



**Large-scale Cell and
Gene Therapy
Catapult
manufacturing
facility for current
and future multi-
product processes**

October 2016

The Catapults

- Part of a **world-leading network** of technology and innovation centres
- **Bridge the gap** between businesses, academia, research and government
- Access technical facilities and expertise to help adopt, develop and exploit innovations
- Established by **Innovate UK**

- The Cell and Gene Therapy Catapult mission:

“ Growing the UK cell and gene therapy industry, delivering health and wealth.”

Cell and Gene Therapy Catapult



Therapy industrialisation

- Process development
- Analytical development
- GMP process proving
- Supply chain
- Commercial-facing manufacturing



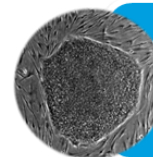
Business

- Business development
- Business models
- Health economics



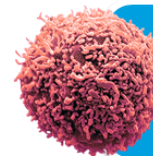
Clinical trial and regulatory

- Regulatory
- Clinical trial sponsor
- Clinical operations
- Pre-clinical safety



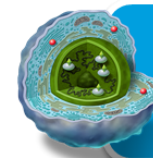
ES and iPS cells
HSC's
MSC's

10



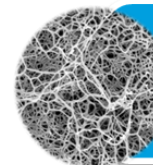
T cells
T Regs
Dendritic cells

7



Somatic cells
• Islet cells
• Fibroblasts

3



Tissue / Scaffold
Tech development

8

Cell and Gene Therapy Catapult today

£125m

£125 million **funding** into the Catapult over 5 years

£21.3m

Invested £21.3 million in projects over the last three years

£13m

Invested more than £13 million in a **state-of-the-art development facility**

£55m

Investing £55 million in **large-scale manufacturing** centre in Stevenage

£27.3m

Leveraged £27.3 million of **third party funding** into businesses and projects in the last three years

Three

Formation of **three spin out companies**

30+

Over 30 **live projects** across our capabilities

120+

Over 120 **cell and gene therapy experts** from health economists and regulatory experts to leading edge translational scientists

A microscopic view of numerous cells, likely oocytes or follicles, arranged in a grid-like pattern. The cells are circular with a prominent nucleus and a surrounding cytoplasm. The background is a light, textured grey.

Removing capital investment risk

Investing in infrastructure

Cell and Gene Therapy Catapult



£70m Development Facility

- **1,200m²** Custom designed cell and gene therapy development facility
- **Prime location** in the heart of the London clinical research cluster
- **120** permanent staff



£55m large scale manufacture center

- **7,200m²** manufacturing centre designed specifically for cell and gene therapies
- **Located** in the Stevenage biocatalyst
- **Opening** 2017

State of the art laboratories in central London

- Replication of any process using configurable pod system
- Range of technologies to support upstream, bioreactor and downstream processing, fill and finish at commercial scale
- Technology transfer to full scale GMP
- Viral vector laboratory



CGT manufacturing centre

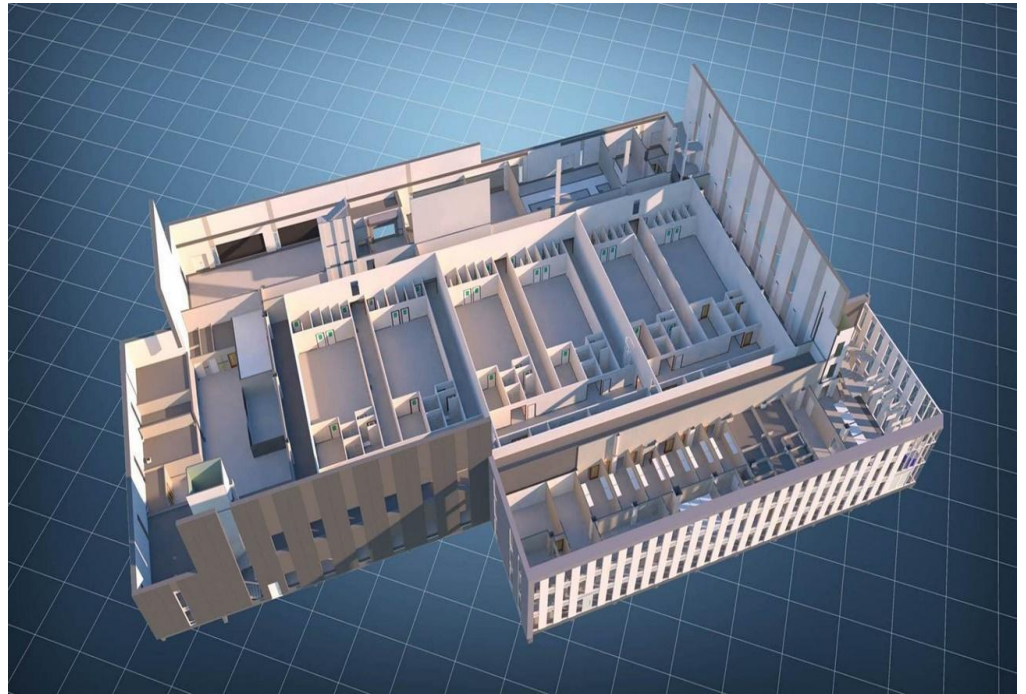


Why are we building a manufacturing centre?

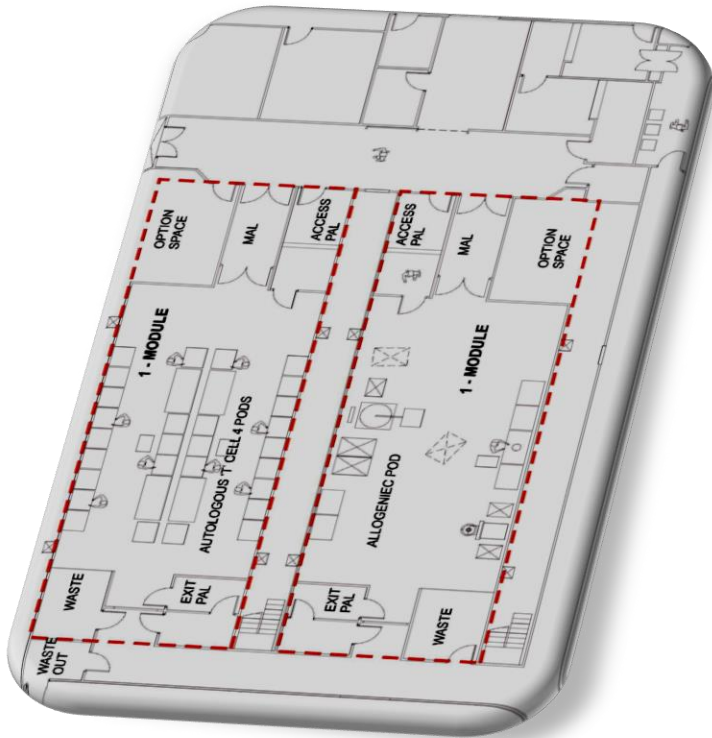
- Market research – Feedback from SME's and Large pharma
- Removing the capital investment risk for cell and gene therapy companies who need large-scale GMP manufacturing facilities.
- Collaborators will have control over their process within the facility.
- **Your process. Your knowledge. Your success. Our support.**

Large-scale GMP manufacturing facility

- Multi-collaborator facility
- 7,200m² footprint
- 12 x 100m² Grade B to C cleanrooms
- Centralised QC, warehouse, facilities management & waste disposal
- Enables companies to scale up manufacture
- Flexible - allogeneic, autologous or viral vector processes



Segregation at heart of design and operation



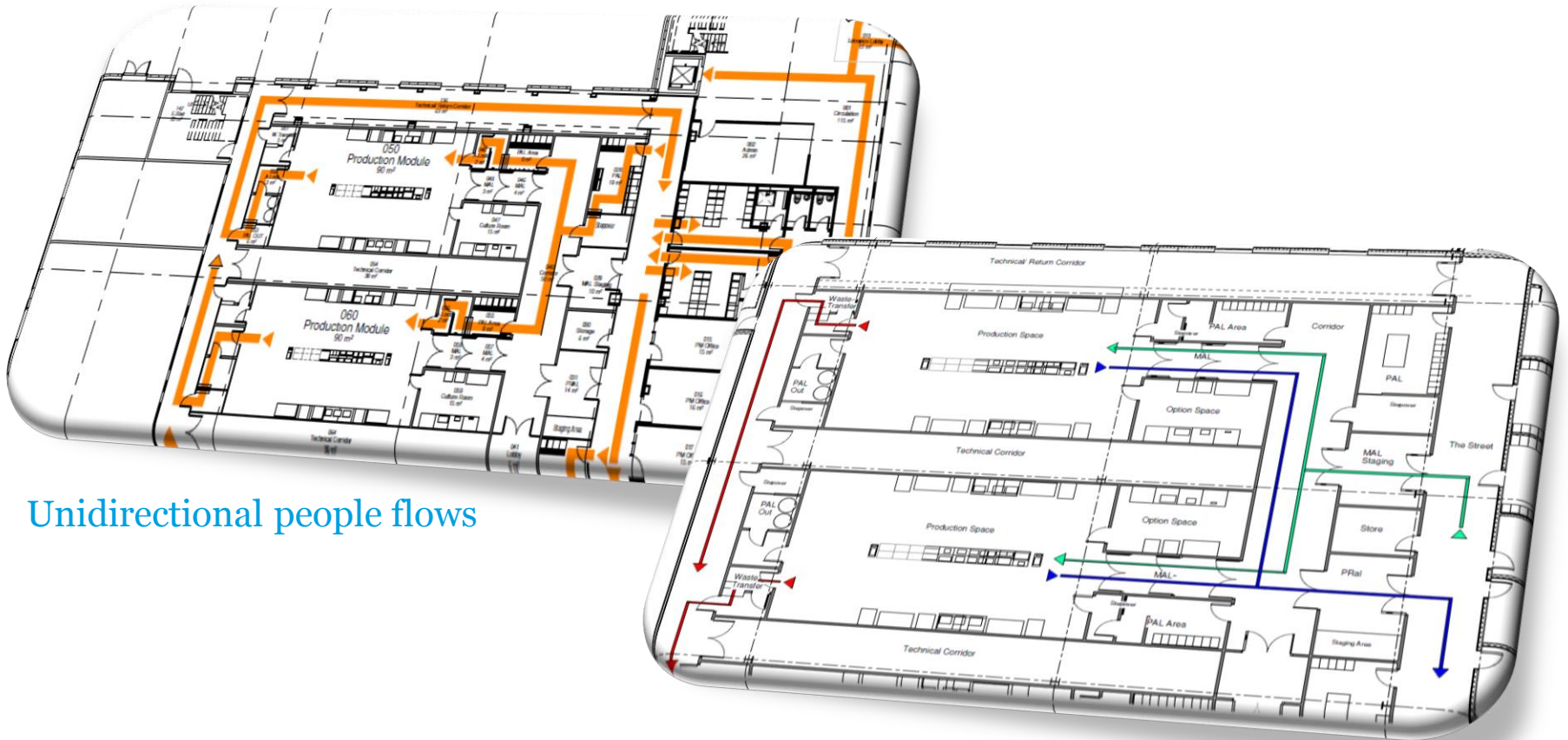
- Physical

- Architecturally segregated modules
- Technical corridors separate modules
- Walk on ceilings for plant access
- Single pass HVAC dedicated to each module
- Negative pressure sinks on all module entry and exit routes.

- Information

- Segregated data within BMS and EMS
- Hardwired & WiFi dedicated, secure Virtual Local Area Network.

People & material flow



Unidirectional people flows

Segregated product, material and waste flows

Flexible manufacturing

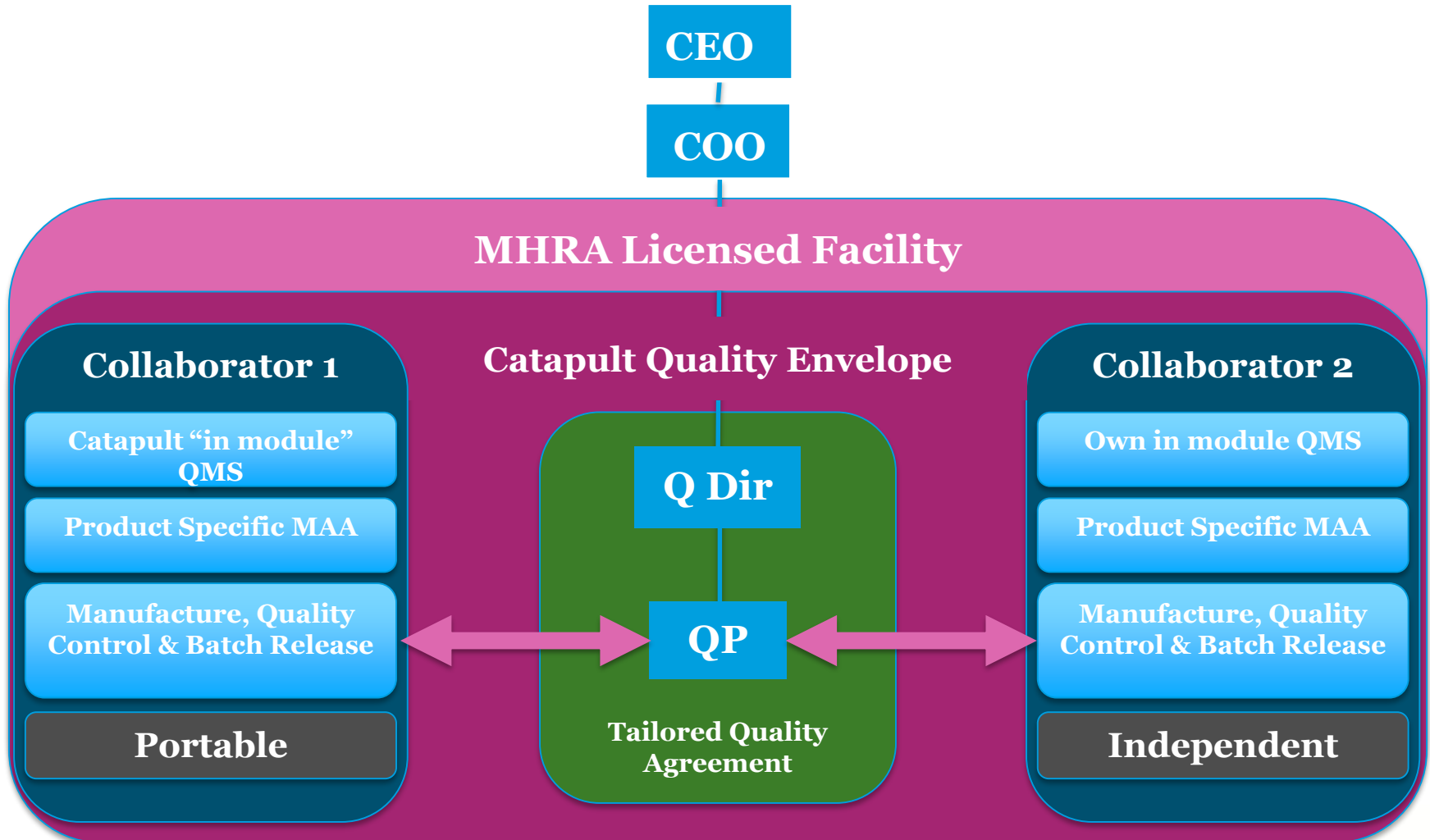
Allogeneic and viral vector



Autologous



Licensed facility

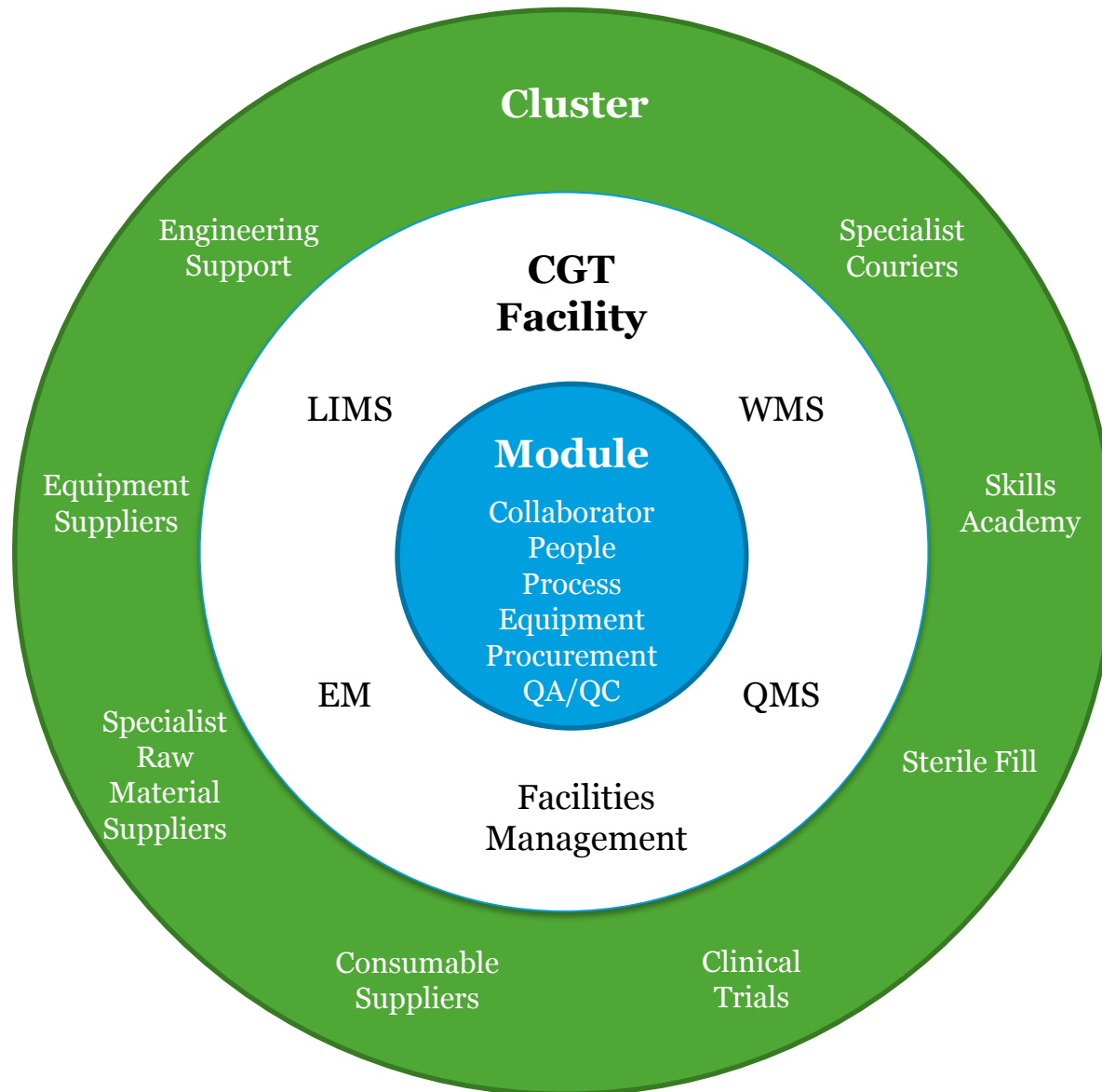


UK Golden Triangle

- Consists of Oxford, Cambridge and London within the greater south east of England.
- Strongest biosciences cluster in Europe.
- Close proximity to strong academic base and a world-leading financial centre.
- The region is often seen as the gateway to Europe by large businesses.
- Consistent, secure, reliable, globally connected transport system.



UK Cluster

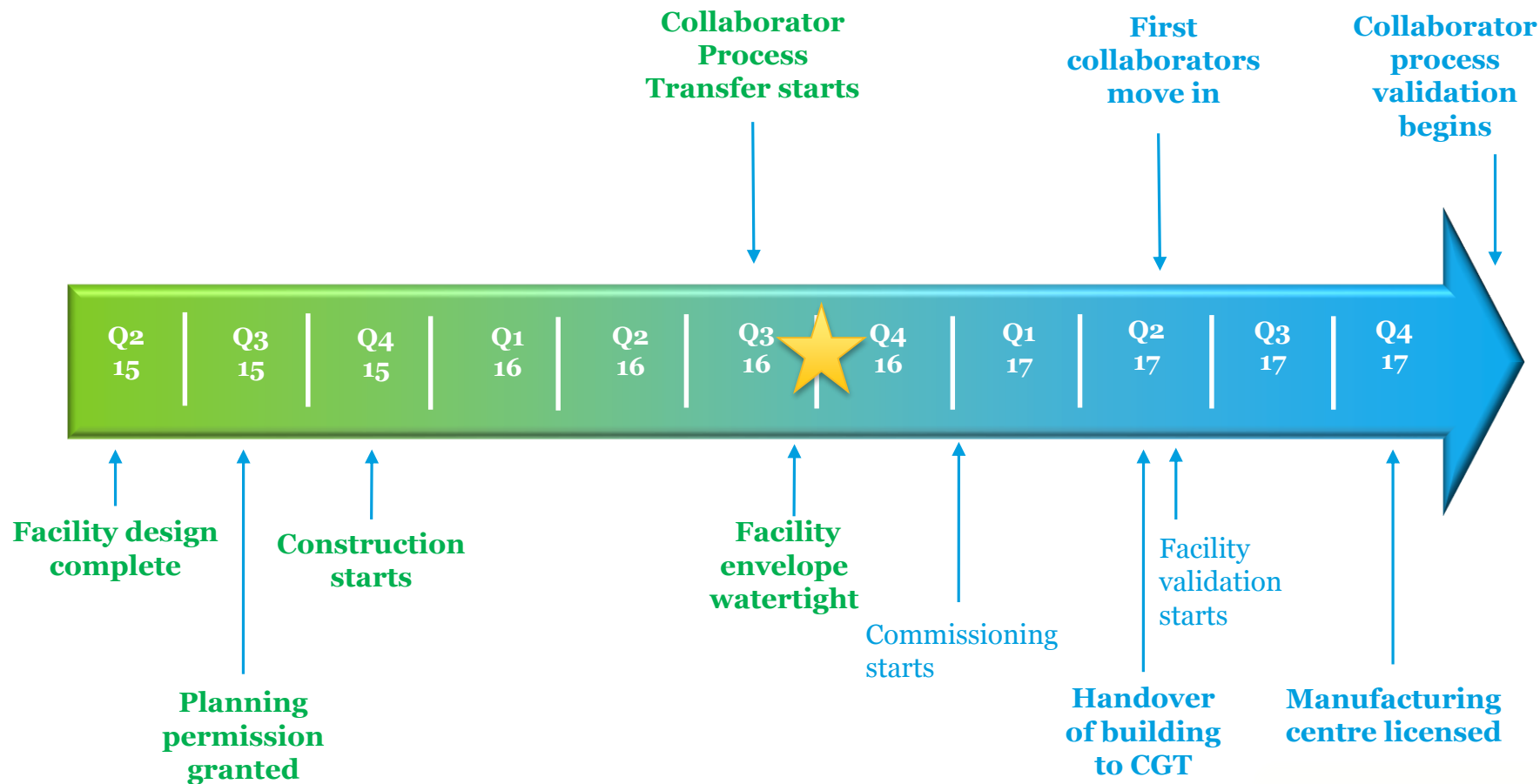


A microscopic view of numerous cells, likely red blood cells, showing their characteristic biconcave disc shape. The cells are densely packed and appear in various shades of brown and tan against a darker background.

The Cell & Gene Therapy Manufacturing Centre Progress

Investing in infrastructure

Accelerated timeline



CGT manufacturing centre

Tue Oct 4 14:31:50 2016



CGT manufacturing centre (Sep 16)



CGT manufacturing centre: Ground floor (Sep 16)



CGT manufacturing centre; Cleanroom ceilings (Sep 16)



CGT manufacturing centre; CNC corridor

(Sep 16)



CGT manufacturing centre; HVAC ductwork (Sep 16)

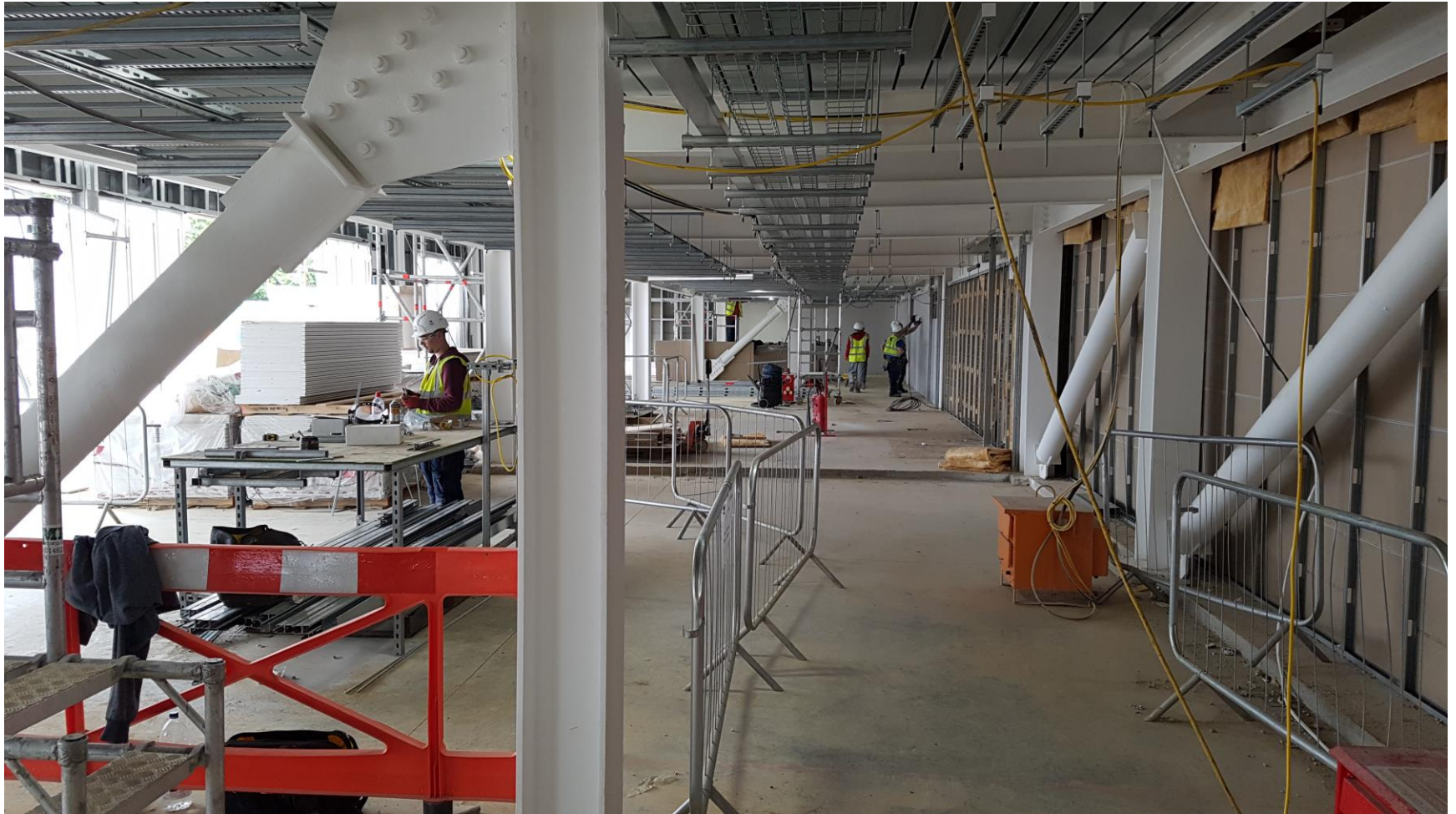


CGT manufacturing centre; Warehouse

(Sep 16)



CGT manufacturing centre; Plant room (Sep 16)



CGT manufacturing centre; Office block (Sep 16)



A microscopic view of numerous cells, likely oocytes or follicles, arranged in a grid-like pattern. The cells are circular with a prominent nucleus and surrounding cytoplasm, set against a dark background.

In Conclusion

Investing in infrastructure

World class expertise

The Cell and Gene Therapy Catapult manufacturing centre is **supported by a team of world-class experts**, with end-to-end knowledge to help collaborators commercialise their therapy.

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

For more information

To find out more about collaborating with us in the manufacturing centre, please contact us:

info@ct.catapult.org.uk

+44 (0) 203 728 9500

ct.catapult.org.uk

- To view a video of the manufacturing centre, [visit our Youtube channel](#).
- To watch the development of the site in real time, [visit our website](#).

A microscopic image showing numerous cells, likely oocytes or follicles, arranged in a grid-like pattern. The cells are stained with a combination of blue, green, and red dyes, highlighting their internal structures and boundaries. The overall image has a high-contrast, textured appearance typical of histological slides.

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Cell and Gene Therapy