

# One year in operation

## Cell and Gene Therapy Catapult manufacturing centre

Business Secretary Greg Clark and Science Minister Sam Gyimah officially opened the Cell and Gene Therapy Catapult manufacturing centre on 23 April 2018. One year on, the Stevenage based centre is now supporting the rapidly growing global cell and gene therapy industry in the UK and five companies are developing GMP manufacturing processes at the centre.

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### Five companies on their way to GMP manufacture

The CGT Catapult manufacturing centre is now home to five innovative cell and gene therapy companies who are developing their GMP manufacturing processes, preparing for large scale and commercial supply. The journey these companies have taken in collaboration with CGT Catapult has resulted in some important learnings for the centre and the wider industry.



Vector manufacturing is one crucial element of Adaptimmune's integrated manufacturing process. This project at CGT Catapult will enable the

Company to have their own dedicated global vector manufacturing capability in the UK.



Autolus, a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer, have developed their own proprietary viral vector and semiautomated cell manufacturing processes. The CGT Catapult manufacturing centre is allowing Autolus to grow their manufacturing capacity, with adjacent cleanrooms for vector and cell manufacturing, as well as to access a range of services provided at the centre.

The CGT Catapult manufacturing centre is enabling Cell Medica to manufacture their allogeneic CAR-NKT cell therapy, working in a purpose-built, cost-effective, collaborative facility.

## FREELINE

Freeline have established their proprietary commercial-scale AAV manufacturing process at the CGT Catapult manufacturing centre. The collaboration

has enabled Freeline to rapidly setup GMP manufacturing operations and accelerate delivery of their clinical pipeline.



TCR² Therapeutics Inc. is CGT Catapult's first US collaborator. They are a clinical-stage immunotherapy company developing the next generation of novel T cell receptor (TCR) therapies for patients suffering from cancer. TCR² are establishing their manufacturing systems and capabilities at the CGT Catapult manufacturing centre.

## On-boarding

Collaborators in the facility have gone through a comprehensive selection and on-boarding procedure to ensure that the centre is suitable and their clean rooms can be adapted appropriately for their development needs, and that the centre remains GMP compliant.



## Increasing licenced GMP capacity for the UK industry

In September 2019 the CGT Catapult manufacturing centre was granted two licences, a Manufacturing and Importation Authorisation (MIA) and an MIA for investigational medicinal product (MIA IMP). These licences are an EU requirement for the production of commercial medicines for patient use or to support clinical trials.

In March 2019 Autolus were the first collaborating company to be granted a manufacturing licence variation in order to be part of the CGT Catapult GMP licences. This has allowed the company to begin manufacturing materials for clinical trial supply from the centre.

Through this experience CGT Catapult has learnt how to best support their collaborators in preparation for their MHRA inspections and interactions and will soon support the other collaborating companies through their own licensing processes.

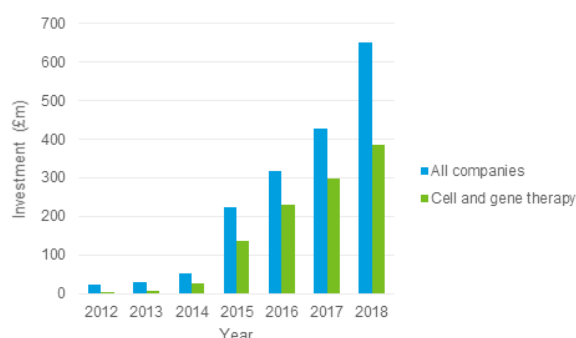


## Extraordinary growth seen at the cell and gene therapy cluster

There are currently 3000 people employed at the Stevenage cluster, and more than 10 cell and gene therapy developers have chosen it as their location including Achilles, Aglaris, Gyroscope, Lift Biosciences and others, making this the biggest cell and gene therapy cluster in Europe. The CGT Catapult collaborators currently employ over 100 people at the centre.

Companies at the cluster have experienced high growth, with cell and gene companies raising a significant amount of investment, over £380m in the past six years.

### Investment raised by companies in Stevenage



Data courtesy of Stevenage Bioscience Catalyst

## ThermoFisher CryoHub providing cryostorage and logistics

Thermo Fisher have opened their first European cell and gene therapy CryoHub adjacent to the CGT Catapult manufacturing centre. The facility is now fully operational and ready to provide:

- Ambient to cryogenic storage of raw materials
- Ambient to cryogenic global logistics solutions
- In-house Qualified Person (QP) release
- Import/export guidance

On site access to these capabilities simplifies processes but more importantly reduces risk in this critical supply chain element.

## Evolving supply chain provision to meet increasing demand

Raw materials supply is a significant challenge for cell and gene therapy manufacturers. The CGT Catapult manufacturing centre operates a GMP warehouse with ambient and controlled temperature storage, delivering bills of material as per demand to the clean rooms. Predicted demand is already significant, with high throughput demands from autologous cell therapy manufacturers and viral vector manufacturers requiring significant storage capacity as they prioritise assurance of essential supplies and economies of scale of ordering.

CGT Catapult has established a consignment stock system, which can be supported with several deliveries per day. CGT Catapult is now working with supply chain experts, both inside and outside the industry, to establish scalable systems that will not only meet the manufacturing centre's predicted demands, but also benefit the wider UK industry.



# Building flexible quality control capabilities

The quality control (QC) function has been built to be flexible to the needs of the collaborating companies. CGT Catapult perform all environmental monitoring for the centre, including collating and presenting all trend data. The collaborators choose to either perform their own QC or to work with CGT Catapult to perform process control and release test for their products.

The QC team has worked with the collaborators to understand their predicted needs as they scale up their manufacturing process, and the QC provision is

being built to meet demand where CGT Catapult can offer collaborators the most benefit.

It is expected that regulators will now increasingly require testing of final material via the 2-temperature sterility test. CGT Catapult has therefore installed and validated a BacTalert system with this capability. This system is already in high demand and further biosafety testing systems are currently being qualified for collaborators to access on a cost-sharing basis.

## Designing process layouts

The process of designing a GMP clean room involves working closely with the operational, quality and facility management teams in order to build in operational quality while also ensuring facility fit. CGT Catapult work with collaborators to help design their process layouts, ensuring fit and maximising throughput in their clean room, which will determine manufacturing capability. We also optimise operator and material movements within the process to increase productivity but also reduce the possibility of contamination. From an early stage the CGT Catapult QA team also input into the design layout, ensuring maintenance of compliance and optimum cleanroom performance, preventing any compromise in clean room grades.



## Looking forward:

We work with  
**Innovate UK**



### Increasing centre capacity through expansion

CGT Catapult has been awarded £3.36m in funding from the European Regional Development Fund (ERDF) and a £12m Industrial Strategy Challenge Fund award to support the expansion of the manufacturing centre. The expansion involves the construction of six additional modules in the already constructed space on the buildings second floor.

The six additional modules will contain grade C clean rooms with a higher throughput design, and also be larger at 130m<sup>2</sup> of production space. The first collaborators are expected to start on-boarding into these new modules at the end of this year.