

## Project Inquiry

Please use [Adobe Acrobat Reader](#) to fill in project information as available to enable us to evaluate a concept for your production.

Information provided will be kept confidential and will not be forwarded to third parties. If no CDA is signed off in the following 3 months from receipt, we will automatically delete provided information from our database and will confirm deletion by e-mail.

Please declare n.n. if information is not available at time of fill out and contact us in case of further questions.

### Contact:

t.appl@cellerata.com  
+49 176 931 892 10

## Client Information

### \*Required fields

First contact name\*

e-mail\*

phone

position

department\*

institution\* (Please include legal entity)

If other, please specify:

### Contractual agreement in place

Confidentiality Agreement

Quality Agreement

Letter of Intent

Service Agreement

Request for Proposal

### Project sponsor (internal)\*

### Project sponsor (external)

Third Party (CDMO project)

Public funding

## Project Request

### Request for service

Value Stream Analysis

Lean Manufacturing evaluation

Capacity and cost evaluation

Production simulation

New facility design

Process automation

Technology Transfer

If other, please specify:

## Product Information

**Project ID\***

**Product name/number\***

**Product category**

**ATMP classification**

**Source of ATMP**

autologous

allogenic

cell bank

*If other, please specify:*

**Number of projects  
in the pipeline**

Development

internal

Tech Transfer

external

Clinical supply (GMP)

in planing

Market supply

## Clinical Trial

**If already registered**

EudraCT, Trial Number:

NCBT, Trial Number:

**Date of registration**



**If not registered**

Expected date for IMPD/IMP submission

**Number of clinical trial sites  
per agency**

EMA

FDA

PMDA

*If other, please specify:*

**Special  
designation**

PRIME

RMAT

Orphan drug designation

*If other, please specify:*

**Most relevant clinical stage  
for current project**

Preclinical stage

Phase I

Phase II (a/b)

Phase III

Phase IV (commercial)

**Expected start of  
patient recruitment\***

**Expected first  
patient treated\***

**Expected clinical  
stage duration**

months

## Clinical Trial Design

**Planned number of sites**

**Active number of sites** *(current stage)*

**Primary indication**

Please specify indication

**Number of patients:**

**Dosing per kg / body weight**

**Number of administration**

**Secondary indication**  
*(if planned)*

Please specify indication

**Number of patients:**

**Dosing per kg / body weight**

**Number of administration**

## History of Batch Productions

**Amount of batches already produced**

Development

Engineering

Qualification

Validation

Clinical supply (GMP)

Commercial

**Amount of batches released for clinical trial**

**Not released / failed batches**

**Range of expected doses per batch production**

Min:

Realistic:

Max:

**Type of batch to be modelled**

## Production Forecast

**Planned number of batch productions per month**

Preclinical

Phase I

Phase II

Phase III

Phase IV

**Total number of batches per year**

## Manufacturing Process

### Clean room concept

### Gowning required

### Tissue specimen

*If other, please specify:*

### Cell type of interest

*If other, please specify:*

### External provision of starting material necessary

### Provider of starting material

*If available, name origins:*

### Qualification of starting material

*If other, please specify:*

## Mode of Starting Material

### Starting material storage

### Maximum interim

 hours

### Shipping condition

### Shipment time from tissue withdrawal to receipt

 hours

### Cell incultivation

### Incultivation volume

 ml

### Mode of cell manipulation

### Other cell stimulation

### Cell expansion platform

*If other, please specify:*

### Cell harvest technology

*If other, please specify:*

### Fill and Finish technology

### Mode of Formulation

*If other, please specify:*

### If genetically modified, which vector is used:

*Origin of viral vector:*

### Cell Culture volume after harvest

 ml

*Expected number of doses per batch:*

### Final Product filling volume

 ml ml ml ml

## Manufacturing Equipment

Cell Separator

Centrifuge

Transfection Device

Automated Filler

Bioreactor

Controlled Rate Freezer

Incubator

Tube welder

*If other equipment, please specify:*

### List of manufacturing equipment available

## Primary Packaging

### Cell bag size

 ml

### Product label info available

### Filling mode

### Vial size

 ml

### Product label will be provided

*If automated, please specify which:*

### Name primary packaging

## Cryopreservation

### Controlled rate freezer

Consarctic

Thermo Scientific

GE System

*If other, please specify:*

### Established freezing protocol

## (Interim) Storage of End Product

### Expected interim storage at manufacturing site before product supply

 days

### Long term storage of End Product

### Available for review

Master Batch Record

Bill of Materials

Media Fills

Incoming Goods Receipt

Manufacturing License

Manufacturing equipment list

Release of materials

Import License

Drug Master File

Executed Batch Records

Site Master File

## End Product Release Testing

### Cellular Assays

#### Automated cell count

##### Device used

#### Flow cytometry in the FACS panel

#### FACS device used

Please specify:

#### Safety Testing

Gene / Vector Copy Number

Endotoxin

Mycoplasma

Sterility

Karyology

Chromosomal

Genotoxicity (In vivo)

Viral Safety Testing

If other, please specify:

#### Functional assay

ELISA

Chromatography (GC/MS (HPLC)

Migration Assay

Potency Assay

If other, please specify:

#### In house QC laboratory

Quality Control Lab

Environmental Monitoring Lab

Incoming Goods Testing

#### List of Quality Control equipment available

#### QC Equipment

Balance

Biosafety Cabinet (BCS)

Nucleocounter

Microscope

MACSquant

PCR Cycler (qPCR)

Plate Reader (ELISA)

If other equipment used, please specify:

## QC Documentation

### Batch documentation

QC batch report

Product Specification

### Batch released by qualified person:

CoA

CoC

### Quality Control Software

Material Enterprise System

Laboratory Information System (LIMS)

Electronic Batch Record

Environmental Monitoring

If other software used, please specify:

## Organisational Structure

### Manufacturing Sites

#### Number of production sites available / qualified:

#### Location of Manufacturing

EU GB China

CH US JP

If other, please specify:

### Clean room availability

#### Total number of clean rooms

#### Clean room back-up available

#### Clean room setting

Product dedicated clean room

Multi product production

Isolators (RABS)

#### Manufacturing campaigns planned

If yes, please fill out:

##### Scenario 1

batches in  months

##### Scenario 2

batches in  months

##### Scenario 3

batches in  months

##### Scenario 4

batches in  months

#### Number of biosafety cabinets (BSC)

per clean room

## Clean room entrance

Number of operators restricted  
per clean room?

## Dedicated Product Team

Process Development

Quality Control

Data Management

Manufacturing

Back office

## Structure of manufacturing Team

FTE Operators required per production of this product

min:

opt:

max:

## Skill Matrix Manufacturing

Please insert number of personnel per each manufacturing process step per batch production.

	Process Scientist	Manufacturing Manager	GMP Operator (Clean Room)	Support in the Clean Room	Sample Manager	Technical Assistance (back office)
Process Steps:						
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Refer to manufacturing process. (Day 0 = Incultivation)

### Anticipated thaw control after cryopreservation

**Fixed weekday(s) for  
production start**

**Qualified in the  
manufacturing process**

**Qualified as GMP operators  
for the process**

### Qualified GMP Operators by media fills

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Number of Quality Managers

Dedicated for the project

Structure Quality Control

QC operators required per  
each production

min:

opt:

max:

Skill Matrix QC

Please insert number of personnel. Refer to analytical methods

Method	Scientist	QC Manager	Lab assistance	Supply chain assistance	Technical Assistance (back office)
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## Quality Control Scheme

Refer to quality control testing as In Process Control

Process Steps	Manufacturing days																						
	-02	-01	0	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20

## Final Product Release Scheme

Refer to quality control testing as In Process Control

Days between harvest and start of product release testing.

Analytical testing steps	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15

Expected product release date  
from Thaw Control

## Number of supportive functions

Supply Chain Manager

Warehouse

Planning & Scheduling  
Manager

Procurement

Qualified Person

Controller

Technical Service

Dedicated Project  
Management

If other operational functions, please specify:

## Operational Excellence

Lean Management

Six Sigma

agile Project Management /  
Scrum

## Daily working hours in the clean room

For GMP operators

hours

Earliest start of working day

time

Latest end of working day

time

Flexible shifts possible

From

to

Fixed start of manufacturing time

time

## Working Shifts (model for GMP operators)

Regular working hours per day

hours

Working days per week

days

Shift Models

Shifts per day

Number of vacation days/year

Calendar for public holidays

Days per week

Weekend shift

Please insert country/region

Night Shift

## Shut down period for facility/clean room

Number of days/period

Number of maintenance periods

Fixed maintenance period (date)

From

to

## IT Infrastructure for production execution

Hardware

office workstations

handhold devices  
(used)

IT Admin

centralized

outsourced

on site  
(decentralized)

Data safety management

internal

external

### Data storage / Server

cloud based

server based

combination server / cloud

Please specify:

### Standard internet browser

MS Explorer, version:

Firefox, version:

MS Edge, version:

If others, please specify:

## Software and Digitalization

### Microsoft.NET Framework 4.7.2.

Windows 7

Windows 10

Office 365

### Process visualization (non GMP)

Microsoft Project

Microsoft Visio

If other, please specify:

### Validated laboratory software (GMP compliant)

### Other software applications

### Software interface for equipment available / implemented

#### Manufacturing equipment

established

implemented

qualified

Please specify for which:

#### Quality Control equipment

established

implemented

qualified

Please specify for which:

### Enterprise Resource Planning

Production Planning Software

Please specify:

Introduced/established since:

Material Enterprise Software

Please specify:

Introduced/established since:

## ***Thank you for filling out the Project Inquiry!***

Please submit it by pressing the button below and send this form per Mail.  
If you got additional comments, please feel free to add them here: