Cellular ATMP Fresh Autologous Example Receipt Checklist

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ATTC Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Example checklist for receipt and storage of autologous, fresh, cellular ATMPs

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This document sets out an example generic checklist for receipt and storage of fresh, autologous, cellular Advanced Therapy Medicinal Products (ATMPs). It may require adaptation to accommodate local procedures or product-specific requirements. The checklist should be adjusted to reflect whether the ATMP is received direct from the manufacturer or via a Stem Cell Laboratory. Institutional readiness checklists produced by the Pan-UK Pharmacy ATMP Working Group for relevant cellular ATMP type should also be considered. (Available from https://www.sps.nhs.uk/).

Separate example checklists are also available for allogeneic fresh cellular products and cryopreserved autologous/allogeneic cellular products.

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FRESH AUTOLOGOUS CELLULAR ATMP PRODUCT RECEIPT & STORAGE CHECKLIST

Product Name				
Sending laboratory if applicable				
Manufacturer				
Patient name				
Patient date of birth				
Patient hospital number				
Date & time received				
Received by (2 staff members)				
Checking step\data	**Yes\No\N/A\ Data**	**Checker Initials**		**Date & time**
Shipping documentation received: Shipping log Returns documents	Yes / No / N/A Yes / No / N/A			
Qualified Person (QP) Release Certificate / Certificate of Conformance/ Certificate of Analysis available (delete as applicable)	Yes / No			
Location of transport container checked on manufacturer's portal **if applicable**[1] (must be expected receiving centre/location)	Yes / No / N/A			
Stem Cell Lab (SCL) ATMP Batch Processing Record is complete and signed for release **if applicable**[1]	Yes / No / N/A			
Temperature log received/ downloaded from manufacturer or SCL and transport/storage temperature within limits[2]	Yes / No			
Any visible damage to transport container?	Yes / No			

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Details and action taken					
Transport container ID matches delivery documentation	Yes / No				
Tamper-evident ties intact? Outer (Tag ID: _____) Inner (Tag ID: _____)	Yes / No				
Tamper-evident tie ID corresponds to documentation	Yes / No				
Transport container Data Logger within specification[3] (i.e. no alarms) on receipt?	Yes / No				
Quantity received (no. of bags/ vials/ syringes)					
Number of bags/vials/syringes matches QP Certificate/ Certificate of Conformance/ Certificate of Analysis	Yes / No				
Product integrity visual check[4]	Pass / Fail				
Lot/Batch number					
Donation Identification Number (DIN) or unique donation identifier correct (may be manufacturer ID)	Yes / No				
Name on product matches manufacturer portal / QP certificate / (circle applicable parts)	Yes / No				
Patient identifiers on product match manufacturer portal /QP certificate (circle applicable parts)	Yes / No				

Product dose matches Certificate of Conformance/ QP certificate/ Certificate of Analysis/ prescription/ SPC/ trial protocol (circle applicable parts)	Yes / No			
Expiry date; Administration planned prior to expiry date?	…… Yes / No			
All documentation filed as per local policy, to be retained for period appropriate to product type?	Yes / No			
Comments:				

[1] ATMPs may be received by Pharmacy/clinical area direct from the manufacturer or via the local Stem Cell Laboratory. The checklist must be amended to reflect local processes. The batch processing records apply only to ATMPs which have been received by a SCL direct from the manufacturer for storage and then subsequently delivered to Pharmacy/clinical area.

[2] For some ATMPs, the temperature log for transport containers may only available in retrospect once the transport container is returned to the SCL/sending laboratory and data logger downloaded. Compliance with transit temperature parameters is assessed by the transport container data logger at the point of receipt.

[3] If temperature deviations or product defects have been identified, place the fresh cellular ATMP into appropriate storage at the correct temperature and label 'under quarantine'. Contact the manufacturer immediately and refer to local Standard Operating Procedures for ATMP product deviations. If an ATMP is leaking from its container, it should be appropriately stored as per local procedure to avoid contamination of other products or medicines and local spillage procedures must be followed.

[4] Product visual integrity check should be undertaken by checking for leakage and holding up the fresh cellular product to a light source. Further guidance on checking product integrity is detailed in the MW-ATTC training resource 'Visual inspection of cell therapy medicinal products', available via https://www.theattcnetwork.co.uk/resources. If defects noted, refer to point 3.

PLACING CELLULAR ATMP INTO STORAGE (if applicable)				
Checking step\data	**Yes\No\N/A\ Data**	**Checker Initials**		**Date & time**
Required storage temperature range (from SPC or trial protocol or manual)				
Product placed into storage, storage location temperature verified and temperature constantly monitored?	Yes / No / N/A			
Refrigerator ID/Room ID (plus entered on local database if required)	Yes / No / N/A			
Receipt documented on manufacturers platform if required	Yes / No / N/A			

Completed receipt checklist sent to Pharmacy (if applicable)	Yes / No	Initials	Date & time

FINAL CHECK	Print name	Signature	Date
Checker 1			
Checker 2			

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