitis B)				
• total number HBsAg screening / repeat test)	Last year:	Current year *(up to the preparation of the SMF):*			
• Number of donors with HBsAg Neutralisation test	Neutralisation (HBsAg)				
	Positive	Indeter-minate	Negative	Not performed	
• last year				☐	
• current year *(up to the date preparation date of the SMF):*				☐	
• Number of donors with PCR test results (HBV)	PCR (HBV)				
	Positive	Negative	Not performed		
• last year			☐		
• current year *(up to the preparation date of the SMF):*			☐		

14. Rejection of donors / Deferral System (s) *- continuation -*					
					Remarks (not to be filled in by the company)
14.5. Number of rejected repeat / qualified donors (new donors not included)	(Hepatitis C)				
• total number (Anti-HCV screening / repeat test)	Last year:		Current year *(up to the preparation of the SMF):*		
• Number of donors with RIBA	RIBA				
	Positive	Indeter-minate	Negative	Not performed	
• last year				☐	
• current year *(up to the preparation date of the SMF)*				☐	
• Number of donors with PCR test results (HCV)	PCR (HCV)				
	Positive		Negative	Not performed	
• last year				☐	
• current year *(up to the preparation date of the SMF)*				☐	
14.6. Number of rejected repeat / qualified donors (new donors not included)	(HIV 1 / 2)				
• Total number (Anti-HIV ½ screening / repeat test)	Last year:		Current year *(up to the preparation of the SMF):*		
• Number of donors with HIV-1 Western blot + HIV-2 *(last year)*	HIV-2 negative		HIV-2 positive	HIV-2 not performed	
• HIV-1 Western blot positive				☐	
• HIV-1 Western blot indeterminate				☐	
• HIV-1 Western blot negative				☐	

14. Rejection of donors / Deferral System (s) *- continuation -*				
				Remarks (not to be filled in by the company)
• Number of donors with HIV-1 Western blot + HIV-2 *(current year, up to the preparation of the SMF)*	HIV-2 negative	HIV-2 positive	HIV-2 not performed	
• HIV-1 Western blot positive			☐	
• HIV-1 Western blot indeterminate			☐	
• HIV-1 Western blot negative			☐	
• Number of donors with PCR test results (HIV)	PCR (HIV)			
	Positive	Negative	Not performed	
• last year			☐	
• current year *(up to the preparation date of the SMF)*			☐	
14.7. Number of rejected repeat / qualified donors (new donors not included)	(HIV-1 p24 Antigen)			
• Total number	Last year:	Current year *(up to the preparation of the SMF):*	Not performed	
			☐	
• Number of donors with HIV-1 p 24 Neutralisation (blocking antibodies)	HIV-1 p 24 Neutralisation			
	Positive	Indeter-minate	Negative	Not performed
• last year				☐
• current year (up to the preparation date of the SMF)				☐
14.8. Rejected new and non qualified applicant donors (Hepatitis B)	Total number (HBsAg screening / repeat test)			
	Last year:	Current year *(up to the preparation of the SMF):*		
14.9. Rejected new and non qualified applicant donors (Hepatitis C)	Total number (Anti-HCV screening / repeat)			
	Last year:	Current year *(up to the preparation of the SMF):*		

14. Rejection of donors / Deferral System (s) *- continuation -*				
				Remarks (not to be filled in by the company)
14.10. Rejected new and non qualified applicant donors (HIV 1/2)	Total number (Anti-HIV 1/2 screening / repeat)			
	Last year:	Current year *(up to the preparation of the SMF):*		
14.11. Rejected new and non qualified applicant donors (HIV-1 p24 Antigen)	Total number (Anti-HIV 1/2 screening / repeat)			
	Last year:	Current year *(up to the preparation of the SMF):*	Not performed	
			☐	

15. Look back information						
						Remarks (not to be filled in by the company)
15.1. Look back Information						
• Procedure defined in writing	Yes: ☐	SOP-No.:			No: ☐	
• Procedure defines: reason and minimum Look back time period	Yes: ☐	SOP-No.:			No: ☐	
15.2. Look back reason	Minimum Look back Period					
	12 months	6 months	3 months	Other time period (specify)	Look back not per-formed	
• HBsAg Repeat reactive	☐	☐	☐		☐	
• Anti-HCV Repeat reactive	☐	☐	☐		☐	
• Anti-HIV 1 / 2 repeat reactive	☐	☐	☐		☐	
• HIV-1 p24 Antigen reactive	☐	☐	☐		☐	
• PCR positive (HBV)	☐	☐	☐		☐	
• PCR positive (HCV)	☐	☐	☐		☐	
• PCR positive (HIV)	☐	☐	☐		☐	
• High risk behaviour	☐	☐	☐		☐	
• CJD	10, 5 years: ☐				☐	☐

15. Look back information – *continuation* -							Remarks (not to be filled in by the company)
15.3. Look back also created when units already have left the collection centre but are still in the same company (e.g. in another location)	Yes: ☐	SOP-No.:				No: ☐	
15.4. Starting point	Look back Information						
• last *negative donation* prior to the reactive test result	*For all* viral marker: ☐		*Not for all* viral marker: ☐				
• *reactive* test result	Yes: ☐	In case of:					
15.5. Procedure if no donation can be found within a period of 6 months prior to the reactive test result	Reactive test result						
	HBsAg	Anti-HCV	Anti-HIV 1/2	HIV-1 p24		PCR (all)	
• looking for the last unit tested negative within a period of 5 years	☐	☐	☐	☐	N / A ☐	☐	
• looking for the last unit tested negative donation within another period (which ?)							
• No Look back Information given to the customer - if no donation can be found within a period of six months -	☐	☐	☐	☐		☐	
15.6. Basis for Look back Information	sent to the customer (e.g. fractionaters)						
• Look back Information on basis of reactive repeat test results	Immediately ☐	Waiting for confirmatory test results: ☐		Even in case of negative confirmatory test results: ☐			
• Confirmatory / Supplementary test results	always additionally sent to the customer: ☐			Not sent out: ☐			

15. Look back information – *continuation* -					
					Remarks (not to be filled in by the company)
15.7. Look back Information Letter also sent (e.g. in copy) to the plasmapheresis centre	sent to the plasmapheresis centre				
	Yes: ☐		No: ☐		
• Centre is required to check look back information letter for correct and complete data	Yes: ☐		No: ☐		
15.8. Number of Look back Information	Based on screening / repeat test results (total number)				
	Last year:		Current year *(up to the preparation of the SMF):*		
• HBsAg (Hepatitis B)					
• Anti-HCV (Hepatitis C)					
• Anti-HIV 1/2 (HIV 1/2)					
• HIV-1 p24 Antigen		N / A ☐		N / A ☐	
15.9. Number of Look back Information	based on other reason (total number)				
	Last year:		Current year *(up to the preparation of the SMF):*		
• High Risk Behaviour					
• PCR (HBV)					
• PCR (HCV)					
• PCR (HIV)					
• Other reason (summarised)					