CATAPULT
Cell and Gene Therapy

Manufacturing centre

To help support the growing industry, we have built a large-scale GMP manufacturing centre, which through collaborations, will help address the manufacturing challenges faced by therapy developers.

The centre will support the development of new large-scale manufacturing systems and capabilities, helping you to bring your cell and gene therapies to market.

Contents

Manufacturing centre

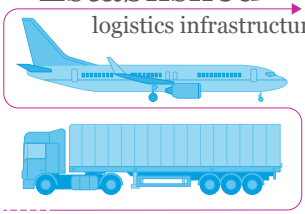
The Cell and Gene Therapy Catapult manufacturing centre will provide you with the supported environment to develop your large-scale manufacturing systems, whilst segregated modules allow you to maintain control of your underlying process.

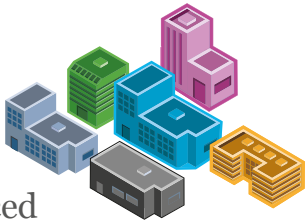
The licensed GMP-compliant manufacturing centre will provide you with the flexibility of your own facility, as well as access to an established supply chain.

Less than 24 hrs

From major European centres

Established logistics infrastructure





Advanced therapies cluster

>7000m² floor space,

space for 12 segregated modules

Benefits

1

Ready when you need it

Through collaborations we will support you to develop new large-scale manufacturing systems, without the need for capital investment or the associated risk of building and licensing your own facility.

The centre can offer the opportunity for acceleration of commercial-scale production.

2

Access established supply chain

The centre's location will enable you to access an established international in-bound supply chain, to support your manufacture. The effective outbound supply chain, with its easy access to Heathrow and major international transport links, will also allow you to receive and deliver your therapies to key clinical centres.

The Fisher BioServices' CryoHub located at the centre will provide a complete cryogenic storage, distribution and logistics solution.

3

Flexible to your needs

The centre is designed to be adaptable to your processing needs, enabling you to flex to your manufacturing strategy and as you grow, take on more modules or replicate your module design in your own facility.

The flexible module design and supporting infrastructure is adaptable to your own process, whether it is allogenic, viral vector or autologous.

4

Control your manufacturing strategy

The centre's architecturally segregated modules allow you to develop your process while retaining your intellectual property (IP) and know how. The people, process, quality management system, batch release and IP are all yours.

We will work with you, managing core operational and quality assurance activities, letting you focus on developing your processes.

5

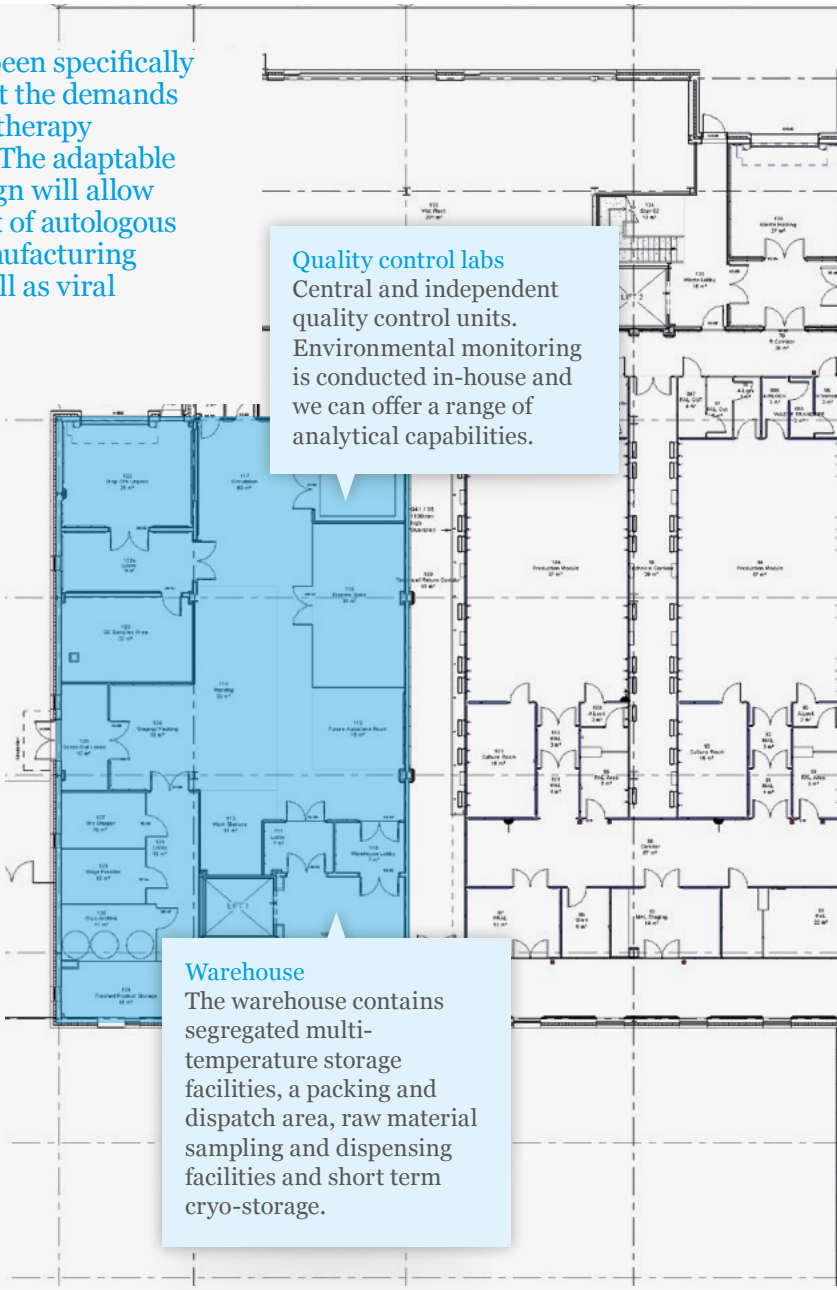
Collaborate with industry specialists

The centre is supported by a team of specialists across the cell and gene therapy lifecycle, who will work with you when you need them. The team have expertise in:

- Health economics
- Regulatory support
- Clinical trial support
- Industrialisation
  - Process development
  - Assay development
  - Technology transfer
  - Manufacturing
  - Validation

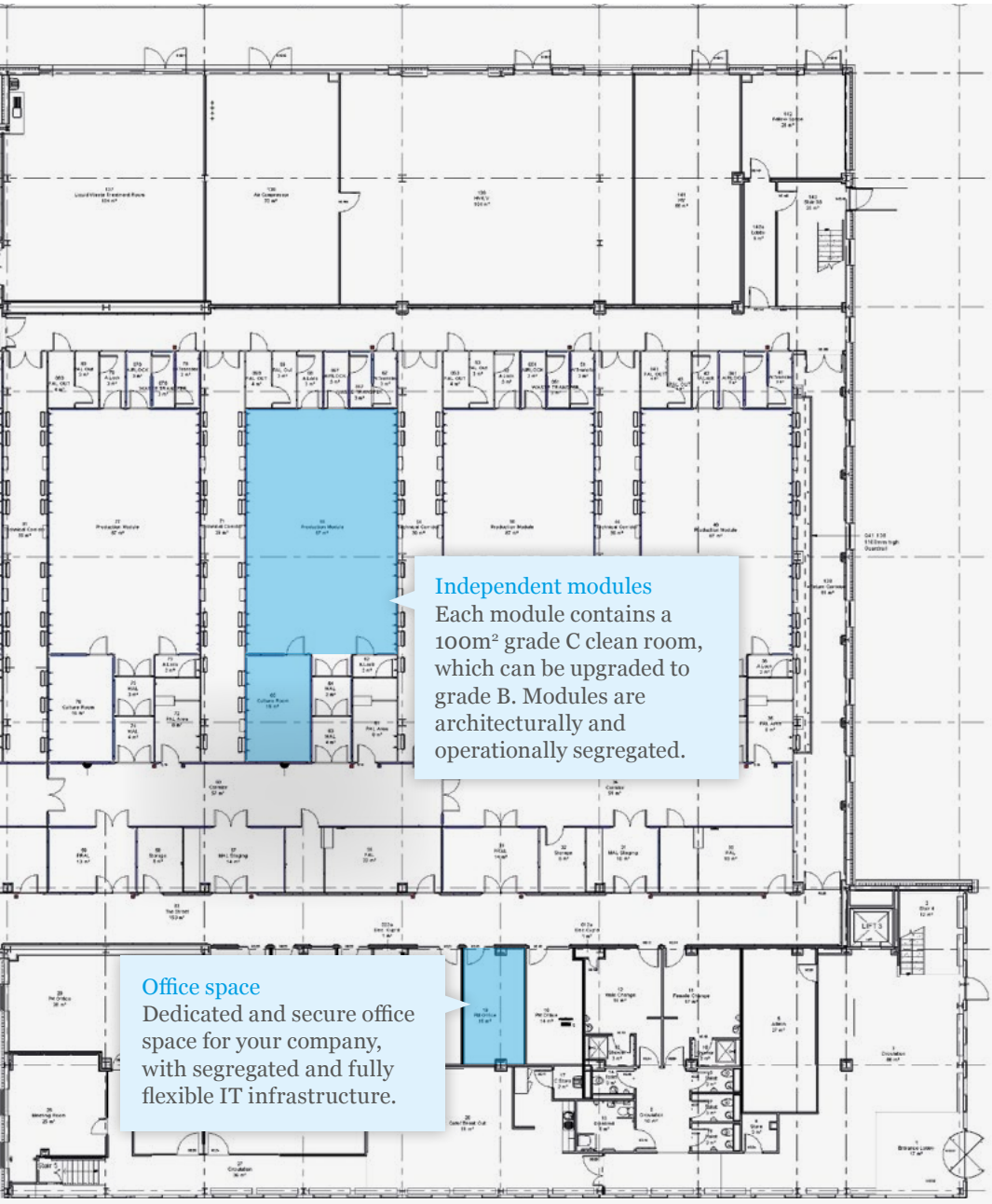
Floor plan

The centre has been specifically designed to meet the demands of cell and gene therapy manufacturing. The adaptable clean room design will allow the development of autologous or allogenic manufacturing processes, as well as viral vectors.



Quality control labs
Central and independent quality control units. Environmental monitoring is conducted in-house and we can offer a range of analytical capabilities.

Warehouse
The warehouse contains segregated multi-temperature storage facilities, a packing and dispatch area, raw material sampling and dispensing facilities and short term cryo-storage.



Independent modules

Each module contains a 100m² grade C clean room, which can be upgraded to grade B. Modules are architecturally and operationally segregated.

Office space

Dedicated and secure office space for your company, with segregated and fully flexible IT infrastructure.

Centre specifications

We will contribute by providing:

- >7,000m² EU GMP-compliant facility licensed for clinical and commercial production
- Central quality control (QC) laboratory
- Dedicated and confidential QC space
- Secure and partitioned private cloud-hosted electronic Quality Management System
- cGMP-compliant quality systems
- Warehousing and waste management
- Welfare areas
- Dedicated and furnished office space
- Bookable meeting rooms with communication facilities
- Communal parking
- Managed reception
- Access to Fisher BioServices' storage and distribution CryoHub

Your individual module will include:

- 100m² grade C clean room, fully compliant with Annex 1 requirements, which can be upgraded to grade B
- Associated airlocks
- Dedicated single pass fresh heating, ventilation and air conditioning
- Flexible in-module service provision
- Dedicated production office
- Individual access control

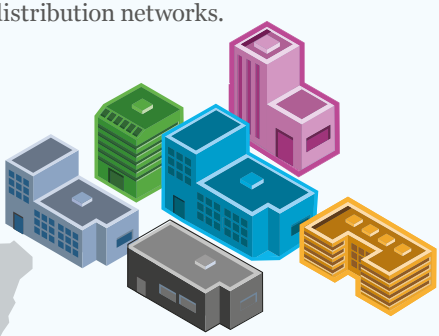
Cluster development

Existing infrastructure

The centre has an excellent supply chain infrastructure and is less than 24hrs from most major European cities.

The cluster at Stevenage Bioscience Catalyst

We are developing a technology support cluster for you to benefit from shared infrastructure, suppliers and distribution networks.



Easy to ship in materials from established global supply chain

Critical materials

Companies that supply consumables such as specialist media to the centre

Patient material from clinic

Manufacturing centre located to enable 24-hour delivery into key global clinical centres

Specialist couriers

Equipment

Global companies that supply technology to the centre

Therapies delivered in hospitals

Whether you're at the very start of your research, looking to manufacture therapies or need regulatory support, we can help. We have the infrastructure and a team of specialists across the cell and gene therapy life cycle, who will collaborate with you when you need us to enable you to get the best possible results.

About us

The Cell and Gene Therapy Catapult's purpose is to grow a UK cell and gene therapy industry, delivering health and wealth.

Our vision is for the UK to be a global leader in the development, delivery and commercialisation of cell and gene therapy. Where businesses can start, grow and confidently develop advanced therapies, delivering them to patients rapidly, efficiently and effectively.

We work with
Innovate UK

Cell and Gene Therapy Catapult

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