



PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 020-3
25 September 2007

PIC/S GUIDANCE DOCUMENT FOR INSPECTORS

SITE MASTER FILE FOR PLASMA WAREHOUSES

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TABLE OF CONTENTS

	Page
1. Document history	1
2. Introduction	1
3. Purpose.....	2
4. Scope.....	3
5. Site master file	3
6. Revision history.....	3

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 Plasma warehouses (SMF – PW) 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 – PW should be completed by the manufacturer. In case of more than one 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 – PW should be completed not earlier than approximately six (6) weeks prior to the inspection.
- 2.4 The SMF – PW 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 – PW provides information on the manufacturer's operations and procedures that can be useful in the efficient planning and undertaking of an inspection. The SMF – PW will also be part of the inspection report.
- 2.6 Copies of the following documents should be added to the SMF - PW (*the inspector may request additional copies of other documents*):

- a) Manufacturing license, if applicable
- b) All amendments / supplements to the manufacturing license, if applicable
- c) Annual Registration (in the U.S.A. only)
- d) Additional State Licenses (if applicable)
- e) 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 Plasma warehouse
- f) Organisation chart for the overall company and for the Plasma warehouse (also showing the *names of responsible persons*)
- g) Actual floor plan with *indication of at least the following areas*
 - Plasma receiving area
 - Shipment preparation area
 - Plasma storage area (quarantine and release status)
 - Storage area for samples (if applicable) and for intermediates from plasma (if applicable)
 - Storage area for other freezing goods (if applicable)
 - Storage area for Look back units and for other rejected material
 - 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) Job descriptions of persons in responsible positions
- d) Training program (and documentation)
- e) Sanitation and pest control program (and documentation)
- f) Incidents, accidents, errors, complaints, recalls (SOP and documentation of execution)
- g) Release and distribution of plasma (SOP and documentation)
- h) Shipment documents
- i) Look back procedures (SOP and documentation) - if performed by the plasma warehouse -

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 – PW 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 Plasma warehouses.
- 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 – PW 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 020-2	Change in the Editor's co-ordinates
25 September 2007	PI 020-3	Change in the Editor's co-ordinates

Annex: Site Master File for Plasma Warehouses

Site Master File for Plasma Warehouses (SMF – PW)

Plasma Warehouse : (Name, address, company, Phone and Fax-No., Email)	
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Signature and title:

(Responsible person from the Corporate Office / Management)

Date of preparation:

Signature and title:

(Manager / Production Manager as responsible person for the Plasma Warehouse)

1. General information			
			Remarks (not to be filled in by the company)
1.1. Contact Person for the Health Authority <i>(Name, title, address, Phone No., Fax No., Email)</i>			
1.2. Opening hours / hours of operation	Day:	Opening hours From (a.m.): Till (p.m.):	
	Mo.		
	Tu.		
	We.		
	Th.		
	Fr.		
	Sa		
	Su		
	Total hours per week: hours		
1.3. Date of opening in the actual location by the current owner / company	<i>(Month, day, year)</i>		

2. Licenses from the competent authority / authorities				Remarks (not to be filled in by the company)
2.1. Manufacturing / Storage License by the national authority <i>(in the U.S.A, Biologics License if applicable)</i>	License available: Yes: <input type="checkbox"/> No: <input type="checkbox"/>		Date of issue:	N/A: <input type="checkbox"/>
	License Number:		Expiry date:	N/A: <input type="checkbox"/>
	Last amendment (date)			None: <input type="checkbox"/>
2.2. Other (national) State Licenses	Available: <input type="checkbox"/>	Not available: <input type="checkbox"/>	Not required: <input type="checkbox"/>	
2.3. Current Annual Registration (U.S.A. only)	Date of issue:		Registration No.:	

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 <input type="checkbox"/>	Inspection report with observations (U.S.A.: Form 483) <input type="checkbox"/>	Warning letter (U.S.A.) <input type="checkbox"/>		
	Number of observations: (if applicable):				
3.2. Previous inspection (s) performed by another authority (e.g. European or PIC/S Health Authority)	Yes : <input type="checkbox"/>		No, first inspection <input type="checkbox"/>		
	Health Authority	Date	accepted		
			yes		no
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>

3. Official Inspections - continuation-

		Remarks (not to be filled in by the company)		
3.3. Relevant changes (warehouse related) since the last inspection (if applicable)	Only in case of repeat inspection !			
• New owner	Yes: <input type="checkbox"/>	Date of change:	No	
	Former owner:		<input type="checkbox"/>	
• Change of National License	Yes: <input type="checkbox"/>	Date of change:	No	
	Kind of change:		<input type="checkbox"/>	
• Closure (especially for GMP related problems)	Yes: <input type="checkbox"/>	Date of closure:	No	
		Date of re-opening:	<input type="checkbox"/>	
	Reason for closure:			
• Relocation	Yes: <input type="checkbox"/>	Date of change:	No	
	Previous address:		<input type="checkbox"/>	
• Major remodelling	Yes: <input type="checkbox"/>	Date of change:	No	
	Kind of change:		<input type="checkbox"/>	
• New SOP Manual	Yes: <input type="checkbox"/>	Date of change:	No	
	Kind of change:		<input type="checkbox"/>	
• Change of persons in responsible positions	Yes: <input type="checkbox"/>	Date of change:	No	
	Which persons?		<input type="checkbox"/>	
• Computer system in the warehouse area (e.g. new software version)	Yes: <input type="checkbox"/>	Date of change:	No	
			<input type="checkbox"/>	
• Other relevant changes	Yes: <input type="checkbox"/>	Date of change:	No	
			<input type="checkbox"/>	

4. Routine storage activities (in the warehouse)			Remarks (not to be filled in by the company)
4.1. Storage of	Storage activities		
<ul style="list-style-type: none"> • Source plasma for further manufacturing 	for injectable products <input type="checkbox"/>	No <input type="checkbox"/>	
	Diagnostic use: <input type="checkbox"/>	No <input type="checkbox"/>	
<ul style="list-style-type: none"> • Intermediate products from plasma 	Cryoprecipitate <input type="checkbox"/>	No <input type="checkbox"/>	
	Paste: <input type="checkbox"/>	No <input type="checkbox"/>	
	Others: <input type="checkbox"/>	No <input type="checkbox"/>	
<ul style="list-style-type: none"> • Plasma samples 	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<ul style="list-style-type: none"> • Look back units 	Even for a short time <input type="checkbox"/>	No <input type="checkbox"/>	
<ul style="list-style-type: none"> • Softgoods (for use in plasmapheresis centres) 	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<ul style="list-style-type: none"> • other material (specify) - only if stored on a routine basis- 	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
4.2. Customers (names and addresses)	See attachment <input type="checkbox"/> <i>(please add attachment and assign the customer to the material to be stored)</i>		

5. Other activities (performed by / on behalf of the plasma warehouse)				Remarks (not to be filled in by the company)
5.1. Transport of plasma (or intermediates from plasma) to the warehouse			Yes <input type="checkbox"/>	
If yes:	Company owned only: <input type="checkbox"/>	Leased: <input type="checkbox"/>	No own trailers: <input type="checkbox"/>	
• trucks in use				
• If yes: trailers in use	Company owned only: <input type="checkbox"/>	Leased: <input type="checkbox"/>	No own trailers: <input type="checkbox"/>	
If no:	1.			
• carrier(s) – name, address -	2.			
	3.			
5.2. Shipment of plasma (or intermediates from plasma) from the central warehouse			Yes <input type="checkbox"/>	No <input type="checkbox"/>
if yes:	Company owned only: <input type="checkbox"/>	Leased: <input type="checkbox"/>	No own trailers: <input type="checkbox"/>	
• trucks				
• trailers	Company owned only: <input type="checkbox"/>	Leased: <input type="checkbox"/>	No own trailers: <input type="checkbox"/>	
if no:	1.			
• carrier(s) – name, address -	2.			
5.3. Handling of look back units			Yes <input type="checkbox"/>	Not performed <input type="checkbox"/>
• shipping to other companies	Yes <input type="checkbox"/>	Companies (name, address):		No
5.4. Other activities of the warehouse	Yes <input type="checkbox"/>	if applicable, specify:		No

6. Quality Assurance (QA)						
						Remarks (not to be filled in by the company)
6.1. Quality Assurance Person (s) / Specialist(s) in the warehouse	Name		No additional functions			
6.1.1. Name (s)	1.		<input type="checkbox"/>			
	2.		<input type="checkbox"/>			
	3.		<input type="checkbox"/>			
	<i>if more than 3 persons please add attachment</i>					
6.1.2. Training / Certification <i>* certification according to the company's own procedure</i>	Training		Certification			
	completed (date)	not completed	Date	not certified		
• QA Specialist No. 1		<input type="checkbox"/>		<input type="checkbox"/>		
• QA Specialist No. 2		<input type="checkbox"/>		<input type="checkbox"/>		
• QA Specialist No. 3		<input type="checkbox"/>		<input type="checkbox"/>		
• Other / more QA Specialists	<i>Please add attachment for names, training and certification</i>					
• Requirement for company's own certification defined in writing (SOP)	Yes <input type="checkbox"/>	SOP-No.:			Not defined: <input type="checkbox"/>	
6.2. Duties of QA persons defined in writing?	Yes <input type="checkbox"/>	SOP-No.:			Not defined: <input type="checkbox"/>	
6.2.1. Regular checks of <u>documentation</u> performed by QA person (s)	Frequency					
	daily	weekly	monthly	quarterly	yearly	Other (which?)
• review of SOP's / Training Manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• review of maintenance log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• review of calibration log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• review of daily temperature log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• compliance of alarm checks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• incident records / accidents, complaints, recalls etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

6. Quality Assurance (QA) – continuation -

6. Quality Assurance (QA) – continuation -						Remarks (not to be filled in by the company)	
6.3. Self Inspections (audits of performance) routinely performed according to a pre-arranged program	Yes <input type="checkbox"/>	SOP-No.:			No <input type="checkbox"/>		
	Routinely done, but not according to a program <input type="checkbox"/>			Sporadically performed <input type="checkbox"/>			
6.3.1. Program defines (at least)	Areas to be audited <input type="checkbox"/>	Frequency per year <input type="checkbox"/>	Auditor <input type="checkbox"/>	No program <input type="checkbox"/>			
6.3.2. Audits performed by							
• Members from the Corporate Office	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Frequency per year (at least)				
			Once: <input type="checkbox"/>	Other (which?)			
	Date of last Audit:		Last Audit				
		Closure date:	Not closed: <input type="checkbox"/>				
• Regional Manager	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Frequency per year (at least)				
			Once: <input type="checkbox"/>	Other (which?)			
	Date of last Audit:		Last Audit				
		Closure date:	Not closed: <input type="checkbox"/>				
• QA Person of the warehouse	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Frequency per year (at least)				
			Once: <input type="checkbox"/>	Other (which?)			
	Date of last Audit:		Last Audit				
		Closure date:	Not closed: <input type="checkbox"/>				
• Other persons from the company	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Frequency per year (at least)				
			Once: <input type="checkbox"/>	Other (which?)			
	Date of last Audit:		Last Audit				
		Closure date:	Not closed: <input type="checkbox"/>				

6. Quality Assurance (QA) – continuation -

6. Quality Assurance (QA) – continuation -				Remarks (not to be filled in by the company)
6.4. Trend analyses				
• performance defined in writing	Yes	SOP-No.:	No	
• performed for	Accidents: <input type="checkbox"/>	Complaints: <input type="checkbox"/>	Recalls: <input type="checkbox"/>	
	Others:			
• Summary reports	Frequency:			
	Provided to :			

7. Personnel				
				Remarks (not to be filled in by the company)
7.1. Responsible Director / Manager / Production Manager of the central plasma warehouse	Name:			
	<ul style="list-style-type: none"> employed as such 	Since (month, year):		
	<ul style="list-style-type: none"> job description 	Date of signature:	N / A <input type="checkbox"/>	
7.2. Number of employees in the plasma warehouse	Total number:	Number of staff, employed		
		Full-time:	Part-time:	
7.3. GMP Training	Training of plasma warehouse employees			
<ul style="list-style-type: none"> performed according to a pre-arranged written program 	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
	<ul style="list-style-type: none"> check of competency after completion of training 	Yes <input type="checkbox"/>	SOP-No.:	
		Written test: <input type="checkbox"/>	Performance check: <input type="checkbox"/>	
<ul style="list-style-type: none"> frequency of re-training per year (at least) 	Once <input type="checkbox"/>	Other (which?):		
<ul style="list-style-type: none"> effectiveness of training periodically assessed 	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
		Written test : <input type="checkbox"/>	Practical test: <input type="checkbox"/>	
<ul style="list-style-type: none"> requirements for trainers (assessment) defined in writing 	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
		Written test: <input type="checkbox"/>	Performance check: <input type="checkbox"/>	
7.4. List of initials / signatures	Responsible persons in the warehouse			
<ul style="list-style-type: none"> requirements defined in writing 	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
<ul style="list-style-type: none"> updated on defined intervals 	Yes <input type="checkbox"/>	Interval:		

8. Rooms and Equipment					
					Remarks (not to be filled in by the company)
8.1. Trucks / trailer	<i>only if company owned or leased</i>				
• Number	trucks:	N / A <input type="checkbox"/>	trailer:	N / A <input type="checkbox"/>	
• Qualification of <u>trailer</u>	completed	Not completed			
• installation qualification	<input type="checkbox"/>				
• operation qualification	<input type="checkbox"/>				
• performance qualification	<input type="checkbox"/>				
• qualification requirement defined in writing	Yes <input type="checkbox"/>	SOP-No.:			No <input type="checkbox"/>
• Procedure defined in case of (critical) equipment change	Yes <input type="checkbox"/>	SOP-No.:			No <input type="checkbox"/>
8.2. Seize of the warehouse facility	In total:		Freezer / freezing rooms:		
8.3. Cold room(s) in front of the freezer(s) / freezing rooms available?	Yes: <input type="checkbox"/>		No: <input type="checkbox"/>		
if yes:	Yes <input type="checkbox"/>	SOP-No.:			No <input type="checkbox"/>
• temperature defined	Temperature (°C):				
• main activities in the cold room(s)	Shipment		Others:		
	Receiving <input type="checkbox"/>	Preparation <input type="checkbox"/>			
8.4. Number of freezer (s), freezing rooms (s)	One <input type="checkbox"/>	Two <input type="checkbox"/>	Three <input type="checkbox"/>	More:	
8.5. Storage capacity in the freezer (s) (for frozen material) -approximately	Litre plasma:		Units of plasma:		
8.6. Storage locations in the freezer(s) / freezing rooms defined or identified by	Numbers for			Others:	
	Fixed pallets <input type="checkbox"/>	Bins <input type="checkbox"/>	Location <input type="checkbox"/>		
8.7. Products stored in the freezer (s) / freezing rooms on racks	Yes <input type="checkbox"/>	Level of racks:			No <input type="checkbox"/>

8. Rooms and Equipment - continuation -

8. Rooms and Equipment - continuation -				Remarks (not to be filled in by the company)			
8.8. Number of compressors for the freezer(s) / freezing rooms	One: <input type="checkbox"/>	Two: <input type="checkbox"/>	more:				
if more than one compressor: • compressors run alternately	Yes <input type="checkbox"/>	Rotation approx. every:	No <input type="checkbox"/>			N / A <input type="checkbox"/>	
8.9. Back up generator available	Yes <input type="checkbox"/>	No <input type="checkbox"/>					
if yes: • frequency of routine maintenance defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>				
• maintenance performed every							
• maintenance includes always a test run	Yes <input type="checkbox"/>	Not always: <input type="checkbox"/>	No <input type="checkbox"/>				
8.10. Outside storage (external location) in use for	documents related to warehouse activities						
<i>If yes:</i>	Address:					Not in use <input type="checkbox"/>	
• unchanged since the last inspection	Yes <input type="checkbox"/>	No, changed since:					
• location / warehouse defined in writing (kind of warehouse, location address, leased, company owned)	Yes <input type="checkbox"/>	SOP (or document) No:	Not defined <input type="checkbox"/>				
• responsibilities defined in writing	Yes <input type="checkbox"/>	SOP (or document) No:	Not defined <input type="checkbox"/>				
• requirements (e.g. restricted access, protection against loss) defined in writing	Yes <input type="checkbox"/>	SOP (or document) No:	Not defined <input type="checkbox"/>				
• storage time <u>in the plasma warehouse</u>	<i>At least (years)</i>		Other:				
	One <input type="checkbox"/>	Two <input type="checkbox"/>					
	Defined in writing: <input type="checkbox"/>	SOP-No.:	Not defined <input type="checkbox"/>				
8.11. Total storage time for documents	years	Defined in SOP No:		Not defined <input type="checkbox"/>			

9. Freezer(s)				
				Remarks (not to be filled in by the company)
9.1. Freezer temperature defined as	at least – 20° C: <input type="checkbox"/>	at least – 30°C: <input type="checkbox"/>	others (specify):	
9.2. Freezer temperature recorders	Number:			
9.3. Frequency of (additional) manual temperature reading (per day)	once <input type="checkbox"/>	other (specify):		N / A
	twice <input type="checkbox"/>			<input type="checkbox"/>
	3 times <input type="checkbox"/>			
• manual reading performed by	company own staff only: <input type="checkbox"/>		external staff: <input type="checkbox"/>	
• maximum acceptable difference of manual temperature reading to automatic temperature recording defined	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
	Maximum temperature difference (°C):			
9.4. Alarm device				
• Alarm start / Alarm set defined	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
	Temperature (C):		Difference to minimum temperature defined as (C):	
9.5. Alarm checks :				
• procedure defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
• procedure includes at least	Temperature causing the alarm (from the probe): <input type="checkbox"/>		Max. acceptable response time of the alarm company : <input type="checkbox"/>	
• Frequency of performance	Monthly: <input type="checkbox"/>	Every 2 months: <input type="checkbox"/>	Every 3 months: <input type="checkbox"/>	
	other (specify):			
• Checks performed	additionally to "real" alarms (caused by accident)			
	Yes <input type="checkbox"/>	No <input type="checkbox"/>		

9. Freezer(s) - continuation -				
				Remarks (not to be filled in by the company)
9.6. Validation of freezer(s) completed	Yes <input type="checkbox"/>	Date of completion:	Not performed / not completed <input type="checkbox"/>	
9.7. Freezer failures				
• Procedure of handling freezer failures defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
9.8. Number of freezer failures	Current year (till preparation of the SMF):		Previous year	
• causing use of dry ice				
• causing plasma reclassification				
• other freezer failures				

10. Hygiene program (sanitation)				
				Remarks (not to be filled in by the company)
10.1. External janitorial company	same company used since: (month, year)			N / A <input type="checkbox"/>
	Contract available: <input type="checkbox"/>		Not available: <input type="checkbox"/>	
10.2. Sanitation program (written procedure) available	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
10.3. Documentation available about cleaning / sanitation of	Storing areas / rooms: <input type="checkbox"/>	Equipment: <input type="checkbox"/>	Others: <input type="checkbox"/>	
• performed by	Janitorial staff: <input type="checkbox"/>		Warehouse staff: <input type="checkbox"/>	
10.4. Pest control				
• Written procedure available	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
• Frequency (routinely)	Once per month: <input type="checkbox"/>	Other frequency (specify):		
• Documentation available, showing at least	Date of performance <input type="checkbox"/>	Areas <input type="checkbox"/>	Measures <input type="checkbox"/>	No <input type="checkbox"/>
• Contract with the external company	Available: <input type="checkbox"/>		Not available: <input type="checkbox"/>	

11. Receiving of plasma (and plasma products)

11. <u>Receiving</u> of plasma (and plasma products)				Remarks (not to be filled in by the company)
11.1. Plasma receiving / arrival	Day	Time (approximately)		N / A
	Mo			<input type="checkbox"/>
	Tu			<input type="checkbox"/>
	We			<input type="checkbox"/>
	Th			<input type="checkbox"/>
	Fr			<input type="checkbox"/>
	Sa			<input type="checkbox"/>
	Su			<input type="checkbox"/>
11.2. Volume per day (approx.):	Cartons:		Litre plasma:	
11.3. Responsibility for the shipment to the plasma warehouse by	Plasma deliverer: <input type="checkbox"/>		Warehouse itself: <input type="checkbox"/>	
	Carriers of plasma: <input type="checkbox"/>		Others: <input type="checkbox"/>	
	Defined in writing: <input type="checkbox"/>		Not defined: <input type="checkbox"/>	
11.4. Temperature during shipment				
<ul style="list-style-type: none"> continuously recorded according to a written procedure? 	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
	<ul style="list-style-type: none"> temperature defined in a written procedure? 	Yes <input type="checkbox"/>	SOP-No.:	
<ul style="list-style-type: none"> temperature defined as 	At least -20°C: <input type="checkbox"/>	At least -05° C: <input type="checkbox"/>	others (specify):	
	<ul style="list-style-type: none"> information to the customer if the temperature (-20°C or colder) is inadvertently exceeded for only one event and for not longer than 72 hours and the temperature was at least -5°C 	Routinely given to the customer <input type="checkbox"/>		Not / not always given to the customer <input type="checkbox"/>
Procedure defined in SOP-No.		Not defined <input type="checkbox"/>		

11. Receiving of plasma (and plasma products) – continuation -

				Remarks (not to be filled in by the company)
11.5. Temperature check on the truck trailer after arrival				
• written procedure available?	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
• temperature checks	Regularly performed on each arrival: <input type="checkbox"/>		No <input type="checkbox"/>	
11.6. Other checks after arrival				
• defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
• checks include	Damage: <input type="checkbox"/>	Ice on cartons: <input type="checkbox"/>	Others: <input type="checkbox"/> N / A <input type="checkbox"/>	
• documentation	Available: <input type="checkbox"/>		No <input type="checkbox"/>	
11.7. Procedure if any of the required checks (after product arrival) failed				
• defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
11.8. Procedure for taking in inventory				
• defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
• includes scanning of	Each carton: <input type="checkbox"/>		No <input type="checkbox"/>	
	Each plasma unit: <input type="checkbox"/>		No <input type="checkbox"/>	

12. Storage of plasma				
				Remarks (not to be filled in by the company)
12.1. Storage procedure • defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
12.2. Cartons placed on pallets	Yes <input type="checkbox"/>	but not in every case: <input type="checkbox"/>		No <input type="checkbox"/>
12.3. Plastic pallets only (at least for storage purposes <u>in</u> the warehouse)	Yes <input type="checkbox"/>	but not in every case: <input type="checkbox"/>		No <input type="checkbox"/>
12.4. Wooden pallets in use for plasma / intermediates from plasma	Yes <input type="checkbox"/>	for shipment only: <input type="checkbox"/>	On arrival (e.g. from third parties): <input type="checkbox"/>	No <input type="checkbox"/>
12.5. Pallets stored on racks / pallet places in the warehouse	Yes <input type="checkbox"/>	Number of		No <input type="checkbox"/>
		Racks:	Pallet places:	
12.6. Pallets with barcodes	Yes <input type="checkbox"/>	Not in every case: <input type="checkbox"/>		No <input type="checkbox"/>
12.7. Each pallet is stretch-wrapped?	Yes <input type="checkbox"/>	Not in every case: <input type="checkbox"/>		No <input type="checkbox"/>
12.8. Storage time in the warehouse (on average) for	Plasma:		Intermediates:	

13. Preparation and shipment of plasma / intermediates from plasma				
				Remarks (not to be filled in by the company)
13.1. Responsibility for the shipment <u>from</u> the plasma warehouse to the customer by	the deliverer of plasma for storing: <input type="checkbox"/>	the warehouse: <input type="checkbox"/>		
	the consignee overseas: <input type="checkbox"/>	other third parties: <input type="checkbox"/>		
13.2. Customers (names and addresses) <i>(routine shipment of plasma / plasma products to other locations / other companies)</i>	See attachment <input type="checkbox"/> <i>(please add attachment and assign the customer to the material to be stored)</i>			

13. Preparation and shipment of plasma / intermediates from plasma - continuation -

		Remarks (not to be filled in by the company)			
13.3. Shipment of plasma / intermediates	Plasma / intermediates from the <u>own</u> company				
• as <u>released</u> products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not only: <input type="checkbox"/>	N / A <input type="checkbox"/>	
• with <u>unchanged status</u>	Plasma / intermediates from third parties				
	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not only: <input type="checkbox"/>	N / A <input type="checkbox"/>	
13.4. Preparation of shipment	Plasma / intermediates from plasma				
• procedure defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>	
• scanning of	Each pallet:	<input type="checkbox"/>	No	<input type="checkbox"/>	
	Each carton:	<input type="checkbox"/>	No	<input type="checkbox"/>	
	Each plasma unit:	<input type="checkbox"/>	No	<input type="checkbox"/>	
• cartons	Unpacked and again packed:	<input type="checkbox"/>	Not unpacked:	<input type="checkbox"/>	
• if cartons are unpacked:	Each plasma unit is scanned	<input type="checkbox"/>	plasma units are not scanned:	<input type="checkbox"/>	
13.5. Shipment	Plasma / intermediates from plasma				
• procedure defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>	
13.6. Shipment temperature					
• in overseas containers defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>	
		Temperature at least -20°C : <input type="checkbox"/>	others (specify):		
• in containers for air lines defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>	
		Temperature at least -20°C : <input type="checkbox"/>	others (specify):		
• controlled during shipment	Yes <input type="checkbox"/>	Kind of control:		No <input type="checkbox"/>	

14. Sorting out of Look back units (if applicable)			
			Remarks (not to be filled in by the company)
14.1. Companies, for which Look back units are sorted out:			
• own company only	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
• other companies (specify)	1.		
	2.		
	3.		
	4.		
	5.		
	6.		
14.2. Procedure			
• defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>
• Look back units scanned by barcode	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
• double check during sorting out	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
• re-labelling after sorting out	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
• storage of Look back units under lock and key (until destruction or shipment)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
14.3. Documentation available about			
• destruction	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
• shipment (if applicable)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

15. General documentation				
				Remarks (not to be filled in by the company)
15.1. Documentation system defined in writing	Yes <input type="checkbox"/>	SOP-No.:		No <input type="checkbox"/>
15.2. Documentation	Fully automatically: <input type="checkbox"/>		Partly / not automatically: <input type="checkbox"/>	
15.3. Changes of entries into the computer system (if applicable) traceable as to the	Date: <input type="checkbox"/>	Time: <input type="checkbox"/>	Person: <input type="checkbox"/>	
15.4. Storage of documents	as hard copies <input type="checkbox"/>		by electronic measures <input type="checkbox"/>	
	Minimum storage time (years) -at least-			
	Defined <input type="checkbox"/>	SOP-No.:		Not defined <input type="checkbox"/>
15.5. Protection of data				
• regular back up	By tape: <input type="checkbox"/>		By other measures (specify):	
• frequency of back up	Daily: <input type="checkbox"/>	Weekly: <input type="checkbox"/>	Other: <input type="checkbox"/>	

16. Incidents, accidents, errors, complaints and recalls

		Remarks (not to be filled in by the company)		
16.1. Incident reports	Reportable / non reportable reports			
• procedure defined in writing	Yes <input type="checkbox"/>	SOP-No.:	No <input type="checkbox"/>	
• (at least most frequent) reasons for incident reports defined	Yes <input type="checkbox"/>	No <input type="checkbox"/>	No <input type="checkbox"/>	
• maximum time period defined for investigation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	No <input type="checkbox"/>	
• QA check of incident reports	Yes, required <input type="checkbox"/>	Maximum time period defined:		
16.2. Errors / incidents (number)	Current year (<i>until preparation of SMF</i>)	Last year		
• related to storing				
• related to transportation / shipment				
16.3. Recalls (number)	Current year (<i>until preparation of SMF</i>)	Last year		
• Total number				
