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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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 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 – 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

Annex:

Site Master File for Plasma Warehouses (SMF – PW)

Plasma Warehouse : (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 as responsible person for the Plasma Warehouse)

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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. 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	*(Month, day, year)*			

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 *(in the U.S.A, Biologics License if applicable)*	*License available:* *Yes:* ☐ No: ☐ *License Number:*		*Date of issue*:	N/A: ☐	
			Expiry date:	N/A: ☐	
	Last amendment (date)			None: ☐	
2.2. Other (national) State Licenses	Available: ☐	Not available: ☐	Not required: ☐		
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 <u>National</u> 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. Official Inspections *- continuation-*				
				Remarks (not to be filled in by the company)
3.3. <u>Relevant</u> changes (warehouse related) since the 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 ☐	
		Date of re-opening:		
	Reason for closure:			
• **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:			
• **Change of persons in responsible positions**	Yes: ☐	*Date of change*:	No ☐	
	Which persons?			
• **Computer system in the warehouse area** (e.g. new software version)	Yes: ☐	*Date of change*:	No ☐	
• **Other relevant changes**	Yes: ☐	*Date of change*:	No ☐	

4. Routine storage activities (in the warehouse)				
				Remarks (not to be filled in by the company)
4.1. Storage of	*Storage activities*			
• **Source plasma for further manufacturing**	for injectable products ☐		No ☐	
	Diagnostic use: ☐		No ☐	
• **Intermediate products from plasma**	Cryoprecipitate ☐		No ☐	
	Paste: ☐		No ☐	
	Others:		No ☐	
• **Plasma samples**	Yes ☐		No ☐	
• **Look back units**	Even for a short time ☐		No ☐	
• **Softgoods** (for use in plasmapheresis centres)	Yes ☐		No ☐	
• **other material (specify)** *- only if stored on a routine basis-*	Yes ☐		No ☐	
4.2. Customers (names and addresses)	See attachment ☐ *(please add attachment and assign the customer to the material to be stored)*			

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 ☐			No ☐	
If yes: • **trucks in use**	Company owned only: ☐	Leased: ☐		No own trailers: ☐	
• If yes: **trailers in use**	Company owned only: ☐	Leased: ☐		No own trailers: ☐	
If no: • **carrier(s)** *– name, address -*	1.				
	2.				
	3.				
5.2. Shipment of plasma (or intermediates from plasma) **from the central warehouse**	Yes ☐			No ☐	
if yes: • **trucks**	Company owned only: ☐	Leased: ☐		No own trailers: ☐	
• **trailers**	Company owned only: ☐	Leased: ☐		No own trailers: ☐	
if no: • **carrier(s)** *– name, address -*	1.				
	2.				
5.3. Handling of look back units	Yes ☐		Not performed ☐		
• shipping to other companies	Yes ☐	Companies (name, address):		No	
5.4. Other activities of the warehouse	Yes ☐	*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.					☐	
	2.					☐	
	3.					☐	
	if more than 3 persons please add attachment						
6.1.2. Training / Certification	**Training**			**Certification**			
** certification according to the company's own procedure*	**completed (date)**		**not com-pleted**	**Date**		**not certified**	
• QA Specialist No. 1			☐			☐	
• QA Specialist No. 2			☐			☐	
• QA Specialist No. 3			☐			☐	
• Other / more QA Specialists	*Please add attachment for names, training and certification*						
• Requirement for company's own certification defined in writing (SOP)	Yes ☐	SOP-No.:				Not defined: ☐	
6.2. Duties of QA persons defined in writing?	Yes ☐	SOP-No.:				Not defined: ☐	
6.2.1. Regular checks of documentation performed by QA person (s)	**Frequency**						
	daily	weekly	monthly	quarterly	yearly	Other (which?)	
• review of SOP's / Training Manual	☐	☐	☐	☐	☐		
• review of maintenance log	☐	☐	☐	☐	☐		
• review of calibration log	☐	☐	☐	☐	☐		
• review of daily temperature log	☐	☐	☐	☐	☐		
• compliance of alarm checks	☐	☐	☐	☐	☐		
• incident records / accidents, complaints, recalls etc.	☐	☐	☐	☐	☐		

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 ☐	SOP-No.:				No ☐	
	Routinely done, but not according to a program ☐			Sporadically performed ☐			
6.3.1. Program defines (at least)	Areas to be audited ☐	Frequency per year ☐	Auditor ☐	No ☐ pro-gram			
6.3.2. 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 Manager	Yes ☐	No ☐	**Frequency per year** (at least)				
			Once: ☐	Other (which?)			
	Date of last Audit:		**Last Audit**				
			Closure date:		Not closed: ☐		
• QA Person of the warehouse	Yes ☐	No ☐	**Frequency per year** (at least)				
			Once: ☐	Other (which?)			
	Date of last Audit:		**Last Audit**				
			Closure date:		Not closed: ☐		
• Other persons from the company	Yes ☐	No ☐	**Frequency per year** (at least)				
			Once: ☐	Other (which?)			
	Date of last Audit:		**Last Audit**				
			Closure date:		Not closed: ☐		

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: ☐	Complaints: ☐	Recalls: ☐	
	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:				
• employed as such	Since (month, year):				
• job description	Date of signature:			N / A ☐	
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**				
• 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* ☐	*Other (which?):*			
• effectiveness of training periodically assessed	Yes ☐	SOP-No.:		No ☐	
	Written test : ☐	Practical test: ☐			
• requirements for **trainers** (assessment) defined in writing	Yes ☐	SOP-No.:		No ☐	
	Written test: ☐	Performance check: ☐			
7.4. List of initials / signatures	***Responsible persons in the warehouse***				
• requirements defined in writing	Yes ☐	SOP-No.:		No ☐	
• updated on defined intervals	Yes ☐	Interval:		No ☐	

8. Rooms and Equipment							
							Remarks (not to be filled in by the company)
8.1. Trucks / trailer	***only if company owned or leased***						
• Number	trucks:		N / A ☐	trailer:		N / A ☐	
• Qualification of trailer	completed	Not completed					
• installation qualification	☐						
• operation qualification	☐						
• performance qualification	☐						
• qualification requirement defined in writing	Yes ☐	SOP-No.:				No ☐	
• Procedure defined in case of (critical) equipment change	Yes ☐	SOP-No.:				No ☐	
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: ☐			No: ☐			
if yes: • temperature defined	Yes ☐	SOP-No.:				No ☐	
	Temperature (°C):						
• main activities in the cold room(s)	Shipment			Others:			
	Receiving ☐	Preparation ☐					
8.4. Number of freezer (s), freezing rooms (s)	One ☐	Two ☐	Three ☐	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 ☐	Bins ☐	Loca-tion ☐				
8.7. Products stored in the freezer (s) / freezing rooms on racks	Yes ☐	Level of racks:				No ☐	

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: ☐	Two: ☐	more:			
if more than one compressor: • compressors run alternately	Yes ☐	Rotation approx. every:		No ☐	N / A ☐	
8.9. Back up generator available	Yes ☐		No ☐			
if yes: • frequency of routine maintenance defined in writing	Yes ☐	SOP-No.:		No ☐		
• maintenance performed every						
• maintenance includes always a test run	Yes ☐	Not always: ☐		No ☐		
8.10. Outside storage (external location) in use for *If yes:*	**documents related to warehouse activities**					
	Address:			Not in use ☐		
• unchanged since the last inspection	Yes ☐	*No, changed since*:				
• location / warehouse defined in writing (kind of warehouse, location address, leased, company owned)	Yes ☐	SOP (or document) No:		Not defined ☐		
• responsibilities defined in writing	Yes ☐	SOP (or document) No:		Not defined ☐		
• requirements (e.g. restricted access, protection against loss) defined in writing	Yes ☐	SOP (or document) No:		Not defined ☐		
• storage time <u>in the plasma warehouse</u>	*At least (years)*		Other:			
	One ☐	Two ☐				
	Defined in writing: ☐	SOP-No.:		Not defined ☐		
8.11. Total storage time for documents	years	Defined in SOP No:		Not defined ☐		

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

9. Freezer(s) *- continuation -*					
					Remarks (not to be filled in by the company)
9.6. Validation of freezer(s) completed	Yes ☐	Date of completion:		Not performed / not completed ☐	
9.7. Freezer failures					
• Procedure of handling freezer failures defined in writing	Yes ☐	SOP-No.:		No ☐	
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 ☐	
	Contract available: ☐		Not available: ☐		
10.2. Sanitation program (written procedure) available	Yes ☐	SOP-No.:		No ☐	
10.3. Documentation available about cleaning / sanitation of	Storaging areas / rooms: ☐	Equipment: ☐	Others: ☐		
• performed by	Janitorial staff: ☐		Warehouse staff: ☐		
10.4. Pest control					
• Written procedure available	Yes ☐	SOP-No.:		No ☐	
• Frequency (routinely)	Once per month: ☐	Other frequency (specify):			
• Documentation available, showing at least	Date of performance ☐	Areas ☐	Measures ☐	No ☐	
• Contract with the external company	Available: ☐		Not available: ☐		

11. Receiving 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			☐	
	Tu			☐	
	We			☐	
	Th			☐	
	Fr			☐	
	Sa			☐	
	Su			☐	
11.2. Volume per day (approx.):	Cartons:		Litre plasma:		
11.3. Responsibility for the shipment to the plasma warehouse by	Plasma deliverer: ☐		Warehouse itself: ☐		
	Carriers of plasma: ☐		Others: ☐		
	Defined in writing: ☐		Not defined: ☐		
11.4. Temperature during shipment					
• continuously recorded according to a written procedure?	Yes ☐	SOP-No.:		No ☐	
• temperature defined in a written procedure?	Yes ☐	SOP-No.:		No ☐	
• temperature defined as	At least -20° C: ☐	At least –05° C: ☐	others (specify):		
• 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 ☐		Not / not always given to the customer ☐		
	Procedure defined in SOP-No.		Not defined ☐		

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 ☐	SOP-No.:		No ☐	
• temperature checks	Regularly performed on each arrival: ☐			No ☐	
11.6. Other checks after arrival					
• defined in writing	Yes ☐	SOP-No.:		No ☐	
• checks include	Damage: ☐	Ice on cartons:☐	Others: ☐	N / A ☐	
• documentation	Available:☐		No ☐		
11.7. Procedure if any of the required checks (after product arrival) **failed**					
• defined in writing	Yes ☐	SOP-No.:		No ☐	
11.8. Procedure for taking in inventory					
• defined in writing	Yes ☐	SOP-No.:		No ☐	
• includes scanning of	Each carton: ☐			No ☐	
	Each plasma unit: ☐			No ☐	

12. Storage of plasma					
					Remarks (not to be filled in by the company)
12.1. Storage procedure • defined in writing	Yes ☐	SOP-No.:		No ☐	
12.2. Cartons placed on pallets	Yes ☐	but not in every case: ☐		No ☐	
12.3. Plastic pallets only (at least for storage purposes in the warehouse)	Yes ☐	but not in every case: ☐		No ☐	
12.4. Wooden pallets in use for plasma / intermediates from plasma	Yes ☐	for shipment only: ☐	On arrival (e.g. from third parties): ☐	No ☐	
12.5. Pallets stored on racks / pallet places in the warehouse	Yes ☐	**Number of**		No ☐	
		Racks:	Pallet places:		
12.6. Pallets with barcodes	Yes ☐	Not in every case: ☐		No ☐	
12.7. Each pallet is stretch-wrapped?	Yes ☐	Not in every case: ☐		No ☐	
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 storaging: ☐	the warehouse: ☐	
	the consignee overseas: ☐	other third parties: ☐	
13.2. Customers (names and addresses) *(<u>routine shipment</u> of plasma / plasma products <u>to</u> other locations / other companies)*	See attachment ☐ *(please add attachment and assign the customer to the material to be stored)*		

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 ☐	No☐	Not only: ☐	N / A ☐	
• **with <u>unchanged status</u>**	**Plasma / intermediates from third parties**				
	Yes ☐	No☐	Not only: ☐	N / A ☐	
13.4. Preparation of shipment	**Plasma / intermediates from plasma**				
• procedure defined in writing	Yes ☐	SOP-No.:		No ☐	
• scanning of	Each pallet: ☐		No ☐		
	Each carton: ☐		No ☐		
	Each plasma unit: ☐		No ☐		
• cartons	Unpacked and again packed: ☐		Not unpacked: ☐		
• if cartons are unpacked:	Each plasma unit is scanned ☐		plasma units are not scanned: ☐		
13.5. Shipment	**Plasma / intermediates from plasma**				
• procedure defined in writing	Yes ☐	SOP-No.:		No☐	
13.6. Shipment temperature					
• in overseas containers defined in writing	Yes ☐	SOP-No.:		No☐	
	Temperature at least –20°C : ☐		others (specify):		
• in containers for air lines defined in writing	Yes ☐	SOP-No.:		No☐	
	Temperature at least –20°C : ☐		others (specify):		
• controlled during shipment	Yes ☐	Kind of control:		No☐	

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 ☐	No ☐	
• other companies (specify)	1.		
	2.		
	3.		
	4.		
	5.		
	6.		
14.2. Procedure			
• defined in writing	Yes ☐	SOP-No.:	No ☐
• Look back units scanned by barcode	Yes ☐	No ☐	
• double check during sorting out	Yes ☐	No ☐	
• re-labelling after sorting out	Yes ☐	No ☐	
• storage of Look back units under lock and key (until destruction or shipment)?	Yes ☐	No ☐	
14.3. Documentation available about			
• destruction	Yes ☐	No ☐	
• shipment (if applicable)	Yes ☐	No ☐	

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

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 ☐	SOP-No.:	No ☐	
• (at least most frequent) reasons for incident reports defined	Yes ☐		No ☐	
• maximum time period defined for investigation	Yes ☐		No ☐	
• QA check of incident reports	Yes, required ☐		Maximum time period defined:	
16.2. Errors / incidents (number)	**Current year** *(until preparation of SMF)*		**Last year**	
• related to storaging				
• related to transportation / shipment				
16.3. Recalls (number)	**Current year** *(until preparation of SMF)*		**Last year**	
• Total number				