Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Creator: NHS Blood and Transplant

Document version number: 1.1

Date written: 22/06/2021

INDUSTRIAL STRATEGY

UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Contents

Purpose

This document can be used to help prompt consideration and recording of the competencies that are needed to work safely while **thawing cryopreserved cell-based therapeutic products.**

This assessment considers competencies required for thawing a product in preparation for it to be administered to the patient. A separate competency assessment is available relating to the safe use of dry shippers and/or dry ice.

This document contains two parts:

Part A: Template Checklist

Part B: Assessor Guidance Notes.

A process flow is provided on the next page to illustrate how parts A and B should be used. It is advisable to repeat the competency assessment after any change in local processes, staff duties or a prolonged period without conducting this type of work.

INDUSTRIAL STRATEGY

UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

ATTC Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Process flow

Amend the template checklist

Training assessor and/or local manager(s) should adapt the **template checklist** (Part A) according to the local environment, procedures and roles/responsibilities of each member of staff. Amend the recommended reading list, signposting to local documents and training information. Remove any irrelevant information and edit competency requirements as appropriate.

Prepare for the assessment

Supply the learner with a copy of the amended competency checklist that should signpost them to the relevant local documents and training opportunities. Arrange a 1:1 meeting for the learner and training assessor to discuss the competency assessment checklist (either in person or remotely).

Carry out the assessment

It is recommended to carry out the assessment via interactive conversations, rather than relying on written communication. The assessor can use the **assessor guidance notes** (Part B) to help determine whether learners have successfully demonstrated competencies around thawing cryopreserved cell-based therapeutic products.

All competencies satisfactorily demonstrated?

NO

If gaps in knowledge are identified, signpost to where the learner can access more information and arrange a follow up assessment.

YES

Record the completed competency assessment according to local practices.

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

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Part A:

Template Checklist

This **template checklist** should be considered as a starting point rather than an off-the-shelf document that is ready for local implementation. The template checklist requires local adaptation by the training assessor and/or local manager(s) according to the local environment, procedures and the roles and responsibilities of each member of staff. The list of competency requirements should not be considered as exhaustive and assessors are encouraged to add, edit or delete information as appropriate. Users should remove information that is not relevant in the local setting. Amend the recommended reading list as appropriate, adding in local documents and training information. The locally adapted checklist should be made available to the learner in advance of their competency assessment, to allow them to prepare and an opportunity to address any training gaps.

The adapted checklist can then be completed by the assessor together with the learner to provide a written record of the competency assessment. The checklist does not need to be completed in one sitting. If gaps are identified in the learner's knowledge, the checklist can be revisited after a period of (re-)training. Once the checklist has been completed and signed, a copy should be retained by the learner, and the assessor should ensure that training records are updated according to local practices.

Separate **assessor guidance notes** (part B) are available; these should be used by the assessor to help determine whether the learner has successfully demonstrated the competencies required.

A draft recommended reading list is provided. Relevant local information should be added to this list. This may include standard operating procedures (SOPs), policies and risk assessments, plus details of applicable study days or training resources.

The form has been completed using an illustrative example of a staff member who will thaw cell-based therapeutic products at the point of care. This document does not cover competency to administer a cell-based therapeutic product to the patient.

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

ATTC Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Resource	Location	Link/details
Training slide deck: Visual inspection of cell therapy medicinal products	ATTC website	https://www.theattcnetwork.co.uk/wp-content/uploads/2020/02/FINAL-cell-therapy-visual-inspection.2.pptx
Pharmacy Institutional Readiness guidance for GTMP/sCTMP/TEP	SPS website	https://www.sps.nhs.uk/networks/pan-uk-pharmacy-working-group-for-atmps/
Exemplar SOP: Thawing Procedure for Cryopreserved Advanced Therapy Medicinal Products using a Water Bath	ATTC website	https://www.theattcnetwork.co.uk/wp-content/uploads/2020/10/SOP-Waterbath-WORD-Version.docx V1.0 point 5, page 6 and points 13-14, page 7.
E.g. SOP: Reinfusion of allogeneic progenitor cells (HPC)	Q-Pulse	Document XXX v2.1, points 3.8, 3.9, 3.16, 3.18, 3.19
E.g. SOP: Administration of immune effector cells	Q-Pulse	Document XXX v1.1 point 3.12
E.g. Risk Assessment: using the water bath to thaw cell therapy products	Q-Pulse	Document XXX v1.0
E.g. SOP: Disposal of GMO waste	Q-Pulse	CRF-GMO-SOP-XX
E.g. SOP: Spillage management	Intranet	Document 387

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Competency assessment

Requirement	Assessment method(s)	Competency evidenced (assessor initials/date)
Signed off as competent in safe use of dry shippers and/or dry ice (as applicable).	Completed form	
Has read and understood relevant risk assessments relating to cell therapy product thawing.	Verbal	
Can explain the term "cryopreserved".	Verbal	
Can discuss the importance of correctly thawing a cell-based therapy.	Verbal	
Can describe the cell-based therapeutic product(s) that they will be thawing.	Verbal	
Can describe the expected physical appearance of the cell-based therapeutic product(s) to be thawed.	Verbal	
Can describe the process for administration of the final therapeutic product(s) to the patient.	Verbal	
Can describe how to assess that the patient is ready to receive the product.	Verbal	
Can describe the contemporaneous completion of relevant documentation.	Verbal	
Can discuss the appropriate course of action to follow in case of a compromised product bag or interruption to the thawing process.	Verbal	
Preparation of thawing device and area in accordance with local policies and product-specific instructions.	Observation	

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

ATTC Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Assessment method(s)	Competency evidenced (assessor initials/date)
Conducts appropriate product checks before thawing.	Observation	
Demonstrates appropriate care in handling product when removing from shipping container and while thawing.	Verbal Observation	
Conducts final inspection of thawed product according to expected characteristics. Can discuss the appropriate course of action if there are any concerns about the product.	Verbal Observation	
Can describe appropriate waste disposal.	Verbal	
Can describe appropriate management of spills.	Verbal	
Can discuss final checks of shipping container and where it is taken after the product has been administered.	Verbal	

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Outcome:

Have the required competencies been demonstrated for thawing cryopreserved cell-based therapeutic products? If certain competencies are not applicable, please explain why.	
Please detail any further training/ re-assessments required & by what date.	
Any additional comments.	

Authorisation:

Trainee	Assessor
Name	Name
Signature	Signature
Date	Date

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

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Part B:

Assessor Guidance Notes

Note: Individuals being assessed (learners) should not use this Part B. These guidance notes are intended for use by training assessors.

This document provides **assessor guidance** notes to help determine whether learners have successfully demonstrated competencies around **thawing cryopreserved cell-based therapeutic products.**

These guidance notes provide further detail on the knowledge and skills that the learner needs to demonstrate in order to meet the competency requirements. Suggested questions are provided for the assessor to pose, but these should not be considered either mandatory or exhaustive – ideally interactive conversation(s) between the learner and assessor can be used to explore the learner's understanding, discuss best practice and answer any questions. The level of detail in the learner's answers should be appropriate to their role and responsibilities. Some adaptation of the expected answers may be required according to local procedures.

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Signed off as competent in safe use of dry shippers and/or dry ice (as applicable). *Have you been signed off for working with dry shippers?*	**The learner must have demonstrated competency to work with dry shippers/dry ice as applicable. It is recommended to use a locally adapted competency assessment checklist to document competency (see recommended reading list). Competency requirements include discussing appropriate behaviours, PPE, cold burn injury/asphyxiation risks and first aid measures.**	**Completed form**
Has read and understood relevant risk assessments. *Which risk assessments have you read that are relevant to thawing cell therapy products?* *Do you have any questions about those risk assessments?*	**Local risk assessments should be in place for thawing cryopreserved cell-based therapeutic products. These risk assessments should be signposted under recommended reading. Ask the learner to confirm which risk assessments they have consulted and if they have any questions.**	**Verbal**
Can explain the term "cryopreserved". *What does cryopreserved mean? Why is DMSO added to the cells?*	**Cryopreserved cells or tissues are cooled to very low temperatures to maintain their viability for long periods of time. A cryoprotective agent (e.g. dimethyl sulfoxide, DMSO) is usually mixed with the cells or tissues before cooling, to protect them from osmotic shock and the formation of damaging ice crystals inside the cells as they freeze.**	**Verbal**

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

ATTC Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Can discuss the importance of correctly thawing a cell-based therapy. *Why is it so important to thaw the product correctly according to the protocol? What could happen if the thawing device is too hot?*	**The learner should explain that a cell-based therapy contains viable (living) cells and that its effectiveness relies on maintaining cell viability and function. They should describe why thawing is a critical step – i.e. if it is carried out incorrectly (e.g. at an inappropriate temperature or thaw rate), this may render the therapy ineffective or unusable. It may not be possible to replace the therapeutic product, with potentially severe consequences for the patient.**	**Verbal**
Can describe the cell-based therapeutic product(s) that they will be thawing. *Can you tell me a bit about this therapy and how it works?*	**The learner should be able to briefly describe the cell type and source, any modification that the cells have undergone and how the therapy is expected to work in the body. Refer to trial protocol/summary of product characteristics (SmPC) or consult product manufacturer. It is recognised that some staff may be working with multiple different product types, for example in clinical trials. The level of detail provided should be commensurate with their role and responsibilities.**	**Verbal**
Can describe the expected physical appearance of the cell-based therapeutic product(s) to be thawed. *What does cryopreserved mean? Why is DMSO added to the cells?*	**The learner should demonstrate an awareness of the product packaging (including lines/ports and whether over-wrapped into an outer bag), expected colour & turbidity (post-thaw). Refer to trial protocol/SmPC or consult product manufacturer or trial sponsor.**	**Verbal**

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Can describe process for administration of the final therapeutic product(s) to the patient. *What happens after this product has been thawed – how is it administered?*	**Some products may require post-thaw aseptic processing prior to administration. The learner should be able to explain post-thaw processes relating to any product they will work with. Refer to the product administration manual/instructions.**	**Verbal**
Can discuss how to assess that the patient is ready to receive the product. *How would you confirm that the patient is ready for the product?*	**The learner should be able to discuss how to assess that the patient is clinically ready to receive the product. This may include completion of a 'Fitness to Treat' checklist or other documentation according to local policies and product-specific instructions.**	**Verbal**
Can describe the contemporaneous completion of relevant documentation *Can you talk me through how the paperwork should be completed?*	**Documentation requirements will vary according to product/trial-specific protocols. It is common practice to document the time that each individual bag is thawed. The learner should explain that in the case of multiple product bags, these must be thawed and administered one at a time. The thawing process should be done in pairs to enable product handling and concurrent documentation.**	**Verbal**

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Can discuss the appropriate course of action to follow in case of a compromised product bag or interruption to the thawing process. *What would you do if a bag started leaking?*	**Seek urgent advice from patient's consultant, pharmacy and the product manufacturer. Contain the compromised product within a sterile bag while determining next steps. Product packaging should be kept for investigation. Follow the appropriate SOP for dealing with product deviation. Refer to #16 re: spill management. Exposure of cells to cryoprotective agent at ambient temperature can result in cell damage; it is important to minimise delay between thawing initiation and administration of the product (exact timeframe will vary between products).**	**Verbal**
Preparation of thawing device and area in accordance with local policies and product-specific instructions. *Can you show me how to prepare the thawing device and the immediate working area?*	**Demonstrates appropriate cleaning and disinfection of thawing device before (and after) use. Correctly sets up device for use, confirming temperature has been reached. Correctly sets an appropriate temperature alarm (where available) or confirms that any pre-set alarm must not be altered. The learner should demonstrate an understanding of how to prepare the thawing environment e.g. sufficient space for two people to work, a suitable surface to complete documentation and examine the product, cleaning and PPE as per local policies and product-specific instructions.**	**Observation**
Conducts appropriate product checks before thawing. *Can you take me through the checks you need to make of the product before thawing?*	**Demonstrates checks of the product's (primary and secondary) labelling and confirms the dose, expiry and correct product for correct patient.**	**Verbal** **Observation**

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Demonstrates appropriate care in handling product when removing from shipping container and while thawing. *How should you handle a frozen product bag and what is it like to the touch?* *What might you see or hear as a product bag is thawing?* *When should you remove the product from the thawing device?*	**Confirm that the learner is aware that frozen product bags may be brittle, may break if dropped, and may emit 'crackling' sound and/or vapour as they warm up. The learner should discuss or demonstrate how to place the product into an over wrap bag as per local policy. The product should be removed from the thawing device at an appropriate stage depending on product- & device-specific instructions (usually when some ice remains & product remains cool to touch).**	**Verbal** **Observation**
Conducts final inspection of thawed product according to expected characteristics.	**The learner should be able to discuss the appropriate course of action if there are any concerns about the product at this stage. Refer to points 6 and 9.**	**Verbal** **Observation**
Can describe appropriate waste disposal.	**Waste disposal to be undertaken accordance with local policies and product-specific instructions e.g. genetically modified materials.**	**Verbal**
Can describe appropriate management of spills.	**Spill management to be undertaken accordance with local policies and product-specific instructions e.g. genetically modified materials.**	**Verbal**

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Requirement	Notes to assessor and expected answers	Assessment method(s)
Can discuss final checks of shipping container and where it is taken after the product has been administered. *What final checks of the shipping container would you need to make after the product has been administered?* *What happens to the empty shipper after administration?*	**The learner should describe the importance of product reconciliation (i.e. number of bags/items delivered matches number of bags/items thawed) and how they would confirm that all product bags/items have been administered (if vapour cloud obscures a visual check this may require reaching inside shipping container, using suitable PPE). Explain local procedure for returning shipping container to the appropriate department e.g. pharmacy/stem cell lab or directly to the sending laboratory.**	**Verbal**

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

First Relapse	
Date of 1st Relapse	
Stage at relapse	
2nd line treatment	
Response to 2nd line treatment	
Second relapse	
Date of 2nd Relapse	
Stage at relapse	
3rd line treatment	
Response to 3rd line treatment	
Third relapse	
Date of 3rd Relapse	
Stage at relapse	
4th line treatment	
Response to 4th line treatment	
Prior Haematopoietic Stem Cell Transplant	
Date of transplant	
Type of transplant – Auto/Allo	
Conditioning	
If Allo – Donor (Sib/MUD/UCB/Haplo)	
If Allo – date immunosuppression ceased	

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

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Critical Treatment Information	
Date of last chemotherapy and type	
Date of last steroid	
Date of last radiotherapy	
Date of last monoclonal antibody and type	
Date of last GCSF	
Date of last IT chemotherapy and type	
Does patient have central venous access?	
If yes, type of line in-situ;	

Additional Information

CAR T Cell Team Contact Details

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