Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Example checklist for receipt and storage of allogeneic cryopreserved cellular ATMPs

Creator: University Hospital of Wales & University Hospitals Bristol & Weston NHS Foundation Trust
Document version number: V1.0
Date written: November 2020

INDUSTRIAL STRATEGY

UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Example checklist for receipt and storage of allogeneic cryopreserved cellular ATMPs

18 Nov 2020

This document sets out an example generic checklist for allogeneic, cryopreserved, 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 autologous fresh and cryopreserved cellular products.

INDUSTRIAL STRATEGY

UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

All staff handling cryopreserved ATMPs must also have demonstrated competency in handling dry ice or low temperature storage vessels as appropriate.

CRYOPRESERVED ALLOGENEIC CELLULAR ATMP RECEIPT & STORAGE CHECKLIST

Product Name				
Sending laboratory if applicable				
Manufacturer (if different to above)				
Patient name if applicable				
Patient date of birth if applicable				
Patient hospital number if applicable				
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 shipper 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			

INDUSTRIAL STRATEGY
UK Research and Innovation
Coordinated by CATAPULT Cell and Gene Therapy

Any visible damage to shipper?	Yes / No			
Details and action taken				
Shipper 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			
Shipper Data Temperature Logger within specification[3] (i.e. no alarms)	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				
Product batch/ID number matches QP certificate/ Certificate of Conformance/ Certificate of Analysis	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 (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 ATMPs received via a SCL, the temperature log for low temperature shippers may only available in retrospect once the shipper is returned to the SCL and data logger downloaded. Compliance with transit temperature parameters is assessed by the shipper data logger at the point of receipt.

[3] If any temperature deviations or product defects have occurred, replace the product in the shipper and label as ‘under quarantine’. For temperature deviations, liaise urgently with the SCL regarding provision of a new shipper for quarantine or on-going quarantine of product in SCL storage facilities. For defective products including cracked bags, return to SCL may be inappropriate due to risk of contamination. Contact the manufacturer immediately and refer to local Standard Operating Procedures for ATMP product deviations.

[4] Product visual integrity check should include checking both sides of the infusion bag and the port for cracks/tears/leakage. 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 tank temperature verified and temperature constantly monitored?	Yes / No / N/A			
Storage tank 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			