Aide Memoire: NHS ATMP Starting Material Procurement Site Qualification

V1.0

Document Information

Purpose

This document is designed to be used by NHS staff in preparation for ATMP starting material procurement site qualification. This document would be best utilised when beginning to set up a service for procurement of a new cell or tissue type but could be used as a checklist for existing cell or tissue type procurement.

Procedure

This Aide memoire will progress though commonly requested industry requirements aligned with regulatory requirements.

To further aide site preparation consideration should be given to providing publically available reports and associated actions from regulators and/or accrediation bodies as appropriate.

Establishments using this aide memoire need to have a clear well-defined process of recording evidence referenced in this document and systems in place to obtain the primary source material / evidence of the appropriate standard.

1.) Site Information

The aim of this section, 1.) Site Information is to gather some brief generic information about your organisation and identify the people involved in the procurement of starting material at your organisation.

1.1) Organisation

This is generic information about the organisation and the person using this aide memoire to prepare the procurement site.

Organisational Information	
Organisation	
Procurement Location	Address: Postcode:
Procurement Method	
Cells or Tissue Product Type	
Date	

1.2) Site Assessor

This is generic information about the person completing this document.

Assessor Information	
Name	
Job Role	
Organisation	
Date	
Sign	

1.3) Site Contacts (Governance)

This section identifies the roles or contacts required to govern the procurement process at your site. Please bear in mind, some role descriptions may not exactly match job titles within your organisation and some people may be responsible for multiple aspects.

Personnel (Governance)	
Designated Individual for the site HTA licence	Name: Directorate: Job Role: Email: Telephone:
Person Designate (*If Applicable*)	Name: Directorate: Job Role: Email: Telephone:
potential / suggested personnel	
Note: *Medical Practitioner and/or Scientific Advisor are subject to the procurement process that is the subject of this document. The Designated Individual on the HTA licence is best placed to advise on the below.*	
Site Nominated Medical Practitioner (*If Applicable*)	Name: Directorate: Job Role: Email: Telephone:
Site Nominated Scientific Advisor (*If Applicable*)	Name: Directorate: Job Role: Email: Telephone:

1.4) Site Contacts (Quality)

This section aims to identify all individuals involved in the quality assurance / control (QA/QC) of procurement of starting material at your site. These job role descriptions may not exactly map to the job titles of everyone involved in QA/QC at your procurement site and some people may be responsible for multiple aspects.

Personnel (Quality) – potential / suggested personnel	
QA Personnel responsible for – **FACT-JACIE**	Name: Directorate: Job Role: Email: Telephone:
QA Personnel responsible for – **The Procurement Team**	Name: Directorate: Job Role: Email: Telephone:
QA Personnel responsible for – **Donor Testing (If applicable)**	Name: Directorate: Job Role: Email: Telephone:
QA Personnel responsible for –	Name: Directorate: Job Role:

Cell Lab / Cell handling lab / Cell processing lab	Email: Telephone:
QA Personnel responsible for – **Quality Control Lab / Flow cytomtery lab / Microbiology lab (*Where Appropriate)***	Name: Directorate: Job Role: Email: Telephone:
QA Personnel responsible for – **Pharmacy (*If Applicable*)**	Name: Directorate: Job Role: Email: Telephone:

1.5) Site Contacts (Operational)

This section aims to identify individuals responsible for or involved of performing the procurement process at any stage including any cell processing, storage, or distribution of materials. Please bear in mind, some role descriptions may not exactly match job titles within your organisation and some people may be responsible for multiple aspects.

Personnel (Operational) – potential / suggested personnel	
Operational personnel responsible for – **Clinician for procurement service (*Where Appropriate)***	Name: Directorate: Job Role: Email: Telephone:
Operational personnel responsible for – **Nursing for procurement service**	Name: Directorate: Job Role: Email: Telephone:
Operational personnel responsible for – **Cell Lab / Cell handling lab / Cell processing lab**	Name: Directorate: Job Role: Email: Telephone:
Operational personnel responsible for – **Quality Control Lab / Flow cytomtery lab / Microbiology lab (*Where Appropriate)***	Name: Directorate: Job Role: Email: Telephone:
Operational personnel responsible for – **Pharmacy (*If Applicable*)**	Name: Directorate: Job Role: Email: Telephone:

1.6) Site Activity

This section aims to demonstrate the level and scope of activity currently undertaken by the procurement site in question. This section also links to 4.1.

Site Activity

Provide evidence of the level and scope of activity currently undertaken at your site. Areas for consideration: Table at front of HTA report Annual activity submission	Please detail
What is the current lead time to have a patients cells or tissues procured within the service in question? *(If Known)*	

2.) Governance

This section aims to identify the structures in place at the sites to properly govern ATMP starting material procurements. This will also demonstrate reporting lines / lines of accountability across the procurement service.

2.1) Site Organisational Chart / Organograms

In this section consider all the teams involved in the chain of custody of starting material from donor evaluation to distribution for manufacture.

Site Organisational Structure – potential / suggested organograms	
Organogram depicting the - **HTA Designated Individual Oversight / Accountability**	Detail here:
Organogram depicting the – **Procurement Service / Department. Inclusive of donor selection (*If Applicable or different to HTA Organogram*)**	Detail here:
Organogram depicting the – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable or different to HTA Organogram*)**	Detail here:
Organogram depicting - **Any other appropriate department.**	Detail here:

Inclusive of donor testing (*If Applicable or different to HTA Organogram*)	

2.2) Site Licensing and Accreditations

This sections demonstrates the licences or accreditations at site that govern the procurement of starting material for ATMPs.

Human Tissue Authority	
Human Tissue Authority Licence Number	
Designated Individual	
Licence Holder Information	Organisation: Address:
Please detail any satellites specific to the cells or tissue being procured:	Please Detail:
Last Inspection Report (Published / Public available on the HTA website)	Date:
Is the last inspection and all associated follow up actions closed?	❑ Yes ❑ No
FACT-JACIE	
FACT-JACIE Accreditation Number	
Last Inspection Report	Date:
Is the last inspection and all associated follow up actions closed?	❑ Yes ❑ No
Testing Laboratory	
Provide evidence of testing lab accreditation	Please detail:

2.3) Site Policy

This section aims to collate applicable policies that give an indication of the organisational approach to procurement of starting material for ATMPs. Not all establishments will have policy that cover all areas, please see Section 5) Procedures which may also fulfil this requirement.

Site Policy – potential / suggested policies	
Policy that covers – **Orginisational commitment / approach to ATMPs**	Title: Version: Author:
Policy that covers – **Cell Lab / Cell Storage / Cell Handling,**	Title: Version: Author:

Contingency or continuity of service	
Policy that covers – **Patient Consenting**	Title: Version: Author:
Policy that covers – **Waste / Discard of cellular material**	Title: Version: Author:
Policy that covers – **Tracability of cells or tissues**	Title: Version: Author:
Policy that covers – **Deviation / Adverse Event / Adverse Reaction Reporting**	Title: Version: Author:
Policy that covers – **Any other policy applicable to the governance of this site ATMP procurement**	Title: Version: Author:

3.) Quality

This section aims to identify the structures in place at the site to ensure the quality of ATMP starting material procurements. This also demonstrates reporting lines / lines of accountability across the procurement service.

3.1) Quality / Quality Technical / Service Level / Third Party Agreements

This section aims to gather all agreements between parties involved in the full chain of custody of cells or tissues.

Quality / Technical / Service Level / Third Party Agreements – potential / suggested quality agreements	
Agreements covering – **Procurement Site & Manufacturer**	Title: Version: Author:
Agreements covering – **Procurement Site & Licence Holder** ***(In the event of procurement as satellite)***	Title: Version: Author:
Agreements covering – **Procurement Site & Site Pharmacy**	Title: Version: Author:
Agreements covering – **Procurement site & Third Parties**	Title: Version: Author:

(E.g. *Couriers*)	
Agreements covering – **Any other QTA appropriate:** Organisation #1:_____ Organisation #2:_____	Title: Version: Author:

* NOTE: Consideration should be given to end user agreements as defined under Human Tissue (Quality & Safety for human application).

3.2) Quality Management System

This section aims to gather all the quality manuals of all departments involved in the chain of custody of cells or tissues.

Quality Manuals that cover relevant areas – potential / suggested quality manuals	
Quality Manual Covering - **Procurement Service / Department. Inclusive of donor selection (*If Applicable*)**	Please detail:
Quality Manual Covering – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	
Quality Manual Covering - **Any other appropriate department. Inclusive of donor testing (*If Applicable*)**	

3.3) Relevant Internal Auditing

This section aims to capture relevant internal audits conducted by the site and how audit findings have been addressed.

Internal Auditing – potential / suggested internal audits relevant to the procedure	
Please detail **internal audits** (self-inspections) – **Procurement Service / Department. Inclusive of donor selction (*If Applicable*)**	Please Detail:

Please detail **internal audits** (self inspections) – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please Detail:
Please detail **internal audits** (self-inspections) – **Any other appropriate department.** **Inclusive of donor testing (If Applicable)**	Please Detail:

3.4) Risk Assessment Associated with Procurement

This section aims to gather evidence of risk assessments of procedures relating to the procurement of starting materials.

Risk Assessment – potential / suggested internal risk assessments / risk assessment areas	
Please detail **internal risk assessments** appropriate to - **Procurement Service / Department.** **Inclusive of donor selection (*If Applicable*)**	Please detail:
Please detail **internal risk assessments** appropriate to – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please detail:
Please detail **internal risk assessments** appropriate to – **Any other appropriate department.** **Inclusive of donor testing (If Applicable)**	Please detail:

3.5) Framework / System of Validation

The section aims show site commitment to the overarching system of validation used to ensure quality of cells or tissues.

Validation – potential / suggested evidence of validation framework	
Please evidence your **sites framework for validation** in – **Procurement Service / Department.** **Inclusive of donor selction (If Applicable)**	Please detail:

Please evidence your **sites framework for validation** in – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please detail:
Please evidence your **sites framework for validation** in – **Any other appropriate department. Inclusive of donor testing (If Applicable)**	Please detail:

3.6) Framework / System of Environmental Control

The section aims show site commitment to the overarching system of environmental control used to ensure quality of cells or tissues.

Environmental Control – potential / suggested evidence of environmental control framework	
Please evidence your **sites framework for environmental control** in – **Procurement Service / Department. Inclusive of donor selection (If Applicable)**	Please detail:
Please evidence your **sites framework for environmental control** in – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please detail:
Please evidence your **sites framework for environmental control** in – **Any other appropriate department. Inclusive of donor testing (If Applicable)**	Please detail:

3.7) Framework / System of Quality Control of Products

The section aims show site commitment to the overarching system of quality control.

Quality Control of products – potential / suggested evidence of quality control framework	
Please evidence your **sites framework for quality control** of products –	Please detail:

Procurement Service / Department. Inclusive of donor selection (If Applicable)	
Please evidence your **sites framework for quality control** of products – **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please detail:
Please evidence your **sites framework for quality control** of products – **Verification of cellular products**	Please detail:
Please evidence your **sites framework for quality control** of products – **Any other appropriate department. Inclusive of donor testing (If Applicable)**	Please detail:

3.8) Document Management System

The section aims show site document management system.

Document Management System – Suggested evidence	
Provide evidence that your **document management system** is of appropriate quality: **Areas of consideration:** Creation of documents Identification of documents Maintenance of documents Including change management) Access of documents Document Retention (Raw data 10 year) Traceability (30 years)	Please detail:

3.10) Framework / System of Database Management

This section aims to demonstrate site use of databases relevant to the procurement off cells or tissues.

Database

Provide **evidence of site database or registry** of procurement, cells or tissues: **Areas of consideration:** Name and location of database What data is captured? Is the data secure?	Please detail:

3.11) Framework / System of Record Keeping

The section aims show site commitment to the overarching system of record keeping relating to quality of cells or tissues.

Records	
Provide evidence of **site record and record** keeping: **Areas of consideration:** Accurate capturing of consent / assent Personnel Involved Lot No/ Expiry of materials contacting cells or tissues Acceptance / rejection / fate of cells or tissues Dates / Times of critical processes Regular review for accuracy of records	Please detail:

3.12) Framework / System of Deviation / Adverse Event / Adverse Reaction Reporting & Handling

The section aims show site commitment to the overarching system of reporting deviations and/or adverse reactions for the maintenance of quality products and procedures.

Adverse / Deviation Reporting	
Provide evidence that your **deviation / adverse reporting system** is of appropriate quality: **Areas of consideration:** Adverse Identification Reporting Lines Adverse Investigation	Please detail:

Recording, Monitoring, of Adverse Events at Site Recording, Monitoring and Completion of Preventative Actions at Site Recording, Monitoring and Completion of Corrective Actions at Site	

4) Premises, Equipment, Materials, Personnel

This section of aims to identify the premises, equipment and personnel involved in ATMP procurements and their validity / competency to deliver the service.

4.1) Capacity / Continuity of Service

Capacity	
Evidence of **site capacity** and/or ability to provide **continual service**: **Procurement Service / Department.** **Inclusive of donor selection (If Applicable)**	Please detail:
Evidence of **site capacity** and/or ability to provide **continual service**: **Cell Lab / Cell handling lab / Cell processing Lab (*If Applicable*)**	Please detail:
Evidence of **site capacity** and/or ability to provide **continual service**: **Any other appropriate department.** **Inclusive of donor testing (If Applicable)**	Please detail:

4.2) Equipment

Equipment	
Provide evidence that **Equipment** used is appropriately documented: **Areas of consideration:** All equipment itemised in asset list	Please detail:

All equipment calibrated and validate as appropriate Maintenance records kept Service Management Agreements	

4.3) Materials

Equipment	
Provide evidence that **Materials** used is appropriately documented: **Areas of consideration:** Material records kept	Please detail:

4.4) Training Programme

Training Programme	
Provide evidence that the sites **training programme** is appropriately: **Areas of consideration:** Health & Safety and fire training scientific & ethical principles relevant to role understanding of organisational structure roles & responsibilities under adverse reporting roles & responsibilities under product recall	Please detail:

4.5) Training Records: Personnel

This section aims to gather the evidence of training and assessment of competency from everyone involved in the chain of custody for cells or tissues.

Training Records	
Provide evidence of **training / competency records** for - **Designated Individual**	Please Detail:

Consider providing relevant job descriptions	
Provide evidence of **training / competency records** for - **Procurement Service / Department.** **Inclusive of donor selection (If Applicable)** Consider providing relevant job descriptions	Please Detail:
Provide evidence of **training / competency records** for - **Cell Lab / Cell handling lab / Cell processing Lab** **(*If Applicable*)** Consider providing relevant job descriptions	Please Detail:
Provide evidence of **training / competency records** for – **Any other appropriate department.** **Inclusive of donor testing (If Applicable)** Consider providing relevant job descriptions	Please Detail:

4.6) Training for Clinical Trials

This sections directly relates to clinical trial activities and may not be relevant to all procurement activities being undertaken.

Training for Clinical Trials	
Provide evidence of **GCP Certification and research CV** in – **Any / All other appropriate department.**	Please Detail:

5) Overarching Procedures

This section enables the gathering of overarching procedures for your site relating to the procurement of cells and tissues. When evidencing site procedures, it would be beneficial to also evidence the associated forms, records and worksheets used to document the procedure.

5.1) Quality Procedures

Quality Procedures	
Provide your **deviation / adverse reporting** procedures:	Title: Version: Author:

	Forms, Records, Worksheets Recorded on: Title: Version: Author:
Provide your **validation** procedures:	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.2) Data Protection / Management

Data Protection / Management	
Information Sharing and Data Protection procedures	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.3) Cleaning Procedures

Cleaning	
Provide evidence of **procurement service cleaning** procedure(s):	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:
Provide evidence of **Cell Lab / Cell handling lab / Cell processing Lab cleaning** procedures:	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.4) Environmental Monitoring Procedures

Monitoring	
Provide evidence of procurement service **environmental monitoring** procedure(s) in critical areas: **Areas for considerations:**	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title:

Storage of reagents	Version: Author:
Provide evidence of Cell Lab / **Cell handling lab / Cell processing Lab environmental monitoring** procedure(s) in critical areas: **Areas for consideration:** Storage of reagents	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.5) Quarantine Procedures

Quarantine Procedure	
Provide evidence of site **quarantine procedure** for cellular products: **Areas for consideration:** Mitigation of cross contamination Mitigation of release without verification Separation of products from main storage	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.6) Discard / Waste Procedures

Discard / Waste Procedures	
Provide evidence of site **procedure for discard / waste** of cells or tissues: **Areas for consideration:** Discards initiated due to adverse / deviation	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

5.7) Product Recall Procedures

Recall	
Provide evidence of site **product recall** procedure: **Areas for consideration:** Communication of roles & responsibilities Clear actions Clear reporting lines	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

Document Retention (Raw data 10 year) Traceability (30 years)	

6) Cells or Tissue Process

This section enables the gathering of procedures directly relating to the procurement of the cell and tissue type being supported in this aide memoire. When evidencing site procedures, it would be beneficial to also evidence the associated forms, records and worksheets used to document the procedure.

6.1) Donor: Selection

Donor: Selection	
Provide evidence of your sites **donor selection** procedure(s): (If Applicable) **Areas for consideration are:** Accurate / appropriate documentation of donor inclusion / exclusion a donor selecting site Autologous vs Allogeneic requirements	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

6.2) Donor: Consent / Assent

Donor: Consent / Assent	
Provide evidence of your sites **donor consent / assent** procedure(s): **Areas for consideration are:** Consent / assent process provided in multiple appropriate formats Consent / assent documentation is collected and maintained	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

6.3) Donor: Testing

Donor: Testing	
Provide evidence of your sites **donor testing** procedure(s): **Areas of consideration are:** Who is performing the testing? How testing is communicated?	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

Testing is validated and uses appropriate kits. The full range of manadatory markers are tested Appropriate plans and tests for any positive results Evidence of timing of tests (Day 0 vs Day 30)	

6.4) Procurement Procedures

Procurement Procedures	
Provide evidence that the sites **procurement** procedure(s): Inclusive of donor selection (If Applicable) **Areas of consideration:** Safety of living donors and clarity over allocation of cells Detail critical materials Are critical steps validated?	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

6.5) Cells or Tissues Handling & Storage

Procurements	
Provide evidence of procedure(s) relating to the **handling and storage of cells or tissues** on your site: **Areas of consideration:** Security of the storage location, including alarms Monitoring of the storage location The maximum storage period	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:

6.6) Cell or Tissues Processing Procedures

Cell Processing Procedures	
Provide evidence of **Cell Lab / Cell handling lab / Cell processing Lab** procedures: **Areas of consideration:**	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version:

Detail critical materials Are critical steps validated?	Author:

6.7) Labelling of Cellular Products

Labelling	
Provide evidence of cellular products **labelling** procedure(s) Note: There may be more than one relevant label. **Areas of consideration:** Current labelling capability Unique coding	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author:
Please affix example labels	

6.8) Transport & Transit Procedures

Transport & Transit	
Provide evidence of **Transport and transit** procedure(s) for cells and tissues: **Areas of consideration:**	Title: Version: Author: Forms, Records, Worksheets Recorded on: Title: Version: Author: