

QUALITY TECHNICAL AGREEMENT

Between

UPS SCS (Nederland) BV

Luchthavenweg 57, 5657 EA, Eindhoven, The Netherlands
subsequently named **UPS SCS**

and

< Rijksinstituut voor Volksgezondheid en Milieu >

<Antonie Van Leeuwenhoeklaan 9, 3721 MA Bilthoven >
subsequently named **DVP**

QUALITY TECHNICAL AGREEMENT

PURPOSE

This Quality Technical Agreement (the "Quality Technical Agreement"), by and between UPS SCS(Nederland) BV (shall be referred to herein as "UPS SCS") and <CLIENT> (shall be referred to herein as "DVP") It supplements the provisions of the *Back-up Storage Agreement for the COVID-19 Vaccination Campaign* being translated from Dutch "*Overeenkomst: Back-up opslag ten behoeve van de COVID-19 Vaccinatiecampagne*" (from hereafter referred to as BSA) signed by and between DVP and UPS SCS relating to Good Manufacturing Practices (as hereafter referred to as the GMP), and/or Good Distribution Practice (as hereafter referred to as the GDP), ISO 9001 and/or ISO 13485. Note: that from hereafter; capitalised terms not otherwise defined herein are used as defined in the BSA for the storage of PRODUCT in The Netherlands and Distribution within and outside the EMEA Territory.

The purpose of the Quality Technical Agreement is to ensure that the roles and responsibilities are clearly defined with respect to relevant GMP and/or GDP activities according to EU council Directives 98/79/EC (IVDD), 93/42/EEC, 2001/83/EC and their amending Directives 2003/94/EC, 2011/62/EU (Falsified Medicines Directive), Commission Delegated Regulation (EU) 2016/161, marketing authorizations, ISO 9001 and/or ISO 13485 standards and applicable laws.

SCOPE

This agreement applies to receipt, storage, relabeling, repackaging and distribution of medicinal products and medical devices. Nothing in this Quality Technical Agreement shall limit a party's obligation to comply with GMP, GDP, ISO 9001 and/or ISO 13485 requirements and all applicable laws.

Products approved under this Quality Technical Agreement falling under any regulation of dangerous goods and/or hazardous chemicals additionally need to be approved and set up in the hazardous chemical storage exhibit.

This Quality Technical Agreement takes the form of a detailed checklist of the activities associated with the receipt, storage, repacking, relabeling and distribution of medicinal products and medical devices. Responsibility for each activity is assigned to either UPS SCS and/or DVP in the appropriate box in the Delegation Responsibility Checklist that follows. For each responsibility listed, the respective party is required to put into effect all applicable procedures and to take all necessary actions to effectuate that responsibility in accordance with GDP, GMP, applicable laws and the marketing authorizations.

To facilitate routine communications between the parties, each party shall designate Key Contacts and Responsible Persons in Appendix 3 of this agreement. Appendix 1 lists the key contact with their approval signatures. Appendix 2 lists the signatures of the Qualified Persons from both UPS SCS and DVP involved in GMP Batch Release. The Appendices may be updated and amended as needed upon agreement of both parties without the need to update the body of this agreement.

Repackaging, re-labelling or the addition of labelling can only be done when authorised by DVP and in accordance with all laws and regulations governing the locality and markets to which the PRODUCTS would be distributed.

This Quality Technical Agreement is subject to the terms and conditions of the BSA. In the event of a conflict between this Quality Technical Agreement and the BSA, this Quality Technical Agreement shall control for Quality aspects and the BSA shall control for non-quality aspects, except that any dispute arising out of or relating to this Quality Technical Agreement shall first be resolved in accordance with Article 7 of this Quality Technical Agreement.

UPS SCS shall assume no further liability under this Quality Technical Agreement as otherwise provided under the terms and conditions of the BSA signed between the Parties.

If not otherwise defined in this Quality Technical Agreement the following general guidelines should be applied: EudraLex Volume 4 as it is related to GMP, 2013/C 343/01 as it is related to GDP, and the European Commission Delegated Regulation (EU) 2016/161 for Safety Features on Medicinal Products for Human Use that supplements Directive 2001/83/EC, with detailed rules for the safety features appearing on the packaging of medicinal products for human use.

In addition where not defined in this agreement, provisions of UPS SCS'S quality management system and standard operating procedures / work instructions shall be applied to DVP's operations.

EFFECTIVE DATE, TERM, AND TERMINATION

The Effective Date of this Quality Technical Agreement shall be the date of the last signature on this Quality Technical Agreement (Effective Date).

The initial term of this Quality Technical Agreement shall begin on the Effective Date and continues for the period as the BSA to which this Quality Technical Agreement relates. This Quality Technical Agreement will be reviewed for correctness and effectiveness as necessary but not to exceed a three (3) year period.

Table of Contents

QUALITY TECHNICAL AGREEMENT	1
PURPOSE	2
SCOPE	2
EFFECTIVE DATE, TERM, AND TERMINATION	3
DEFINITIONS	6
RESPONSIBILITY DELEGATION CHECKLIST.....	10
1 REGULATORY AUTHORIZATIONS AND COMMUNICATIONS.....	10
1.0 FACILITY LICENSURE & REGISTRATION	10
1.1 CUSTOMER LICENSE VERIFICATION.....	10
2 GDP AND GMP COMPLIANCE	12
2.0 ORGANIZATION AND PERSONNEL.....	12
2.1 BUILDINGS AND FACILITIES	12
2.2 EQUIPMENT AND UTILITY SERVICES	13
2.3 SYSTEM VALIDATION	14
3 PROCESS CONTROLS.....	14
3.0 (CLIENT SPECIFIC) WORK INSTRUCTIONS	14
3.1 PROCESS CHANGE CONTROL	15
4 PRODUCT HANDLING.....	16
4.0 SHIPPING, STORAGE AND TRANSPORTATION.....	16
4.1 NON SELLABLE PRODUCT	17
4.2 DISTRIBUTION RECORDS.....	17
4.3 PRODUCT INSPECTION.....	18
5 QUALITY CONTROL/ASSURANCE	19
5.0 NON-CONFORMANCE INVESTIGATIONS.....	19
5.1 MATERIAL DISPOSITION/REJECTION/DESTRUCTION	19
5.2 RECORDS RETENTION	19
5.3 CUSTOMER COMPLAINTS, THEFT, DIVERSION, FALSIFIED MEDICINAL PRODUCTS, COUNTERFEIT AND ADVERSE EVENTS.....	20
5.4 MARKET ACTIONS	20
5.5 SECONDARY PACKAGING.....	21
5.6 RETURNS	22
6 DVP OVERSIGHT	23
6.0 AUDITS	23
6.1 REGULATORY INSPECTIONS/NOTIFICATIONS	24
6.2 REVIEW & REVISION OF QUALITY TECHNICAL AGREEMENT	25
6.3 REVIEW, REVISION AND SIGNING OF DOCUMENTS.....	25
7 DISPUTE RESOLUTION.....	26
8 DATA INTEGRITY	26

9 SERIALISATION (EU FMD)	26
VERSION HISTORY	29
APPENDIX 1: APPROVALS	30
APPENDIX 2: SIGNATURE REFERENCES QUALIFIED PERSONS.....	31
APPENDIX 3: KEY CONTACTS AND RESPONSIBLE PERSONS	32
APPENDIX 4: UPS SCS COMMUNICATION ESCALATION MATRIX.....	34
FLOW CHART I: QUALITY/ REGULATORY ISSUES	34
FLOW CHART II: CUSTOMER SERVICE ISSUES	34
FLOW CHART III: OPERATIONS ISSUES.....	35

DEFINITIONS

Terms used in this Quality Technical Agreement shall have the following definitions:

“API”	Active Pharmaceutical Ingredient
“Adverse Event”	Any untoward <i>medical</i> occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.
“Agency”	“AGENCY” shall mean EMA or any governmental authority involved in regulating any aspect of the manufacture, packaging and/or labeling of the PRODUCTS, including GMP, GDP, safety and environmental regulations.
“Applicable laws”	“Applicable laws” shall mean all laws, ordinances, rules and regulations applicable to the storage and distribution of PRODUCT and the obligations of UPS SCS or DVP, as the context requires under this Quality Technical Agreement, including, without limitation, (i) all applicable federal, state and local laws (ii) the GMP, (iii) GDP and (iv) AGENCY requirements.
“Business Day”	A day that is not a Saturday, a Sunday or a public holiday in the place concerned. So essentially a business day is Monday through Friday of any given week, minus public holidays.
“Change”	A change that includes, but is not limited to, the addition, deletion, or modification to existing systems, processes, methods or specifications for the PRODUCT.
“Client”	The entity that UPS SCS has contractual obligations with for providing 3PL services.
“Counterfeit”	A medicinal product made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or rights. Counterfeit medicines infringe trademark law. <i>Counterfeiting</i> can apply to both branded and generic products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
“Customer”	The entity to whom the client directs UPS SCS to ship their products. These are the customers of the UPS SCS client.
“Designated Wholesaler”	Designated by the marketing authorization holder to store and distribute the products covered by their marketing authorization on their behalf.
“Deviation/ Non-conformance”	Any deviation or non-conformance from approved policies, procedures, work instructions, methods, standards, plans, or GMP/GDP protocols with (possible) impact on the PRODUCT.
“Diversion”	The re-allocation of medicinal products or medical devices to intended purposes or markets different from the original purpose and/or market.
“EMA”	“EMA” shall mean the European Medicines Agency.
“EU FMD”	“EU FMD” shall mean European Falsified Medicines Directive.
“GDP”	“GDP” shall mean Good Distribution Practices. <i>That part of</i>

	<i>Quality Assurance which ensures that the quality of medicinal products is maintained throughout all stages of the supply chain from the site of manufacturer to the pharmacy or person authorised or entitled to supply medicinal products to the public.</i>
"GMP's"	<i>"GMP's" shall mean Good Manufacturing Practices. That part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.</i>
"Facility"	<i>"Facility" shall mean the UPS SCS facility on the Louis Pasteurweg 1, 6045 GW Roermond (The Netherlands) as the primary facility and Marco-Poloweg 22-24, 5928 LE Venlo (The Netherlands) as Back-up facility for the manufacturing activities as specified in the BSA.</i>
"Falsified Medicinal Product"	<i>Any medicinal product with a false representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used.</i>
"ISO 13485"	<i>"ISO 13485" Quality Management System - Requirements for regulatory purposes based on International Standards for Medical Devices.</i>
ISPM 15	<i>International Standards For Phytosanitary Measures No. 15. This International Standard describes the phytosanitary measures that reduce the risk of introduction and spread of quarantine pests associated with the movement in international trade of wood packaging material made from raw wood. Wood packaging material covered by this standard includes dunnage but excludes wood packaging made from wood processed in such a way that it is free from pests (e.g. plywood).</i>
"Hazardous Waste"	<i>"Hazardous Waste" – Any such material that, upon its destruction, is considered to be Hazardous material or Hazardous waste by the local governing agencies and as such requiring specific documentation, authorization, and procedures for disposition of such PRODUCT.</i>
"Marketing Authorizations"	<i>"Marketing authorizations" shall mean all pending and approved authorizations, permits, applications and registrations granted by or filed with any governmental authority to manufacture, market, store, distribute and/or sell the PRODUCT.</i>
"Manufacturing License"	<i>"Manufacturing License" shall mean an official authorisation issued by the local/governmental authority to a manufacturer of medicinal product allowing the company to manufacture a certain range of medicinal products according to the current laws and regulations.</i>
"Medical Device"	<i>'Medical Device' will mean any device or In Vitro Diagnostic as defined in 98/79/EC (IVDD) and 93/42/EEC.</i>

	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices effective as of 26 May 2021. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices effective as of 26 May 2021.
"PRODUCT"	"PRODUCT" shall mean any medicinal finished goods, sample product, Medical Devices and InVitro Diagnostic Device (IVDD).
"Qualified Person"	Qualified Person or QP shall mean the person defined in Article 48 of Directive 2001/83/EC, as amended, and Article 52 of Directive 2001/82/EC. Within UPS the QP is a part of the Management and is together with the RP responsible for the Quality System. Furthermore, the main focus of the QP within UPS is to ensure proper rework (such as repackaging and batch inspection) and batch release is performed. Other responsibilities include, amongst others, involvement in deviation handling, management review, customer complaints, recalls and (self) inspections.
"RECORDS"	"RECORDS" shall mean any written or electronic accounts, notes, data, record of, and information and results obtained from performance of all work done under this Quality Technical Agreement.
"Responsible Person"	The Responsible Person shall have the meaning described in Directive 2001/83/EC, Title VII, Article 79 and EU Guideline 2013/C 343/01, Chapter 1, paragraph 1.2 and the responsibilities described in EU Guideline 2013/C 343/01, Chapter 2, paragraph 2.2.
"SAMPLES"	"SAMPLES" shall mean any finished medicinal, Medical Device or InVitro Diagnostic Device (IVDD) PRODUCT labeled and marketed for sampling. This can be supplied direct to physicians or through sales representatives and labeled as "Sample Product Only – Not For Sale". This can also be a reference/retention sample or samples for EU testing. <u>Reference sample</u>: a sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analyzed should the need arise during the shelf life of the batch concerned. <u>Retention sample</u>: a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes.
"Services"	"Services" shall mean all storage, distribution and other activity that UPS SCS is engaged to provide to DVP as defined in the BSA.
"Standard Operating Procedures"	"Standard Operating Procedures" [SOP(s)] shall mean controlled written documents that describe the overlying policies and procedures defined by UPS SCS to ensure compliance with all GDP and GMP requirements as it relates to the receipt, storage and distribution of PRODUCTS and applicable ISO 9001 and/or ISO 13485 requirements.

“Subcontractors”	“Subcontractor” shall mean any direct or indirect individual or company performing services on behalf of and under the express direction or control of UPS SCS as defined under Chapter 7 “Outsourced Activities” of the European Guidelines on Good Distribution Practices of medicinal products for human use [2013/C 343/01].
“Third Party Logistics Provider (3PL)”	“Third Party logistics Provider.” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.
“Wholesale Dealer License”	“Wholesale Dealer License” shall mean a Wholesale Distribution Authorisation to procure, hold, supply or export medicinal products to anyone other than the patient using the medicinal product.
“Work Instructions”	“Work Instructions” [WI(s)] shall mean controlled written documents (either (client specific) or generic), that describe the detailed methods and action steps to be followed for the receipt, storage and distribution of the PRODUCTS which have been approved by all concerned parties following the UPS SCS procedure and in compliance with all GDP, GMP and ISO 9001 and/or ISO 13485 requirements.

RESPONSIBILITY DELEGATION CHECKLIST

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
1 Regulatory Authorizations and Communications			
<i>1.0 Facility Licensure & Registration</i>			
1.0.1	Will maintain all licenses and authorizations as are required by applicable laws to operate a GMP/ GDP medicinal product and medical device facility.	X	X
1.0.2	Will act as liaison with the Marketing Authorization holder for the approval, maintenance and updating of PRODUCT labeling in the Market Authorizations.	X	
1.0.3	Will obtain and maintain a facility registration number from the appropriate AGENCY and provide DVP with such license / registration information for the facility upon their request.		X
1.0.4	Will, upon request, provide copies of all documentation necessary for the other party to respond to inquiries by AGENCY relating to PRODUCT.	X	X
<i>1.1 Customer License Verification</i>			
1.1.1	Obtain supplies of medicinal products only from persons who are themselves in possession of a wholesale distribution authorization, or who are in possession of a manufacturing authorization which covers the product in question.	X	
1.1.2	Hold a manufacturing license if medicinal products are received from third countries for the purpose of importation, i.e. for the purpose of placing these products on the EU market.	X	
1.1.3a	Verify that the supplier complies with the principles and guidelines of EU GDP and that they hold an authorization, for example by using the Union database, where medicinal products are obtained from another distributor.	X	
1.1.3b	Perform checks based on procedure to verify that the suppliers approved by DVP comply with the principles and guidelines of EU GDP.		X
1.1.4	Perform appropriate qualification and approval of suppliers prior to any procurement of medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked.	X	

RESPONSIBILITIES		DVP	UPS SCS
1.1.5	Carry out 'due diligence' checks when entering into a new contract with new suppliers in order to assess the suitability, competence and reliability of the other party. Pay attention to: (i) the reputation or reliability of the supplier; (ii) offers of medicinal products more likely to be falsified; (iii) large offers of medicinal products which are generally only available in limited quantities; and (iv) out-of-range prices.	X	
1.1.6	Monitor transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances or other dangerous substances. Investigate unusual sales patterns that may constitute Diversion or misuse of medicinal product and report to competent authorities where necessary. Take steps to ensure fulfillment of any public service obligation that is imposed.	X	
1.1.7	Inform DVP in case of irregularities in the sales patterns of products to help him to monitor the transactions.		X
1.1.8	Ensure medicinal products are supplied only to persons who are themselves in possession of a wholesale distribution authorization or who are authorized or entitled to supply medicinal products to the public as meant in 'Geneesmiddelenwet' Article 61, Section 1, sub [a] and sub [b] or as meant in 'Regeling Geneesmiddelenwet' Article 6.5	X	
1.1.9	Perform checks and periodic rechecks that may include: requesting copies of customer's authorizations according to national law, verifying status on an authority website, requesting evidence of qualifications or entitlement according to national legislation.	X	
1.1.10	Provide new customer information and revised customer information which will include if applicable: - Customer Name - Valid Sales Order number (SO) / Purchase Order number (PO) - A specific Customer Delivery and Invoice address. - Product code(s) and Quantity - Requested Delivery Date.	X	
1.1.11	Perform random license verification on the applicable suppliers/ customer orders. In case any issues are identified during the verification process, the order will not be handled before a resolution has been arranged between UPS SCS and <CLIENT>.		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
2 GDP and GMP Compliance			
<i>2.0 Organization and Personnel</i>			
2.0.1	Will maintain a quality system with clearly defined responsibilities, policies, and procedures as to comply with all GMP, GDP requirements outlined in SOPs and (client specific) WIs (if applicable).	X	X
2.0.2	Appoints a Responsible Person (RP) who has the authority and responsibility for implementing an appropriate quality system in compliance with European GDP guidelines.	X	X
2.0.3	Will be responsible to maintain the authority to approve or reject all inbound product, cold chain shipping containers, and product deviations based on the defined product storage conditions and stability testing data.	X	
2.0.4	Will ensure that responsibilities and procedures applicable to the quality unit are documented in writing and consistently followed.		X
2.0.5	Will conduct internal audits of all relevant activities to ensure compliance with GMP, GDP and applicable SOPs.	X	X
2.0.6	Through a defined Vendor Qualification Program, will ensure that the use of outside vendor services is supported by documented verification that the vendor(s) has (have) the sufficient education, training, experience, or any combination thereof, to advise/perform to the subject/services for which they are retained.		X
2.0.7	Will provide and document initial and on-going GDP/GMP and process specific training of employees involved in shipping, transporting and storage of the PRODUCT. Training will include applicable laws, regulations, SOPs and (DVP specific) WIs. (if applicable).		X
2.0.8	Will maintain adequate and qualified warehouse personnel in the facility during the storage of PRODUCT to ensure compliance with GMP, GDP and similar local regulations. Will ensure that individuals working at the facilities have the general skills, experience and training necessary to perform their job as outlined in the SOPs.		X
<i>2.1 Buildings and Facilities</i>			
2.1.1	Will perform storage of the PRODUCT in the facilities outlined in the BSA.		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
2.1.2	Will maintain and operate the facility in compliance with the GMP/GDP and all applicable regulations and license requirements documented in SOPs.		X
2.1.3	Will maintain controlled access to the facility.		X
2.1.4	Will maintain and implement a written pest control program, per GMP / GDP guidelines, which includes locations of bait stations and chemicals that may be used and the frequency of the inspection for pest activity.		X
2.1.5	Will keep records of pest control inspections and initiate actions where required		X
2.1.6	Will perform temperature mapping studies of product storage areas as appropriately defined on a risk-based approach.		X
2.1.7	Housekeeping - Storage areas are cleaned on a regular basis and maintained free of dust, debris and extraneous material. Cleaning supplies are segregated from PRODUCT storage areas. A procedure is in place describing the activities of the housekeeping program.		X
2.2 Equipment and Utility Services			
2.2.1	Will qualify, maintain and calibrate equipment and utility services associated with storage and distribution of the PRODUCTS in accordance with GMP / GDP, applicable laws, and SOPs.		X
2.2.2	Will provide defined storage and transportation requirements (to include temperature ranges, relative humidity requirements and any acceptable excursion limits) for all PRODUCTS to UPS SCS prior to handling of the respective PRODUCTS by UPS SCS team.	X	
2.2.3	Will execute and document all necessary validation protocols for the various storage environments necessary for DVP's PRODUCTS to ensure that all defined storage conditions can be maintained. (DVP will have the opportunity to review/audit all executed validations upon completion and provide any necessary recommendations.).		X
2.2.4	Will monitor and record all necessary storage conditions for DVP's PRODUCTS as defined in the product master data sheets . Will also notify DVP's representatives of any and all unacceptable temperature excursions experienced as outlined in the client specific WI(s).		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
2.2.5	Will maintain, control and calibrate equipment critical to the warehousing process (ie. Temperature monitoring devices.).		X
2.3 System Validation			
2.3.1	Will provide, upon request, adequate documented proof of validation of the warehouse operating system, as required by and defined in 21 CFR Part 11 and applicable EU law.		X
2.3.2	Will maintain change control documentation for all changes to the validated system to include risk assessment and will perform additional validation testing/ documentation for all GMP-related system enhancements and changes in order to maintain a validated state.		X
2.3.4	Will have the right to periodically audit the UPS SCS system validation and change control documentation. (No more than annually unless for cause. UPS SCS would require 30 days' notice prior to any IT and/or system validation audit request.). Request period is required by UPS SCS to secure the availability and commitment (including any travel arrangements) of the appropriate IT, QA/Validation and/or applicable resources.	X	
3 Process Controls			
3.0 (Client Specific) Work Instructions			
3.0.1	QA will be responsible for ensuring that the operations unit is following all applicable SOPs and (Client Specific) WIs (if applicable). Will ensure that the storage and distribution of the PRODUCTS are in compliance with all applicable laws and regulations governing the storage and distribution of medicinal products, medical devices and IVDD PRODUCTS from the distribution center, including without limitation GMPs and GDPs.		X
3.0.2	Quality unit shall be responsible for reviewing, approving and controlling distribution of WIs, and SOPs.		X
3.0.3	Will review, approve and sign all SOPs and WIs to be used for DVP process prior to implementation.		X
3.0.4	If applicable, DVP will review, approve and sign all client specific WI(s) prior to implementation.	X	

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
3.1 Process Change Control			
3.1.1	Will maintain document control and all applicable revision history for all processes and procedures as defined in the written SOPs and (client specific) WIs		X
3.1.2	Will submit written notification with respect to any proposed changes to the storage and distribution of the PRODUCT, as defined in the client specific WI(s), to the other party for review and approval, prior to the implementation of such changes and the submission of any such changes to the AGENCY, if applicable. See articles 3.1.4 and 3.1.5 for changes driven by agency requirements.	X	X
3.1.3	Will provide the other party with written approval of changes on all DVP specific WIs.	X	X
3.1.4	For those changes required to comply with applicable laws and AGENCY requirements, UPS SCS will notify DVP of such requirements as soon as possible within a reasonable timeframe after UPS SCS becomes aware of the need for such change, e.g.: ▪ Changes to PRODUCT specification. ▪ Change of Management Representative. ▪ Change to the warehouse temperature control or monitoring system with (possible) impact on the PRODUCT. Any change in the status of licenses resulting in license withdrawal by the Licensing Authority. Consent/Approval from DVP shall not be required for such changes. (DVP will have the right to consult with UPS SCS and provide recommendations on the proposed change).		X
3.1.5.a	For those changes required to comply with applicable laws and AGENCY requirements, DVP will notify UPS SCS of such requirements as soon as possible within a reasonable timeframe after DVP becomes aware of the need for such change.	X	
3.1.5.b	For determining the timelines for the implementation of these changes, both DVP and UPS SCS will agree upon on a case by case basis.	X	X
3.1.6	Will not subcontract any activities for storage and distribution of PRODUCTS without prior consent by DVP.		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
3.1.7	Will enter an appropriate written contract with subcontractors and ensures the qualification of subcontractors following UPS SCS Supplier Qualification Process.		X
3.1.8	Ensures that any third party used to perform services is in compliance with the applicable guidelines, UPS SCS SOPs and the requirements laid down in this Quality Technical Agreement.		X
4 Product Handling			
<i>4.0 Shipping, Storage and Transportation</i>			
4.0.1	Will arrange for PRODUCTS to be delivered to the UPS SCS Facilities in a segregated manner, free from contamination, properly marked and packaged for efficient handling.	X	
4.0.2	Will maintain adequate and segregated storage areas for PRODUCT in accordance with specifications, SOPs, DVP requirements, GMPs, GDP, and all applicable laws.		X
4.0.3	Will ensure that PRODUCT is stored, packed and transported under appropriate conditions of temperature and humidity until PRODUCT is turned over to DVP's distributors and/or customers.		X
4.0.4	For PRODUCTS with expiration date to maintain a FEFO (First Expired First Out) stock rotation system with regular, frequent checks to ensure that the system is operating correctly and that PRODUCTS reaching their expiration date are separated from usable stock and neither sold, nor shipped, without written consent from DVP QA.		X
4.0.5	DVP Logistics team is responsible for providing a written consent for shipment and/or destruction of PRODUCTS reaching their expiration date.	X	
4.0.6	For PRODUCTS without expiration date to maintain a FIFO stock rotation system with regular, frequent checks to ensure that the system is operating correctly and neither sold, nor shipped, without written consent from DVP.		X
4.0.7	DVP Logistics team is responsible for providing a written consent for shipment and/or destruction of PRODUCTS without expiration date.	X	
4.0.8	Will maintain PRODUCT under appropriate security and will have appropriate controls to prevent product deterioration, cross-contamination or mix-ups of such PRODUCTS.		X

RESPONSIBILITIES		DVP	UPS SCS
4.0.9	Will arrange for and manage inbound/ outbound transportation of the PRODUCTS to/from UPS SCS using only pre-approved and qualified Carriers.	X	X
4.0.10	Will ensure that vehicles and equipment used to transport the PRODUCT to/from UPS SCS facility are suitable for their use and appropriately equipped to prevent exposure of the PRODUCT to conditions that could affect its stability and packaging integrity or contaminate it in any way.		X
4.1 Non Sellable Product			
4.1.1	Will ensure that applicable PRODUCT remains under appropriate electronic status to prevent pre-mature release via validated electronic system.		X
4.1.2	Will provide a written communication of the change in product status as defined in the UPS SCS procedure and/ or (client specific) WIs (if applicable).	X	
4.1.3	Will have final release or disposition authority.	X	
4.1.4	Will provide notification within 24 hours of quality events that involve material that has previously been released.	X	X
4.1.5a	Will isolate PRODUCT that has been rejected by either party by labeling and physical segregation and appropriately update product status in the inventory system.		X
4.1.5b	Ensures PRODUCT status is up to date in the inventory system.	X	
4.2 Distribution Records			
4.2.1	Will be responsible for maintaining sufficient distribution records of PRODUCT shipped to customers covering the name and strength of PRODUCT, name and address of the consignee, date and quantity shipped, and lot or control number of PRODUCT for a period of 11 years (as defined in the UPS SCS Records Retention SOP) to allow eventual batch traceability where needed.		X
4.2.2	DVP Responsible Person (or delegate) to provide written approval prior to destruction by UPS-SCS of any distribution records.	X	
4.2.3	Will have appropriate defined procedures for the receipt, storage, segregation, and eventual shipment/ transportation of all sellable and/or non-sellable PRODUCT to the defined DVP vendor for determination of final disposition as defined in the SOPs and WI (as applicable).		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
4.2.4	Will ensure that no hazardous materials or products that would be determined to become hazardous waste will be sent to the UPS SCS facility or handled by or stored within the UPS SCS facility. UPS SCS will protect DVP PRODUCT from any such materials at UPS SCS.	X	X
4.2.5	DVP will be responsible for the delivery address of products shipped from UPS SCS facility and should indicate this address to UPS SCS as the only one to be delivered the products shipped from UPS SCS facility.	X	
4.2.6	Provide a monthly record in which are included all the orders shipped from UPS SCS facility to the final customers (final authorized address). This record must be signed of conformity by the client.		X
4.2.7	Will ensure all the shipments have been delivered to the address indicated in the delivery note and provide a Proof of Delivery to DVP.		X
4.3 Product Inspection			
4.3.1	Will verify the actual stock received against the delivery documentation. (<i>verification of Product Identity/ pack size/ quantity/ expiry date/ batch numbers, Absence of data (e.g. batch number), Damages to product or pallet, Deviations from the required special storage conditions, Conditions of the delivery vehicle, Non-compliant packs etc</i>). Will promptly notify DVP on any discrepancy or non-conformance from the delivery documentation,		X
4.3.2	Will perform both inbound and outbound visual inspection of PRODUCT for damages and/ or other signs of contamination as defined in the (client specific) work instruction(s) and SOPs.		X
4.3.3	Ensure all wooden pallets shipped to/ from UPS SCS facilities are heat treated in accordance with International Standards for Phytosanitary Measures (ISPM 15).	X	
4.3.4	In case not heat treated pallets, UPS SCS to visually inspect and perform re-palletization to heat treated pallets compliant with ISPM 15.		X
4.3.5	Evidence that the pallets received with the products are fumigated pallets or have been treated against any kind of mold, fungi or similar pests. (pallets identified as fumigated or provide treatment certification together with the products)	X	

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
5 Quality Control/Assurance			
5.0 Non-Conformance Investigations			
5.0.1	Will notify DVP Logistics team immediately (not to exceed one (1) business day) upon discovery of any major/ critical process non-conformances / deviation related to their PRODUCT that may directly or indirectly affect the quality of the PRODUCT. Non-conformities such as: ▪ Any significant inventory inaccuracy (e.g. stolen or lost), ▪ Any issues where PRODUCT storage or transportations requirements are not met, ▪ Deviations related to a Data Integrity failure. At point of notification, will provide DVP with the applicable details of the event to allow DVP to make any necessary judgments on the safety and quality of the PRODUCT.		X
5.0.2	As soon as possible, will provide DVP an initial written report (Non-Conformance Report) that will outline the specific details of the non-conformance and the original requirements. A follow up report will be provided to DVP (within 30 days) once UPS SCS has completed a detailed root-cause-analysis and identified corrective/preventive actions.		X
5.0.3	Will have the right to review and provide recommendations for possible corrective and preventive actions directly related to the storage and distribution of PRODUCT for DVP	X	
5.0.4	DVP will have the right to conduct an independent investigation related to any deviations, with prior consultation to UPS SCS.	X	
5.0.5	Will have a system to appropriately document and handle Non-Conformance.	X	X
5.1 Material Disposition/Rejection/Destruction			
5.1.1	Will determine final disposition of any rejected or returned PRODUCT .	X	
5.1.2	Will provide all needed elements to support DVP decision making process.		X
5.2 Records Retention			
5.2.1	Upon DVP's request, will promptly make any original documentation related to the PRODUCT available for DVP's inspection at the facility.		X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
5.2.2	DVP will notify UPS SCS for any exceptional or special document retention period requirements before such documents are due to be destroyed following regular retention period requirements as defined in the UPS Records Retention SOP (11 years).	X	
5.2.3	Will provide the original documents when requested within 15 days upon receipt of the request.		X
<i>5.3 Customer Complaints, Theft, Diversion, Falsified Medicinal Products, Counterfeit and Adverse Events</i>			
5.3.1	Upon request DVP to provide UPS SCS training on how to deal with quality complaints, medical information queries and Pharmacovigilance issues.	X	
5.3.2	Provide a safe and secure environment for DVP PRODUCT and ensure tampering, theft and contamination is prevented.		X
5.3.3	Will forward all calls / inquiries relating to complaints, theft, Diversion, Falsified and adverse events immediately to the designated DVP representative as defined in the UPS SCS SOPs.		X
5.3.4	Any complaints received by UPS SCS relating to an DVP ² PRODUCT must be notified within 24 hours to DVP.		X
5.3.5	Will assist DVP in investigating and resolving all PRODUCT complaints related to the storage and distribution of the PRODUCT.		X
5.3.6	In the event the complaint is related to the storage and shipment of the PRODUCT, a follow up report will be provided to DVP (within 30 days) once UPS SCS has completed a detailed root cause analysis and identified corrective/preventive actions.		X
5.3.7	Will take any corrective actions to avoid future occurrences of PRODUCT complaints.	X	X
5.3.8	Will issue all reports relating to critical complaints and adverse events to appropriate AGENCY.	X	
5.3.9	Will provide all current and correct information related to labeling, patient information leaflet and packaging of their products in order to detect any Falsified products. If required, to establish a WI.	X	
<i>5.4 Market Actions</i>			
5.4.1	Responsible for notification of recall or PRODUCT withdrawal to appropriate AGENCY.	X	

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
5.4.2	Responsible for management of recall or PRODUCT withdrawal.	X	
5.4.3	Responsible for formal notification by the DVP QA Department of any recall in case UPS SCS will be involved in the support of the recall for putting product on hold, segregation of inventory and/or physical transportation as requested. A formal notification to be provided to the following email alias: UPS Roermond II Management: 5.1.5 @ups.com	X	
5.4.4	DVP will provide the necessary instructions, to perform a recall.	X	
5.4.5	Responsible for following written instruction specifically approved by DVP in case of recall, stock recovery, and destruction of PRODUCTS. In conjunction with UPS SCS SOPs and WIs (as applicable).		X
5.4.6	Will notify DVP immediately of any information of which it is aware related to the storage of the PRODUCT which may affect the continued marketing of the PRODUCT or result in a potential recall or market withdrawal.		X
5.4.7	Responsible for decision to initiate recall or PRODUCT withdrawal.	X	
5.4.8	In case of any recall or another market action, the PRODUCT stock in possession of UPS SCS, will be placed on hold in UPS SCS Warehouse Management System as soon as possible.		X
5.4.9	Will abide by DVP's decision to recall the PRODUCT and fully cooperate with DVP's requests for information and action in a timely manner.		X
5.4.10	When requested by DVP will provide preliminary information within 24 hours.		X
5.5 Secondary Packaging			
5.5.1	Procurement of packaging materials	X	
5.5.2	Will provide copies of the approved artwork and component specifications for printed packaging materials.	X	
5.5.3	Will inspect and release prior to packing, each print run of components according to current DVP requirements translated into UPS SCS SOP(s).		X
5.5.4	DVP Quality will provide the up to date instructions and specifications necessary for the execution of the required re-pack operations for review and approval by UPS QA.	X	

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
5.5.5	UPS QA will review and approve the instructions and specifications necessary for the execution of the required re-pack operations provided by DVP.		X
5.5.6	UPS QA will send UPS approved packaging specifications to DVP QP for final approval.		X
5.5.7	Will provide UPS SCS information about the maximum time out of the refrigeration while performing any repackaging according to the packaging specification.	X	
5.5.8	Will prepare the required Manufacturing Instructions and Records to perform the re-pack operations requested by DVP and authorise them by the UPS Quality department.		X
5.5.9	Assures that through the repacking procedure the exposure of the refrigerated PRODUCT to room temperature (15-25°C) does not exceed the instructed time specified on the packing specification or on the instructions given by client.		X
5.5.10	Ensures that written procedures are in place to control the addition of the non-product use information such as: labels, local PRODUCT identifiers, special bar codes, holograms etc.	X	X
5.5.11	Will provide instructions about the statistical method to perform the inspection on the repacked PRODUCTS.	X	
5.5.12	Will perform a statistical inspection on re-packed PRODUCT according to current DVP requirements translated into UPS SCS SOP(s)		X
5.5.13	Stores one finished PRODUCT sample as a retention for one year passed expiry date.		X
5.5.14	Provide a copy of the completed Manufacturing documentation to DVP following the UPS Qualified Person approval for compliance to the instructions and GMP.		X
5.5.15	Will place all completed PRODUCTS into quarantine status until the formal release approval is received from the appropriate DVP location.		X
5.6 Returns			
5.6.1	Is responsible for the notification of the announced and the unannounced returns to UPS SCS at all times	X	

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
5.6.2	DVP Qualified Person or Responsible Person will determine final disposition of any returned PRODUCT.	X	
5.6.3	Have procedures in place for handling and processing customer returns and to ensure they are not redistributed without a proper review and approval by a Qualified Person or Responsible Person. Procedure addresses the proper record keeping, safe handling and disposal of customer returns.		X
5.6.4	Is responsible to review the packaging materials, patient information leaflet and labeling of the returned products in order to detect any tampering of the safety features of the products (e.g. tamper evidence, serial number, GTIN and data matrix), in order to detect any Falsified products..		X
6 DVP Oversight			
6.0 Audits			
6.0.1	Will allow and support annual quality audits by DVP personnel per facility. (UPS SCS will require 30 days' notice for any scheduled audit.)		X
6.0.2	Will provide reasonable prior notice to UPS SCS for scheduling quality audits. (30 days)	X	
6.0.3	Will allow and support additional audits for cause as requested by DVP to address specific quality problems related to the PRODUCT or in response to AGENCY requirements. (UPS SCS would request 2 business days' notice upon scheduling any audits for cause)		X
6.0.4	During audits, will provide reasonable access to all areas within the facility where handling of the PRODUCT and related documentation occur.		X
6.0.5	Will provide UPS SCS with a written report detailing observations and conclusions arising from each quality audit within 30 days from audit closeout.	X	
6.0.6	Will provide DVP with a written response within thirty (30) days of receipt of DVP's written report on audit observations and conclusions.		X
6.0.7	Will discuss and mutually agree on corrective action plans to address audit observations and conclusions.	X	X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
6.0.8	Will have the right to periodically (no more than annually unless for cause) review and audit the vendor qualification records maintained by UPS SCS for any applicable suppliers, contractors, or sub-contractors utilized by UPS SCS and related to the storage of PRODUCT upon reasonable prior notice to UPS.	X	
<i>6.1 Regulatory Inspections/Notifications</i>			
6.1.1	Will notify DVP within forty-eight (48) hours of learning of any proposed inspection or visit of the FACILITIES by any governmental authority, including, without limitation, any AGENCY or any environmental regulatory authority that may potentially impact the storage of the PRODUCT.		X
6.1.2	Will notify DVP as soon as reasonably possible (not more than 48 hours) after the commencement of any unannounced visit or inspection of the FACILITY by any governmental authority, including, without limitation, any AGENCY or any environmental regulatory authority that may potentially impact the storage of the PRODUCT.		X
6.1.3	Will permit one or more representative(s) of DVP to be on-site for the portion of the inspection by any governmental authority, including, without limitation, any AGENCY or any environmental regulatory authority, relating to or affecting the PRODUCT, if requested by DVP and not limited by the agency.		X
6.1.4	If DVP is not present during such proposed or unannounced visit or inspection, will provide DVP with a written summary of the inspection results within forty-eight (48) hours of the conclusion of the inspection relating to or affecting the PRODUCT		X
6.1.5	Will notify DVP immediately of any AGENCY request for PRODUCT samples. Duplicate samples will be retained of any DVP PRODUCT sampled by any regulatory agency.		X
6.1.6	Will notify DVP as soon as reasonably possible but no more than forty-eight (48) hours from receipt of any information regarding any threatened or pending action by any AGENCY relating to or potentially impacting the PRODUCT.		X
6.1.7	Will cooperate in the development and review of responses required by the applicable AGENCY and relating to the storage of PRODUCT prior to submission to the AGENCY. Nothing contained within this article shall restrict the right of either party to make a timely report of such matter to any AGENCY or take other action that it deems to be appropriate or required by applicable laws.	X	X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
<i>6.2 Review & Revision of Quality Technical Agreement</i>			
6.2.1	Will review every three (3) years the Quality Technical Agreement as agreed by either party to incorporate new compliance responsibilities. DVP and UPS to notify DVP QA and UPS QA when updates are due.	X	X
6.2.2	Will obtain written approval from both parties for any amendments to the Quality Technical Agreement.	X	X
6.2.3	Will maintain revision control of the Quality Technical Agreement and issue a revised document as appropriate.		X
<i>6.3 Review, Revision and Signing of Documents</i>			
6.3.1	<i>With regards to review, revision and signing of DVP related UPS SCS documents such as non-conformances, change controls, client specific work instructions / forms):</i> a. DVP QA will review and provide comments via email within five (5) working days after receipt. b. Once there is an agreement on the content, DVP QA will not provide formal written approval but rather approval via email. c. In case DVP QA has not responded on time (i.e. within five (5) working days), UPS will proceed with the next steps. d. Responses received after five (5) working days will be taken into consideration with next revision.	X	X
6.3.2	<i>Review and sign off of Planned Deviations:</i> DVP will not review/ sign off any Planned Deviations being part of UPS SCS Quality System raised by UPS impacting the services provided to DVP PRODUCT.	X	X

<u>RESPONSIBILITIES</u>		DVP	UPS SCS
7 Dispute Resolution			
7.0.1	Will attempt to amicably resolve any dispute arising out of or relating to this Quality Technical Agreement by escalating such disputes to senior executives within the Quality organizations of both parties. PRODUCT release decisions and PRODUCT recall decisions by DVP cannot be disputed.	X	X
8 Data Integrity			
8.0.1	Ensures that all data and Metadata (electronic or paper) relevant to GDP, GMP and ISO 13485 activities conducted pursuant to this Quality Agreement are Attributable, Legible, Contemporaneous, Original, Accurate, controlled and safe from intentional or unintentional manipulation or loss throughout the retention period for this data.		X
8.0.2	Ensures that documentation and data management practices (paper and electronic) are well defined and that they are understood and implemented by all Personnel. Procedures, automaton systems and/or management controls must ensure data integrity is upheld and periodically assessed.		X
8.0.3	Ensures that any breach of data integrity that directly impacts, or potentially impacts the service is formally notified and reported to one another with undue delay in writing. All breaches shall be investigated.	X	X
8.0.4	DVP shall support the investigation of any data integrity breaches that directly impacts or potentially impacts the service and approve the final investigation.	X	
8.0.5	DVP shall confirm Data Integrity requirements are satisfactory as part of the auditing process.	X	
9 Serialisation (EU FMD)			
9.0.1	Ensure procedures are in place describing the Verification, Decommissioning, and potentially Undo-Decommissioning processes for EU pharma products, as per EU FMD.		X
9.0.2a	SKU master data, Order notification, ASN notification regarding EU FMD needs to be provided by DVP.	X	
9.0.2b	SKU master data, Order notification, ASN notification regarding EU FMD needs to be setup in UPS system.		X

RESPONSIBILITIES		DVP	UPS SCS																
9.0.3	Provide clear instructions when Verification, Decommissioning and/or Undo-Decommissioning activities are needed. For example (but not limited to): - Inbound - Returns - Repackaging or Relabelling Non-routine customers (article 23 customer, samples, export, donations, etc).	X																	
9.0.4	Ensure below system transactions are performed for the following FMD specific reasons as per DVP instructions: <table><tr><th>Events</th><th>Description</th></tr><tr><td>DESTROYED</td><td>Products leaving for destruction.</td></tr><tr><td>EXPORTED</td><td>Serialized product distributed outside of the European Union (and/or EEA).</td></tr><tr><td>FREE SAMPLE</td><td>Serialized products converted to Non-commercial for Free Samples</td></tr><tr><td>NCA SAMPLE</td><td>Serialized products converted to samples for National Competent Authorities</td></tr><tr><td>STOLEN*</td><td>Product that has been stolen (confirmed)</td></tr><tr><td>LOCKED*</td><td>Product that is currently under investigation (e.g. possibly stolen)</td></tr><tr><td>SUPPLIED</td><td>Product that has been supplied to the market (e.g. Article 23 customers, donations)</td></tr></table> *Reasons marked with an asterisk are not eligible for Undo-Decommissioning within 10 days of Decommission.	Events	Description	DESTROYED	Products leaving for destruction.	EXPORTED	Serialized product distributed outside of the European Union (and/or EEA).	FREE SAMPLE	Serialized products converted to Non-commercial for Free Samples	NCA SAMPLE	Serialized products converted to samples for National Competent Authorities	STOLEN*	Product that has been stolen (confirmed)	LOCKED*	Product that is currently under investigation (e.g. possibly stolen)	SUPPLIED	Product that has been supplied to the market (e.g. Article 23 customers, donations)		X
Events	Description																		
DESTROYED	Products leaving for destruction.																		
EXPORTED	Serialized product distributed outside of the European Union (and/or EEA).																		
FREE SAMPLE	Serialized products converted to Non-commercial for Free Samples																		
NCA SAMPLE	Serialized products converted to samples for National Competent Authorities																		
STOLEN*	Product that has been stolen (confirmed)																		
LOCKED*	Product that is currently under investigation (e.g. possibly stolen)																		
SUPPLIED	Product that has been supplied to the market (e.g. Article 23 customers, donations)																		
9.0.5	Ensure verification and/or decommissioning events are performed according to DVP instructions within a timely manner.		X																
9.0.6	Ensure sufficient validated GS1 compliant barcode scanning equipment is available at the right locations for verification and decommissioning activities and personnel is trained in the usage of the scanners. Forecasts to be provided.	X	X																
9.0.7	Ensure undo-decommissioning events are performed within 10 days as per DVP instructions.		X																
9.0.8	Ensure EU FMD based reporting tools are available.		X																

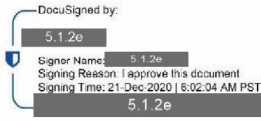
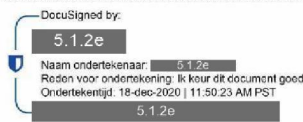
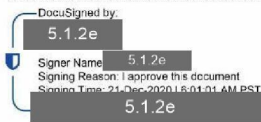
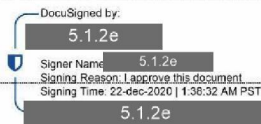
<u>RESPONSIBILITIES</u>		DVP	UPS SCS
9.0.9	Clearly identify and separate products that triggered an alert during verification and/or decommissioning.		X
9.0.10a	When an alert is triggered, inform DVP immediately and await instructions for further action.		X
9.0.10b	DVP to give instruction to UPS SCS for further action related to a triggered alert.	X	
9.0.11	In case of system downtime, impacting EU FMD transactions, shipment delays should be avoided and system transactions should be performed immediately when system is back up and running.		X
9.0.12	In case during Verification and/or Decommissioning at UPS SCS any (suspected) Falsified PRODUCT is encountered, UPS SCS will notify this to DVP and the AGENCY.		X
9.0.13	In case any (suspected) Falsified PRODUCT is encountered at any other moment (i.e. outside UPS SCS facility), DVP will report this to the AGENCY.	X	
9.0.14	Article 20/ 21 / 33h Ensure the PRODUCTS are shipped from the manufacturer to UPS SCS directly.	X	
9.0.15	In case the PRODUCTS are shipped from elsewhere than the manufacturer, UPS SCS will perform 100% verification checks on inbound.		X
9.0.16	Article 20/ 21 / 33h: UPS SCS will NOT perform 100% verification checks on inbound in case: - The PRODUCTS are shipped from the manufacturer to UPS SCS directly. - The medicinal PRODUCT changes ownership but remains in the physical possession of UPS SCS; - The medicinal PRODUCT that is distributed between two UPS SCS warehouses belong to the same legal entity.		X

VERSION HISTORY

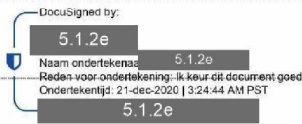
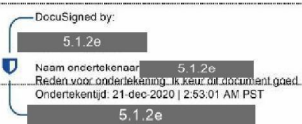
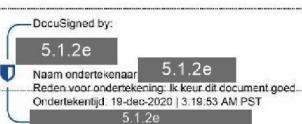
Version 00	Initial Quality Technical Agreement executed between UPS SCS and DVP.

APPENDIX 1: APPROVALS

IN WITNESS WHEREOF, the parties hereto have caused this Quality Technical Agreement to be executed by their duly authorised representatives as of the effective date.

Approved by (Quality Function):	
DVP	UPS SCS
Name : 5.1.2e	Name : 5.1.2e
Position : 5.1.2e	Position : 5.1.2e
Signature : 	Signature : 
Date : 21-dec-2020	Date : 21-Dec-2020
Name : 5.1.2e	Name : 5.1.2e
Position : Qualified Person / Responsible Person	Position : 5.1.2e
Signature : 	Signature : 
Date : 18-dec-2020	Date : 21-Dec-2020
Name : N/A	Name : 5.1.2e
Position : N/A	Position : 5.1.2e
Signature : N/A	Signature : 
Date : N/A	Date : 22-Dec-2020

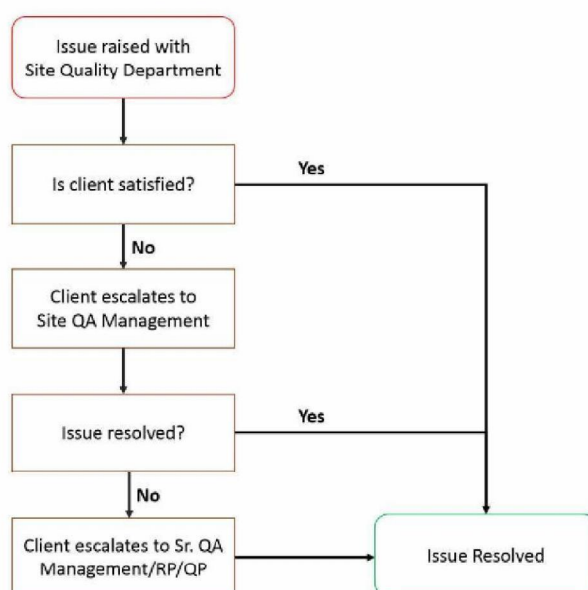
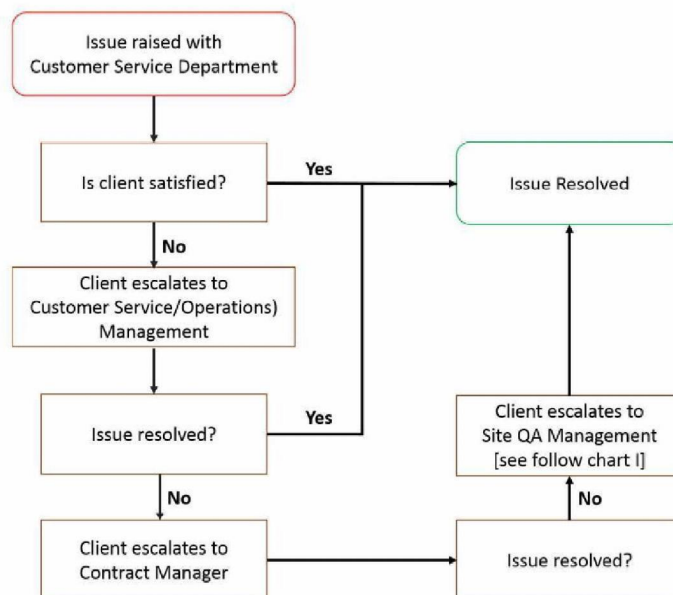
APPENDIX 2: SIGNATURE REFERENCES QUALIFIED PERSONS

UPS SCS QUALIFIED PERSONS	
Full Name	: 5.1.2e
Signature	: 
Date	: 21-dec-2020
Full Name	: 5.1.2e
Signature	: 
Date	: 21-dec-2020
Full Name	: 5.1.2e
Signature	: 
Date	: 19-dec-2020
DVP QUALIFIED PERSONS	
Full Name	: 5.1.2e
Signature	: 
Date	: 18-dec-2020

APPENDIX 3: KEY CONTACTS AND RESPONSIBLE PERSONS

UPS SCS			
Department	Name	Position	Phone/ Email
Main Quality Contact Roermond II	5.1.2e	5.1.2e	P: +31 (0) 5.1.2e M: +31 5.1.2e Email: 5.1.2e @ups.com
General Quality Communications Roermond II		Site Quality Department	E: 5.1.5 @ups.com
Recall Management Roermond II			E: 5.1.5 @ups.com
UPS NL Responsible Persons			E: 5.1.5 @ups.com
Key Quality Contact/ Product Release	5.1.2e	5.1.2e	M: +31 (0) 5.1.2e E: 5.1.2e @ups.com
Product Release (Deputy)	5.1.2e 5.1.2e	Backup GDP Responsible Person	M: +31 (0) 5.1.2e E: 5.1.2e @ups.com
Product Release (Deputy)	5.1.2e	Backup GDP Responsible Person	M: +31 (0) 5.1.2e E: 5.1.2e @ups.com
Product Release	5.1.2e	Qualified Person	P: +31 (0) 5.1.2e M: +31(0) 5.1.2e E: 5.1.2e @bfc.nl
Product Release (Deputy)	5.1.2e	Qualified Person	P: +31 (0) 5.1.2e M: +31(0) 5.1.2e E: 5.1.2e @bfc.nl
Product Release (Deputy)	5.1.2e	Qualified Person	P: +31 (0) 5.1.2e M: +31 (0) 5.1.2e E: 5.1.2e @bfc.nl
Distribution	5.1.2e	5.1.2e	P: +31 (0) 5.1.2e M: +31 (0) 5.1.2e E: 5.1.2e @ups.com
Distribution	5.1.2e	5.1.2e	M: +31 5.1.2e E: 5.1.2e @ups.com

DVP			
Department	Name	Position	Phone/ Email
Logistics	5.1.2e	5.1.2e	M: +31 (0) 5.1.2e E: 5.1.2e@rivm.nl
Product release	5.1.2e	Qualified Person / Responsible Person	M: +31 (0) 5.1.2e E: 5.1.2e@rivm.nl
Product release	5.1.2e	Responsible Person	M: +31 (0) 5.1.2e E: 5.1.2e@rivm.nl
Logistics	5.1.2e	Team	P: +31 (0) 5.1.2e E: 5.1.2e
Logistics	5.1.2e	5.1.2e	M: +31 (0) 5.1.2e E: 5.1.2e@rivm.nl
Logistics	5.1.2e	5.1.2e	M: +31 (0) 5.1.2e E: 5.1.2e@rivm.nl
Quality Assurance	5.1.2e	5.1.2e	M: +31 (0) 5.1.2e 5.1.2e@rivm.nl
Quality Assurance	QA team	Team	5.1.2e@rivm.nl

APPENDIX 4: UPS SCS COMMUNICATION ESCALATION MATRIX**Flow chart I: Quality/ Regulatory Issues****Flow chart II: Customer Service Issues**

Flow chart III: Operations Issues