Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Manufacturing Product Template

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Background

The new product introduction process is the process stretching from first discovery to market launch and covers developing, testing and manufacturing a new product.

Project Details

Project Name	
Project Lead Contact Name	
Contact address and telephone number of project lead	**Address:** **Tel:** **E-mail:**
Date of completion	

Starting material

Product classification: *(Tick as appropriate)*

Allogeneic ☐

Autologous ☐

What is the source of the starting material, e.g. hospital patient or commercially purchased?

Please provide a list of raw material suppliers, including addresses and contacts if available.

(These may be hospital trusts or private companies)

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Does the donor providing starting material require any testing in addition to mandatory screening tests?

HTA only (Q&S) ☐

Extended testing ☐ *(provide details below)*

Are any follow up tests/screening required?

No ☐

Yes ☐ *(provide details below)*

What are the acceptance criteria for the raw material?

Donor Screen: **Yes** ☐ **No** ☐ *(if No, provide justification below)*

Additional criteria:

What are the storage requirements of the starting material?

Maximum hold time: **N/A** ☐

Hold temperature: **N/A** ☐

Minimum/maximum volume or weight: **N/A** ☐

Other acceptance criteria:

Are there any specific equipment requirements for harvest/storage or starting material?

Yes ☐ *(Please describe as fully as possible)*

No ☐

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What are the Critical Quality Attributes (CQA) of the starting material?
Critical Quality Attributes are chemical, physical, biological and microbiological attributes that can be defined, measured, and continually monitored to ensure final product outputs remain within acceptable quality limits.

Has a CQA assessment has been carried out?

No ☐

Yes ☐ *(please attach report to this form)*

Are there any assay release specifications for the raw material?

Yes ☐ **(Please describe as fully as possible, including test platform, assay validation status etc).**

No ☐

Is any specialist staff training required to handle the starting material?

No ☐

Yes ☐ *(provide details below)*

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Does procurement site have appropriate HTA licence? Yes ☐ No ☐ Not known ☐ Licence

No:_____

Are all technical agreements in place for procurement of the starting materials? Yes ☐ No ☐

Ref:_____

Equipment required for collection, storage and acceptance of starting material:

Porta-Box ☐

Temperature loggers ☐

Sterile welder ☐

Balance ☐

MACSQuant ☐

Additional equipment required? Yes ☐ No ☐

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Manufacturing

Complete the Gantt chart below to illustrate the process map.
(Where activity is repeated, use range, e.g Feed, Days 3 – 7, Grade A/B)

Stage	Day
Starting material receipt and storage	
Starting material processing	
Cell culture	
Harvest	
Final fill	
Cleanroom Grade required	
Time for completion of stage (hours)	

Total cleanroom time required:_____

Will any out of hours work be required? Yes ☐ **No** ☐ **(if Yes, provide justification below)**

Working hours are 9am-5.30pm Monday to Friday

Is Grade A space required? Yes ☐ **No** ☐

If Yes, what capacity is required, i.e number of BSC II hoods/isolators? _____

Is there a selection/purification step? Yes ☐ **No** ☐ **If yes, what platform is used:**

CliniMACS Plus ☐

CliniMACS Prodigy ☐

CliniMACS Tyto ☐

Other ☐ *(provide details below)*

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Do cells require culture? Yes ☐ No ☐

If Yes, where is this performed:

CliniMACS Prodigy ☐

Incubator ☐ Number of Products per incubator:_____

Terumo Quantum ☐

Other ☐ *(provide details below)*

Does culture require hypoxic conditions? Yes ☐ No ☐

If yes, what % O2 is required?_____

What gas supplies are required:

CO2 ☐ _____%

N2 ☐

Compressed air ☐

Mixed gas ☐ Specification:_____

Is any other equipment required for the manufacturing process? Yes ☐ No ☐
(provide details below)

Raw materials required:

Material _____ Proposed supplier_____

Grade
(e.g GMP/Medical/Research)_____

Approx. requirement per process_____

Is a TSA statement available for all items? Yes ☐ No ☐
(If No, provide details of items requiring assessment below)

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What in-process testing is required? *e.g. QC and sterility tests*

Flow cytometry based phenotype ☐

Cell count ☐

Sterility ☐

Other, please provide details ☐

Are staff/personnel being provided to support the manufacture?

Yes ☐ **No** ☐

Number of staff provided:_____

If staff are provided, do they have previous GMP experience?

Yes ☐ **No** ☐ **Not known** ☐

Will any randomisation or blinding be performed in the study?

Yes ☐ **No** ☐

If yes, please provide details of mechanism of blinding for final product:

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Do existing licences cover process? Yes ☐ No ☐

Is starting material procured under UoB HTA licence? Yes ☐ No ☐

Is dosage form covered by existing MHRA Licence? Yes ☐ No ☐

If no, what is dosage form?_____

Are additional vendor qualifications required? Yes ☐ No ☐

If yes, is a site audit required? Yes ☐ No ☐

Are new Technical Agreements required? Yes ☐ No ☐

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Facility demand:

Maximum No. of hours per processing session:_____ If > 4 hours, are additional teams required? Yes ☐ No ☐

Maximum no. of processing hours per week:_____

No of days a week the cleanroom will be required e.g. frequency of cell feeding/manipulation:_____

Are additional pieces of equipment required? Yes ☐ No ☐

If yes, has suitable space been identified? Yes ☐ No ☐

Proposed location of equipment:

Personnel demand:

Are there any operator validations required for the processing? Yes ☐ No ☐

Existing staff? Yes ☐ No ☐

New appointments? Yes ☐ No ☐

Number of scientists required or to be seconded?_____

Do all staff need to operate to GMP? Yes ☐ No ☐

If no:

No. of cleanroom operators: _____

No. of non-cleanroom operators: _____

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Final fill / formulation

How is final product released to the patient?

Fresh ☐

Cryopreserved ☐

What grade areas are required for final manipulation?

A ☐ B ☐ C ☐

How is the final product manipulated prior to release?

Centrifuge ☐

CliniMACS Prodigy ☐

CliniMACS Plus ☐

Other ☐ *(provide details below)*

What final release assays are required?

Phenotype ☐ - MACSQuant compatible? Yes ☐ No ☐

Sterility ☐ - BacT/ALERT compatible? Yes ☐ No ☐

Mycoplasma ☐

Endotoxin ☐

Cell count ☐

Other ☐ *(provide details below)*

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What is the container closure device?

Fill method: **Manual** ☐ **Automated** ☐

Does filling require specific equipment? (e.g. M1 filling line) **Yes** ☐ **No** ☐
(provide details below)

Do product labels fit on primary packaging? **Yes** ☐ **No** ☐ **Not known** ☐

If no, is secondary packaging designed? **Yes** ☐ **No** ☐ **Not known** ☐

Are the labels Annex 13 compliant? **Yes** ☐ **No** ☐ **Not known** ☐

For cryopreserved products only:

What controlled rate freezing device is required?

Via Freeze ☐

Planer CRF ☐

Other ☐ *(provide details below)*

Is a manual seeding step required? **Yes** ☐ **No** ☐ **Not known** ☐

Where is the cryopreserved product to be stored?

What is the freezer type?
e.g. LN2 tank, mechanical freezers or other

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Computer Systems

Is any specific software required for the process? Yes ☐ No ☐

If yes, has software been validated? Yes ☐ No ☐ N/A ☐

(provide validation report if avaiable)

Will RFID or barcode technology be used for sample identification/tracking? Yes ☐ No ☐

If yes, is additional hardware required? Yes ☐ No ☐ N/A ☐

(provide details below)

Is specialist support required from IT department?

Yes ☐ No ☐ Not known ☐

If yes, has a call been raised?

Yes ☐ No ☐ Call Ref:

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Transfer to patients

Where will the product be administered?

Local hospital(s) ☐ (Delivery by foot)

National hospital(s) ☐

International sites ☐

Details of site and personnel:

Site	Address	Contact
.....		
.....		
.....		

Name: .....
Tel: .....
E-mail: .....

Site	Address	Contact
.....		
.....		
.....		

Name: .....
Tel: .....
E-mail: .....

Site	Address	Contact
.....		
.....		
.....		

Name: .....
Tel: .....
E-mail: .....

Site	Address	Contact
.....		
.....		
.....		

Name: .....
Tel: .....
E-mail: .....

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What is the transport container?

Dry Shipper ☐ **(LN2 based or ViaShipper)**

Circle as appropriate

Cryopod ☐

Ambient box ☐

Other ☐ *(Specify)*

Is a contract/technical agreement in place with a specialist courier?

Yes ☐ **No** ☐ **Not known** ☐

If yes please provide details

Agreements

What agreements are required for project progression?

Commercial agreement ☐

MTA ☐

NDA/CDA ☐

SLA ☐

Other ☐ *(Specify)*

Are Quality Agreements in place with all required parties?

Yes ☐ **No** ☐ **Not known** ☐

If yes please provide details

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Details of contracts

Provider	Contact	Agreement reference/date

Name: .....
Tel: .....
E-mail: .....
Agreement type: .....
Reference: .....
Date of completion: .....

Name: .....
Tel: .....
E-mail: .....
Agreement type: .....
Reference: .....
Date of completion: .....

Name: .....
Tel: .....
E-mail: .....
Agreement type: .....
Reference: .....
Date of completion: .....

Name: .....
Tel: .....
E-mail: .....
Agreement type: .....
Reference: .....
Date of completion: .....

Name: .....
Tel: .....
E-mail: .....
Agreement type: .....
Reference: .....
Date of completion: .....

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Do existing sterility test validations cover product specification? Yes ☐ No ☐

Will additional validation of other third part release assays be required? Yes ☐ No ☐

Have local release assays been validated? Yes ☐ No ☐

Is additional equipment required for container closure? Yes ☐ No ☐

If yes, is there capacity to install? Yes ☐ No ☐

Location:_____

Are new agreements required? Yes ☐ No ☐

If yes, have these been actioned? Yes ☐ No ☐

Details:

Is additional storage capacity required? Yes ☐ No ☐

Is additional shipping capacity required? Yes ☐ No ☐

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