ATIMP/ ATMP Vertical Audit

Creator: Manchester University Foundation Trust

Document version number: 1

Date written: Jan 2019

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ATIMP/ ATMP Vertical Audit Product transportation, receipt, processing, distribution, ATIMP receipt & infusion.

Audit Details		
Date of Audit:	Audit Number:	
Department: Therapeutic Stem Cell Laboratory	Procedure / Examination: ATMP / ATIMP	Lab Number:
Auditors:	Staff Interviewed: N/A Findings will be agreed by	

Instructions

Select a product CT number and examine all aspects of the movement of this product through the procedure.

The audit questions in this document are for guidance, please add more observations if considered appropriate.

Consider the journey of the product. Did anything unusual happen, was the process smooth, timely and well executed?

Note all document numbers, titles, version number and any relevant pages

Ensure a note is made of all staff witnessed and interviewed and their responses.

Don’t forget to note points of excellence and best practice.

Further questions arising during the audit can be added at the end of this document.

This audit may find areas of non-conformity, the team need to decide if the non-conformity requires further investigation either at this audit or if a further, more detailed audit needs to be scheduled for the non-conformity.
This must be discussed with the departmental Quality Lead/DI.

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
These questions should be decided in advance; they can be directly from the JACIE/HTA standard or other standard(s) or be a mixture of standard and questions decided by the requirements of the department.	Note the document name, QP ID, version, and if relevant, page numbers. Note evidence in detail and clearly identify Non conformities or excellence and best practice
If this is a re-audit have previous findings been closed? If not list outstanding NC. Are there any re-occurring issues? If so, the effectiveness of previous actions will need to be reviewed. List here……	
Legislation & Regulatory affairs	
Regulatory requirements in place? HTA Licencing (export & distribution) PPD approval Manufacturer audit / CAPA completion	
Receipt/ Distribution & Export of starting products	
Has the request to process been received detailing starting product requirements	
Full donor ID present in accordance with labelling policy? Labelling and documentation complies with ISBT128/SEC coding requirements	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Other unique identifier required E.g. trial number, manufacturer number	
Full donor consent & clearance available?	
Can the product be unequivocally traceable from the collection procedure? How is this process recorded and has this process been carried out correctly?	
Does the department have established written procedures for determination of the identity of the patient from whom the product is collected?	
Does the department have established written procedures for determination of the identity of the person labelling the product, recording the collection times, date and signature?	
Instructions for storage conditions prior to collection by the SCL? Contingency arrangements in place should SCL not be available?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Does the department have established written procedures for collection activities from the Haem day unit to the SCL? Within an appropriate time-frame? Within a specified temp range? In a manner to maintain integrity of the product?	
Do transport arrangements meet regulatory & H&S requirements?	
If any problems are encountered during procurement there are procedures in place to document the problem and where applicable notification of the appropriate staff & agencies?	
The date & time of receipt of the product recorded and time placed into interim/overnight storage facility?	
Are the SOPs compliant with requirements? There is no need to detail these in this report unless there is a NC, however, please give the SOP QP ID, edition number and page for the items. If the items are noted as 'not applicable' has a reason been given?	
• purpose of the procedure	
• principle and method of the procedure	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
• type of product required (e.g. mobilised CD34, PBMC's)	
• required equipment and reagents	
• environmental and safety controls	
• procedural steps;	
• quality control procedures;	
• References and related documents	
• Transfer / shipping procedure; requirements, methods, pre-shipment checks	
Procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations. Are the SOPs in plain English and clear to understand? What locations should the SOPs be in and are they available and in what format? (Doc control policy & Template SOP)	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Any condensed document format (e.g. Laboratory Instructions) shall correspond to the documented procedure. Is there any instructions or other condensed documents? If so, do they conform, do they reference the original SOP? Do they follow the original SOP? Is the full documented SOP available for reference?	
Information from product instructions for use may be incorporated into examination procedures by reference. Are any product instructions required for this process? Has the information from the product instructions been incorporated into the SOP? Have the product instructions been referenced? Is a copy of the product instructions available on Q-Pulse or a link to an electronic version /paper version given?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, shall be subject to document control. Are these documents stored on Q-Pulse or their origin and location stored on Q-Pulse?	
If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure. If this has happened in this procedure how this has been accomplished depending on local circumstances. For example, methods include directed mailings, laboratory newsletters or part of the examination report itself.	
Were procedures followed in accordance with documented method? Please give full details of evidence. Include any forms, worksheets or other paperwork completed as this sample has passed through this procedure	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Does this procedure require validation? Verification?	
Laboratory equipment	
Has the equipment used been checked prior to use?	
Has the calibration status been recorded and date of re-calibration? e.g. blood fridge, LFC's, LN2 freezers, water-bath, dry shipper, thermometers if applicable	
Is metrological traceability to a reference material or reference procedure available?	
Is the equipment related to this procedure in a safe working condition and in working order? If equipment is defective has it been taken out of service and clearly labelled?	
Is there a documented programme of preventive maintenance which follows the manufacturer's instructions?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Have the reagents and consumables (if applicable) been verified for performance before use in examinations?	
Is reagent/consumable storage temperature monitored?	
Are records available for date of receiving, the expiry date, date of materials entering into service and if applicable the date the material was taken out of service?	
Reagents and consumables	
Has laboratory stored received reagents and consumables according to manufacturer's specifications?	
Has reagents/kits that affect the quality of this product been verified for performance before use in examinations?	
Does the system for inventory control segregate uninspected/unqualified reagents & consumables from those in use?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Are instructions for the use of reagents and consumables, including those provided by the manufacturers, readily available?	
Have records been maintained for each reagent and consumable that contributes to the performance of examinations.	
Does the laboratory have an inventory control system for reagents & consumables?	
Ensuring quality of internal results	
Are there written procedures for IQC?	
Is there acceptance criteria?	
Is quality control data reviewed at regular intervals?	
Is there a relevant EQA scheme?	
If a recognised EQA scheme is not available has the laboratory developed other approaches and objective evidence for determining acceptability of the examination?	
Receipt of Manufactured ATIMP/ATMP at MFT	
Delivery information received in advance of delivery? (Including waybill number if applicable)	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
ATIMP/ATMP receipt form completed? Storage managed as per manufacturer instructions? Evidence of dry shipper temperature logs for duration of shipment?	
Infusion of ATIMP/ATMP	
Release documentation received and appropriately completed as per policy? (Doc ref)	
Thaw & infusion checklist (Doc Ref) completed with any additional manufacturer documentation requirements?	
Infusion form completion & filed?	
Details annotated in patients notes by SCL?	
Infusion reaction form received, completed and spreadsheet updated accordingly?	
Post examination processes	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
Is there a written procedure(s) for review of end points?	
Have any adverse incidents been reported in ATIMP/ATMP procurement, distribution or infusion? Have these incidents been investigated and reported to the appropriate authorities?	
Are there documented procedures for the retention of records pertaining to ATIMP/ATMP's? Collection, retention, indexing, storage & infusion?	
Reporting	
Is there a procedure for the release of reports?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
The final infusion report shall include: • the procedure • Laboratory issuing report • Patient ID • Unique ID from lab/trial/manufacturer • Date of primary sample collection • Product name/type (infused product) • Cell dose infused • Date infused • ID of person reviewing data & issuing report • Date of report • Reports are legible • Interim reports followed by final reports	
Is there a procedure for issuing revised reports?	
Work Environment	
Are areas compliant to GMP working conditions/practices?	
PPE available in all areas?	

Audit criteria	Records/methods checked & procedures witnessed, NC and best practice
All areas for the transport, processing & storage procedures risk assessed. Regular H&S inspections taken place?	
Personnel	
Is there evidence of staff training & education in these procedures? Attended SIV/Training sessions? Acknowledged SOP in QP?	
Evidence staff trained in GMP & GCP?	
Competency records available? Evidence of CPD?	
Evidence in last 12 months of: Appraisal Mandatory training H&S	

Administration	
Q-pulse	
Has a check of the effectiveness of the actions been added to Q-pulse?	