



# **Quality Technical Agreement for Outsourcing the Receipt, Storage, and Onward Supply of Marketed Cryopreserved ATMPs**

**Pan UK Pharmacy Working Group for  
ATMPs**

**Edited by:**

**Adam Walker**

Highly Specialist QA Pharmacist & QP  
Newcastle upon Tyne Hospitals NHS  
Foundation Trust

**Anne Black**

Regional QA Specialist  
Newcastle upon Tyne Hospitals NHS  
Foundation Trust

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## **The first stop for professional medicines advice**



The Pan UK Pharmacy Working Group (PWG) for Advanced Therapy Medicinal Products (ATMPs) acts as an expert and informed body to support the activities of UK Pharmacies to facilitate ATMP usage. The group consists of pharmacists from across the UK that specialise in the governance, prescribing, administration and monitoring of ATMPs. The aims of the group are to promote good practice, identify and resolve pharmacy issues to maximise the effectiveness and development of services for hospitals to administer advanced therapies. The Pan UK PWG for ATMPs has a governance and regulatory subgroup which identified a need for this template technical agreement (TA).

The editor would like to thank all who have contributed to the production of this guidance, including Lynn Morrison (RQA Scotland) and other members of the Governance and Regulatory subgroup.

Please contact the editor of this document with any questions:

**Adam Walker** – Highly Specialist QA Pharmacist & QP

Email: [Adam.Walker10@nhs.net](mailto:Adam.Walker10@nhs.net)

For information about the Pan UK PWG for ATMPs, please contact:

[Anne.black7@nhs.net](mailto:Anne.black7@nhs.net)

## Introduction

Advanced Therapy Medicinal Products (ATMPs) are innovative medicines which provide challenges in delivery.

Chief Pharmacists are required to ensure that governance arrangements are in line with safe and secure handling of medicines recommendations.

As the use of Advanced Therapy Medicinal Products (ATMPs) continues to grow, more and more NHS centres are offering these innovative medicines to their patients.

Cell and tissue based ATMPs have specialist handling requirements and it is therefore often necessary to outsource Receipt, Storage, Preparation and Issue of these ATMPs.

Similar to outsourcing preparation of any medicine, it is necessary for a Technical Agreement to be set up by the NHS provider (Contract Giver) with the outsourcing partner (Contract Acceptor).

This template Technical Agreement is suitable for adaptation by NHS Pharmacies, where there is a requirement to outsource any aspect of cell or tissue based ATMP handling for ATMPs *which hold a marketing authorisation*.

N.B. This TA does not apply to outsourcing of ATIMP handling for clinical trials.

## How to Use this Technical Agreement

1. Access the word copy of the template TA
2. Tailor it locally by completing the details of both Contract Giver and Contract Acceptor.
3. Complete all sections highlighted in yellow.
4. If the Contract Acceptor is undertaking a preparation step (e.g. aseptic manipulation or thaw) tailor the blue sections in the template accordingly.

If there is no preparation step, delete the blue sections. (Blue sections are unlikely to be needed for marketed CAR-T as the service will be limited to Receipt, Storage and Transportation).

5. Agree the content of the TA with the Contract Acceptor and get authorised signatories from each party.



**QUALITY TECHNICAL AGREEMENT  
FOR THE RECEIPT, STORAGE, AND ONWARD SUPPLY OF CRYOPRESERVED ADVANCED  
THERAPY MEDICINAL PRODUCTS (ATMPs) which hold a marketing authorisation (MA)**

**SITE DOCUMENT REFERENCE NUMBER**

**Between**

**SITE PHARMACY**

**And**

**VENDOR PROVIDING SERVICE**

**QUALITY TECHNICAL AGREEMENT  
FOR THE RECEIPT, STORAGE, AND ONWARD SUPPLY OF CRYOPRESERVED ADVANCED THERAPY MEDICINAL  
PRODUCTS (ATMPs) ON BEHALF OF **SITE PHARMACY****



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**QUALITY TECHNICAL AGREEMENT (Site Document Ref. xxxxxx)**

FOR THE RECEIPT, STORAGE, AND ONWARD SUPPLY OF CRYOPRESERVED ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPs) ON BEHALF OF **SITE PHARMACY**

This Technical Agreement is made between:

**SITE PHARMACY**

Site Address

Site Address

Site Address

Site Address

Site Address

hereinafter referred to as Contract Giver 'CG'

and

**SERVICE PROVIDER**

Provider Address

Provider Address

Provider Address

Provider Address

Provider Address

hereinafter referred to as Contract Acceptor 'CA'

List any additional sites if more than one here

List any relevant regulatory authorisations if the activity is carried out under those authorisations

## 1. Definitions

ATMP	Advanced Therapy Medicinal Product
CA	Contract Acceptor; the provider of services within this agreement
CAPA	
CG	Contract Giver; The Site Pharmacy responsible for oversight of the outsourced activity under the terms of this agreement
GMP	Good Manufacturing Practice; Guidance on the manufacture and testing of medicinal products, as defined in <a href="#">EudraLex Volume 4</a>
GDP	Good Distribution Practice; Guidance on the storage and distribution of medicinal products. This is not mandatory for IMPs, but application of the principles of GDP is expected to ensure safety and security of the supply chain, and maintenance of appropriate storage conditions to maintain product quality. Guidance can be found in <a href="#">EC 2013/C 343/01</a>
MHRA	Medicines and Healthcare Products Regulatory Authority; the Competent Authority responsible for medicines manufacture and supply.
PPM	Planned Preventative Maintenance; the scheduled, planned maintenance work performed on critical equipment to ensure it remains within calibration and operational parameters
PQS	Pharmaceutical Quality System; the system setting out responsibilities, processes and risk management principles in relation to the sites activities
RP	Responsible Person; the individual named on the site WDA(H) as responsible for the management and maintenance of the PQS in order to remain compliant with the requirements of GDP
QTA or TA	Quality Technical Agreement; this Agreement describing the allocation between the parties of roles and responsibilities relating to quality and operational responsibilities with regard to the provision of the activities described
VMP	Validation Master Plan; a document summarising the key elements of the sites qualification and validation programme
WDA(H)	Wholesale Dealers Authorisation for Human Medicinal Products; the Licence issued by the MHRA

## 2. Scope of agreement

This Technical Agreement defines the roles and responsibilities between the CG and CA in ensuring compliance with GMP, GDP and the Human Medicines Regulations 2012 (SI 2012:1916 as amended) with regard to the provision of pharmaceutical services as specified in '**Appendix 1: Drug Products and Services**', of this agreement.

All parties will strictly observe the detailed pharmaceutical responsibilities which are specified in '**Appendix 2: Responsibilities of each Party**', of this agreement.

All parties must appoint Contact Persons as named in '**Appendix 3: Key Contact Persons**' of this agreement.

In circumstances where CA subcontracts certain activity, this is permitted where agreed in advance and accepted by CG. Any providers to whom activity is sub-contracted by CA will be listed in '**Appendix 4: List of Subcontractors**', of this agreement. The responsibilities defined in this agreement apply to the sub-contractor as they do to CA. Additionally, CA must ensure appropriate agreements are in place with sub-contractors which compliment those contained in this TA.

This agreement covers activity relating to the receipt, storage and onward supply of cryopreserved ATMPs holding a marketing authorisation on behalf of CG. Any additional 'preparation activities' subcontracted remain the responsibility of CG and may either be added to this agreement where required, or managed via a separate TA. Any such arrangements must take into account the requirements of the SmPC and GMP as it relates to the activities involved. Where these services are provided, the provider must operate within the regulatory framework which applies (for example, compliance with GMP and operating under an MS licence). Finally, where additional services beyond receipt, storage and distribution are included, a thorough review of the content of this TA is recommended to ensure it covers the necessary activity.

## 3. Regulatory information

The parties acknowledge that CG shall procure the ATMP, and arrange for its delivery directly to CA. Thus, will perform all the obligations and responsibilities of a purchaser of authorised medicinal products. CG will own the product throughout the activity.

This TA is supplementary to any agreement between the manufacturer of the ATMP and CG. This TA can be shared with manufacturers in support of their assessment of appropriate arrangements when conducting site qualification assessments of prospective clinical sites. The CG responsibilities contained in this TA cannot be delegated to the manufacturer.

CA has the full capability and appropriate authorisations to carry out the activity described in this TA as described in Appendix 1 of this agreement. Any services will be at all times processed and controlled in compliance with the appropriate regulations, where applicable, Good Distribution Practices for medicinal products for human use. It is anticipated that in order to comply with the regulatory requirements relating to this activity, it will be carried out at a site operating a WDA(H) under the supervision of an appropriately experienced RP.



## 4. The Technical Agreement (including termination)

This Agreement becomes effective on the date of the final signature and shall remain valid up to 5 years (“Term”). This agreement will be reviewed and updated every **five (5) years** unless the parties agree to amend the agreement prior to this with mutual consent, in writing.

Any variances from this Agreement must be in writing and approved by all Parties to this Agreement. Appendices may be modified and updated independently from the main Agreement, it is the responsibility of both parties to ensure that all sections of the Agreement on file is current.

Each party may terminate this Agreement at 3 (three) months’ notice in written form to the other party.

Termination of this Agreement, however caused, shall not prejudice or affect any rights, action or remedy which shall have accrued before termination or shall accrue thereafter to any party.

This Agreement and its Appendices shall be made available to the relevant authorities in the concerned countries upon their request.

Compliance with this Technical Agreement may be jointly reviewed annually by both parties. Resolution to any noncompliance, where it is identified, must be jointly agreed by both parties within defined timelines.

This agreement may be executed digitally using appropriate electronic signatures, or physically with wet signatures. Where the former is used, the fully executed digital version will be considered the original and must be provided to both parties. Where wet signatures are used, the Agreement must be executed in duplicate originals with each Party retaining one original for its records. Each party agrees to deliver to the other all such documents and information as may be required for the other party to perform its obligations under this Agreement.

## 5. Documentation Practices

Completed documentation will be archived in accordance with current regulatory guidance and retained for a period of at least 5 (five) years after the expiry of the product to which it relates. This documentation includes, but is not limited to the following:

- Delivery notes
- Temperature monitoring data
- Deviation reports
- Validation data

## 6. Quality Assurance

CA must maintain a suitable Pharmaceutical Quality System, which meets the requirements of the MHRA. Regulatory inspection results must be communicated to CG, and major or critical observations identified during regulatory inspections must be assessed for their impact on the products which have been handled under the terms of this agreement. Appropriate CAPA must be agreed by both parties with appropriate timescales for implementation.

CG is responsible for sourcing ATMPs from bona fide suppliers and establishing they are not at risk of counterfeit through suitably robust measures agreed with the manufacturer. These checks may be facilitated by CA, but final checks on the integrity of the product must be completed by CG at the point of receipt from CA.

## 7. Complaints

Any complaint from CG regarding quality of the supplied service must be acknowledged by CA within 2 working days.

A report containing details of the investigation with corrective and preventative actions must be forwarded to CG within 30 working days. CA must make every effort to complete investigations and provide feedback, including actions assigned, to CG in a timely manner.

## 8. Recall and Returns

CG must notify CA of any recall or near miss (company or MHRA-led) relating to any drug product(s) handled under this Agreement. Coordination of the return of such products will be performed between manufacturer and CG, CA will facilitate any collections and ensure stock subject to recall is appropriately quarantined and stored until it is returned.

CG and CA maintains the right to notify the relevant regulatory authority of potential recall situations where they believe this is the correct course of action but is not agreed by the either party or the manufacturer.

## 9. Audit

CG or their representative is entitled to conduct a routine audit of CA facilities relevant for the services detailed in this agreement on a 2 yearly basis. Dates for routine audits should be mutually agreed at least 4 weeks in advance.

CG or their representative will be permitted to perform a 'for-cause' audit in response to a critical deviation affecting the services or products covered by this TA with a maximum of 7 days' notice.

Any activity sub-contracted by CA must be in line with CA vendor qualification procedures, any audit reports should be made available to CG on request.

CA will be routinely audited by the relevant competent authority in line with their risk-based approach to inspections.

## 10. Confidentiality

The information contained in this agreement is confidential and must not be divulged to any other party without the permission of all signatories with the exception of regulatory authorities.

## 11. Final Provision

Amendments to this Quality Technical Agreement and its Annexes may only be carried out by mutual consent and shall be made in writing. Any amendments to the appendices **1 to 7** may be made in isolation to the rest of the document provided they do not contradict any content. Upon signing by both CA and CG the amended appendices will be binding on both parties and replace the previous appendix.

## Appendix 1: Drug Products and Services

FOR THE RECEIPT, STORAGE, AND ONWARD SUPPLY OF CRYOPRESERVED ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPs) ON BEHALF OF **SITE PHARMACY**

Use this section to describe in broad terms the activity which will be outsourced, examples of a suitable scope is stated below, but this must be reviewed to ensure it covers all applicable activity. Where additional activity needs are identified later, this can be added to a new version of this TA, or can be described in a stand alone TA. All activities described in this TA must have been considered and accepted during the assessment of the CAs capability to perform the activity by CG or their representative. Where specific activity was not covered within the scope of CA assessment, additional 'top-up' vendor assurance should be considered by CG.

### Services Provided:

Description	Start date	Product Specific or General	Contact Person
Activity below are examples, amend according to local requirements.			
Receipt of ATMP			
Storage of ATMP			
Onward transportation of ATMP to CG site			
ADDITIONAL 'EXTRA' ACTIVITY (Consider regulatory requirements where these are included)			
Thawing of ATMP			
Reconstitution of ATMP and preparation for administration			
Labelling of ATMP with administration label			
Labelling of ATMP with shipping label			

### **Receipt**

Upon receipt check that the tamper evidence is intact and ensure material has been transported in accordance with requirements contained in the SmPC:

- If evidence of tampering is identified contact CG immediately
- Supplies must be appropriately labelled and segregated to prevent mix-up (especially when handling autologous ATMPs)
- Deliveries may include additional monitoring equipment such as temperature logging devices, shock sensors or GPS tracking devices. CA must comply with the requirements of both the manufacturer and CG in terms of handling these devices, downloading and transmitting data, and quarantine status of the product until the data has been analysed and product authorised for use where this applies

### **Storage**

- Products must be stored according to the manufacturer's instructions as stated in the SmPC
- Storage areas must be validated and subject to routine PPM in line with the equipment manufacturer's recommendations and CAs VMP
- Storage areas must be continuously monitored using appropriately calibrated monitoring systems. Arrangements for responding to alarms in the event of system failure or temperature deviations must be in place including out-of-hours
- Products must be appropriately segregated and identifiable throughout
- Temperature deviations must be formally assessed and communicated to CG. The impact of any deviations affecting products under this agreement must be assessed by the manufacturer
- Appropriate arrangements must be in place to allow for redundancy in the event of equipment failure (e.g. emergency backup generators or UPS systems)

### **Onward Transportation to CG Site**

- Products must be packaged and transported according to the manufacturers instructions as stated in the SmPC
- Where this activity is subcontracted, the supplier of the service must have been qualified by CA, and be named in Appendix 4: List of Subcontractors
- Any deviations during transportation must be treated as they would should they have occurred when the product was in the possession of CA (e.g. notification, impact assessment etc)
- Collection and delivery must be performed as agreed with CG, no transportation of the product is permitted without prior written consent (email is acceptable)

### **Further processing at CA site**

Any further processing should be performed in accordance with GMP or other local regulations which apply.

- Activities carried out as 'reconstitution' do not require regulatory authorisations where they are carried out by or under the supervision of a pharmacist (section 10 exemption), but should be performed applying the principles of GMP, ensuring product quality is not compromised during these activities
- Additional processing activity may be required in several forms, specialist advice is advised when adding such activity to a Technical Agreement, this section has been included as a 'placeholder' only.

### **Temperature Excursion Management**

Marketing Authorisation Holders are required to perform the review, assessment and final disposition decision for temperature excursions that occur during transportation, storage at depots onward transportation to clinical sites. Manufacturers may supply (dependant on available stability data) a temperature excursion memorandum that will detail allowable excursion ranges. Any excursions should be communicated to CG, who should then escalate them to the manufacturer.



### ***Notifications and Recalls***

If during the course of the study, CA becomes aware of any issue affecting the quality of the material, CA will notify CG, in a timely manner, who must then notify the manufacturer. The responsibility for the recall of any medicinal products lies with the manufacturer and MHRA, following consultation with CA, CG and/or any other company in the case of services supplied by them.

CG must notify CA of any changes to the SmPC that may affect the storage of the ATMP concerned. CG must inform CA of these changes to ensure compliance with live documents.

### ***Destruction***

Destruction of stock remaining at CA site is to be performed by CG, in accordance of Good Manufacturing Practice, Good Distribution Practice and in accordance with any National Regulatory requirement. Authorisation of destruction of stock at storage sites is the responsibility of CG.

## Appendix 2: Responsibilities of each Party

The following are examples of responsibilities which may be included in a Technical Agreement and should be reviewed for applicability to the planned activity

Regulatory	CG	CA
Approve the technical agreement	X	X
Supply regulatory and product specific documents required for outsourced activity	X	
Provide updated documents to CA as soon as practicable when these are received from the manufacturer	X	
Maintain all authorisations required for planned activity <i>e.g. For marketed CAR_T: WDA(H) and JACIE accreditation to 6.01 for IEC</i>		X
Maintain and archive all records required to perform contracted activity		X
Drug Products		
Order supplies of ATMP to CA site from manufacturer	X	
Coordinate delivery of ATMP to CA site CA	X	
Receipt of ATMP according to requirements of SmPC or manufacturers supplied SOPs		X
Confirmation that manufacturer has appropriate arrangements in place for supply of ATMP via an authorised route (e.g. UK QP certified or imported from EU with UK RPi oversight)	X	
Maintain a live stock management system to identify storage location of all products on site		X
Store ATMP according to the product requirements according to the SmPC or manufacturers instructions		X
Any processing steps (reconstitution, thawing, dilution) must be carried out following the principles of GMP (as defined by EudraLex Volume 4)		X
Packaging and Processing Materials		
Procurement of packaging materials		X
Supplier approval (packaging and process materials)		X
Generate label drafts		X
Approve label drafts	X	
Creation of a batch file for all processing and packaging operations		X
Maintain appropriate facilities, staff and resources to comply with the requirements of contracted services in accordance with relevant regulations and this TA.		X
Printing of labels		X

Supply of randomisation list	X	
Manage any required unblinding activity	X	
Secure storage of all packaging, randomisation data and labels	X	X
Coding and assigning of batch numbers for finished product		X
Secondary packaging and control		X
Assignment of expiry date(s) based on information received from manufacturer for processed material		X
<b>Documentation</b>		
Archiving original processing documents for at least 5 (five) years after expiry of the product		X
Retention of relevant documentation according to 2013/C 343/01		X
Notification of intention to discontinue to treat patients with products that require this service	X	
<b>Destruction</b>		
Destroy materials or records (those not controlled under records retention policies) following notification by CG		X
Authorise destruction of materials or records (those not controlled under records retention policies) according to local practices	X	
Destruction of remaining products (which may have expired) that remain at CA when authorised by CG		X
Destruction of remaining products (which may have expired) that remain at CG	X	
<b>Storage and Logistics</b>		
Place orders with CA when ATMP is required at the clinical site	X	
Provide information concerning special requirements for packaging and monitoring supplies during shipment	X	
Storage and management of stock at CG		X
Storage and management of stock at Clinical Site	X	
Selection of carrier for shipping and shipping conditions of drug products from CA to CG		X
Supply of temperature monitoring data for shipping of finished products (if applicable) to clinical sites		X
Fulfil orders following local procedures, and the requirements of the SmPC.		X
Use in-house or contracted logistics providers and qualified transportation methods appropriate to the storage conditions of the ATMP		X
Continuously monitor storage areas and equipment for maintenance of required storage condition using qualified monitoring system		X
Report any deviations from storage requirements to CG within 1 working day during product storage or transportation		X
Communicate with manufacturer to determine batch disposition in response to a temperature deviation	X	

Take immediate action as necessary to mitigate against any storage condition deviation including out-of-hours		X
Determination of CAPA following deviations during storage or transport to clinical sites.	X	X
<b>Complaints and Product recall</b>		
When notified of a recall by manufacturer, inform CA within timescales required by the recall classification (Class 1 = Immediately including out of hours, Class 2 = within 48 hours, Class 3 = within 5 days)	X	
Make available relevant information to assist in investigations relating to product recalls.	X	X
Comply with all instructions provided by a regulator or manufacturer in order to execute a product recall	X	X
Receive, collect and administer any Adverse Reactions (ARs) suffered by patients, which are or may possibly be due to the product. These must be reported to the manufacturer	X	
Investigate complaints related to activity under this agreement, these may or may not relate to ARs reported to Marketing Authorisation Holder		X
Maintain a complaints system		X
<b>Handling of any product returns</b>		
Storage in an appropriately controlled, dedicated area		X
Communicate with CG regarding any product returns and obtain their decision on product disposition	X	
<b>Data</b>		
Patient identifiable data will not be shared between organisations unless absolutely necessary	X	X
Where patient data is required to be shared, CG authorises the method by which this data is shared and confirms compliance of the agreed process with NHS Data Security requirements	X	
CA must comply with all Data Security requirements of CG		X
<b>Change Control</b>		
Notification to CG of all major changes to process covered by this agreement in advance of implementation (e.g. changes in storage locations, logistics providers, key personnel, etc.)		X
Approval of all major changes to contracted process	X	
Update of relevant documents affected by changes	X	X
<b>Deviations</b>		
Notification to CG of all deviations relating to activity covered by this agreement (e.g. non-compliance with internal procedures, equipment failure) within 1 working day of identification of the deviation		X
Agree appropriate mitigating action with CA within appropriate timescales	X	
Comply with actions and timelines agreed with CG in the event of deviations		X





Submit a written report including investigation of deviations to CG within 1 week of identification. Extensions to this deadline may be agreed in advance with CG		<b>X</b>
Approve closure of all deviations relating to contracted services within 1 week of receipt of the final report	<b>X</b>	
Update of relevant documents affected by changes	<b>X</b>	<b>X</b>
<b>Quality Audits and Auditing</b>		
Permit CG or its representatives to audit the site (specific to the services covered in this agreement) providing at least four (4) weeks' notice is given for routine audits.		<b>X</b>
Where CG determines a 'for-cause' audit is required, permit CG or its representatives to audit the site (specific to the services covered in this agreement) providing at least ONE (1) weeks' notice		<b>X</b>
Permit regulatory authorities to audit the site.		<b>X</b>
Inform CG of regulatory audits and observations relevant to the services covered in this agreement.		<b>X</b>
Selection and audit of vendors (sub-contracted parties) for outsourced activity via a formally documented vendor-approval process		<b>X</b>
Supply of appropriate documentation requested by CA to enable approval of selected vendors for outsourced activity		<b>X</b>
Approval of selected subcontractors for outsourced activities	<b>X</b>	<b>X</b>



### Appendix 3: Key Contact Persons

CG

Name	Designation	Contact number	E-mail

CA

Name	Designation	Contact number	E-mail

## Appendix 4: List of Subcontractors

*e.g. Couriers, Monitoring System Providers and Contractors*

CA Subcontractors	
<b>Logistics Provider</b>	Add description of activity subcontracted here
<b>Temperature Monitoring Services</b>	Add description of activity subcontracted here
<b>Contract RP Services</b>	Add description of activity subcontracted here

## Appendix 5: Technical Agreement Approval

### Agreed on behalf of the CG

Name:

Name:

Title:

Title:

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

### Agreed on behalf of CA

Name:

Name:

Title:

(Responsible Person)

Title:

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_



### Appendix 6: Version History

Version Number	Date of Amendment	Amendment(s) Made
1		First Issue



**Specialist  
Pharmacy  
Service**



NHS Specialist Pharmacy Service  
[www.sps.nhs.uk](http://www.sps.nhs.uk)