

# Clinical Biotechnology Centre (CBC)

GMP manufacturer of  
plasmids and viral vectors



Service portfolio

# Clinical Biotechnology Centre (CBC)

CBC is an experienced, UK-based, CDMO providing services of the highest quality at affordable prices. Our aim is to be your preferred provider of quality-assured plasmids, viral vectors, and gene therapy therapeutics. As part of NHS Blood and Transplant's (NHSBT's) Cellular and Molecular Therapies (CMT) function, we have over 20 years of experience manufacturing to GMP, under an MHRA IMP licence, and receive routine audits from our internal audit programme.

An ambition to drive innovation and collaborate with partners is central to our longer-term strategy. The commitment to develop and scale services within the gene therapies field is assured and demonstrated through significant investment in our manufacturing facilities. We work with healthcare, academic and commercial customers worldwide.

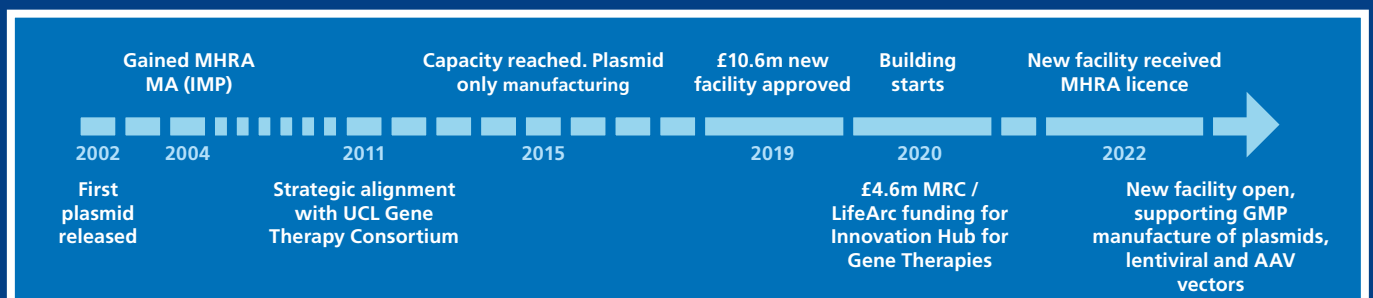
We are your 'one-stop-shop' for gene therapy products.



As part of the NHS we provide a reliable service on a cost recovery basis, so our prices are affordable. We also benefit from the resilience of a national infrastructure, so our customers can be confident that they'll have a stable, reliable partner committed to a long-term collaboration. We aim to support partners in progressing their gene therapies through clinical trials to, ultimately, increase patient access to novel lifesaving therapies.

NHSBT's advanced cell therapy facilities manufacture various GMP cell therapies under MHRA licence for use in clinical trials. Advanced Therapy Units are found in Barnsley, Birmingham, Liverpool and in Filton (adjacent to CBC).

We have supported numerous clinical trials, treating patients around the world with a broad range of infectious, malignant or inherited disorders including, but not limited to: age-related macular degeneration, renal cell carcinoma, B-lineage acute lymphoblastic leukaemia, haemophilia, HIV and cystic fibrosis. With a wealth of expertise and experience, we manufacture products for a variety of research, pre-clinical and clinical campaigns, for academic and commercial partners. We have the experience to de-risk your project plans, and the know-how to overcome the challenges of transferring manufacturing processes to GMP compliance.



# Facilities



Custom designed GMP facility covering 940m<sup>2</sup> of space over two floors

Flexibility to manufacture different product types



Total of ten clean rooms for spatially and campaign segregated manufacture using single-use disposables



Dedicated fill and finish room



Dedicated laboratories equipped to undertake pre-GMP manufacture, process development, and QC



Capacity to manufacture GMP-grade plasmids in parallel



# Service portfolio



## Plasmid

### Research grade plasmid

- CBC offers R&D grade plasmids and batch sizes typically range from 50mg to 400mg

### GMP grade plasmid

- Plasmids may be used for direct vaccination of patients, for cell therapies or as the starting material for viral vector production
- Production ranges from 0.2g up to 3g, using our 30 L single use fermenter systems, with the ability to tailor to individual customer requirements
- Typically 14 weeks manufacturing time from initial preparation to release



## Quality control testing

- Using our quality control assays, we can establish the identity, content, purity, and safety of your products



## Viral vector

- Viral vector process development for adeno-associated and lentiviral vectors, technology transfer, and contract manufacturing to GMP
- Stirred-tank, as well as fixed-bed, bioreactor process development
- Manufacturing ranges from small-scale to 50L bioreactor volumes



## Cell banking

- NHSBT offers GMP manufacture of cell banks
- We can work with a bacterial line of your choice, or can provide recommendations on a suitable strain for your project



## Process development and transfer to GMP

- Manufacturing processes for advanced therapy medicinal products (ATMP's) often require additional documentation or development to ensure compliance with GMP regulations
- CBC offers over 20 years of experience in de-risking this process with a proven outcome in the successful delivery of GMP-grade products for clinical trials



## Fill and finish

- CBC fills products using a grade A positive-pressure isolator in a grade C background. The isolator has an integrated VHP decontamination system
- An Aseptic Technologies Crystal™ M1 closed vial filling system, with a laser sealing device and disposable needle, is used to fill up to 500 bottles per batch in a single session at various fill volumes, from less than 1mL to 50 mL
- We also offer production of sterile products utilising our fully disposable system, meeting strict sterility and GMP requirements

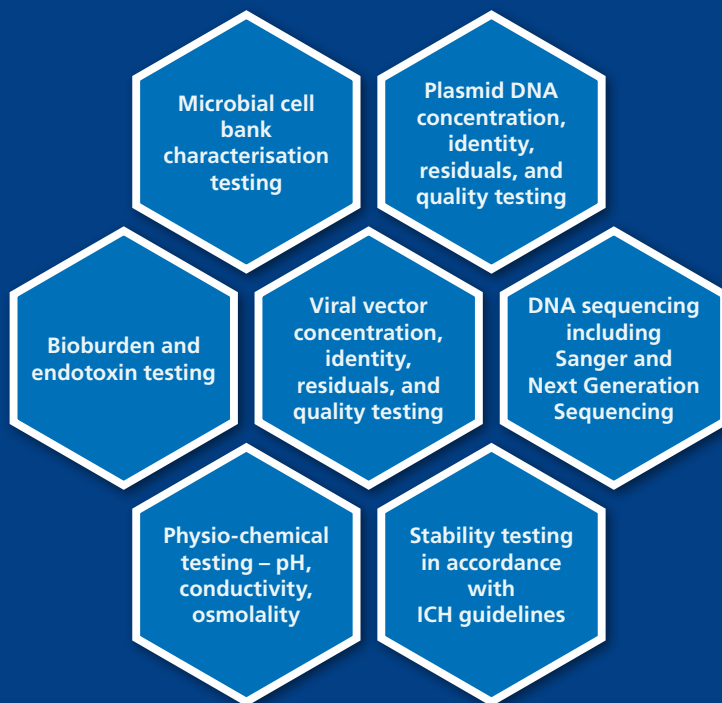
# Quality control

We operate in a highly regulated environment to GMP and we're governed by The Medicines for Human Use (Clinical Trials) Regulations 2004. We understand the complex and quickly evolving environment for ATMPs and we have had an MIA(IMP) licence since 2004.

## Quality control and assay services

We develop, optimise and validate product-specific assays, enabling us to offer a complete range of analytical testing services. Using our quality control assays, we can establish the identity, content, purity and safety of your products.

## Our services include:



# Viral vector manufacturing: Innovation Hubs for Gene Therapies

NHSBT manufactures GMP-grade lentiviral vectors and adeno-associated viral vectors for academic and commercial customers.

We offer our platform technology for producing and purifying vectors and welcome technology transfer of alternative methods, based on clients' requirements. We can manufacture up to 100L using HEK293 suspension cells grown in stirred tank bioreactors. Other scales and cell culture formats are supported. We offer non-GMP vector manufacturing to support developers at pre-clinical stages, helping translate more therapies to clinical stages.

A range of downstream purification methods are available including; filtration, affinity chromatography, ion-exchange chromatography and ultrafiltration. Vector formulation and vialing are also a part of our services.

We offer viral characterisation and quality control testing along with QP release.

**CBC is one of three Innovation Hubs for Gene Therapies (IHfGT), which aim to accelerate the academic-led development of novel gene therapies throughout the UK. The Innovation Hubs are funded by the independent research charity LifeArc, the Medical Research Council (MRC), and the Biotechnology and Biological Sciences Research Council (BBSRC). The IHfGT operate as a coordinated network, sharing technical skills and resources.**

The NHSBT Hub functions within CBC and supports early phase academic-led gene therapy trials and facilitates the provision of cost-effective viral vectors to stimulate the UK's gene therapy sector.



**Innovation Hubs for  
Gene Therapies**

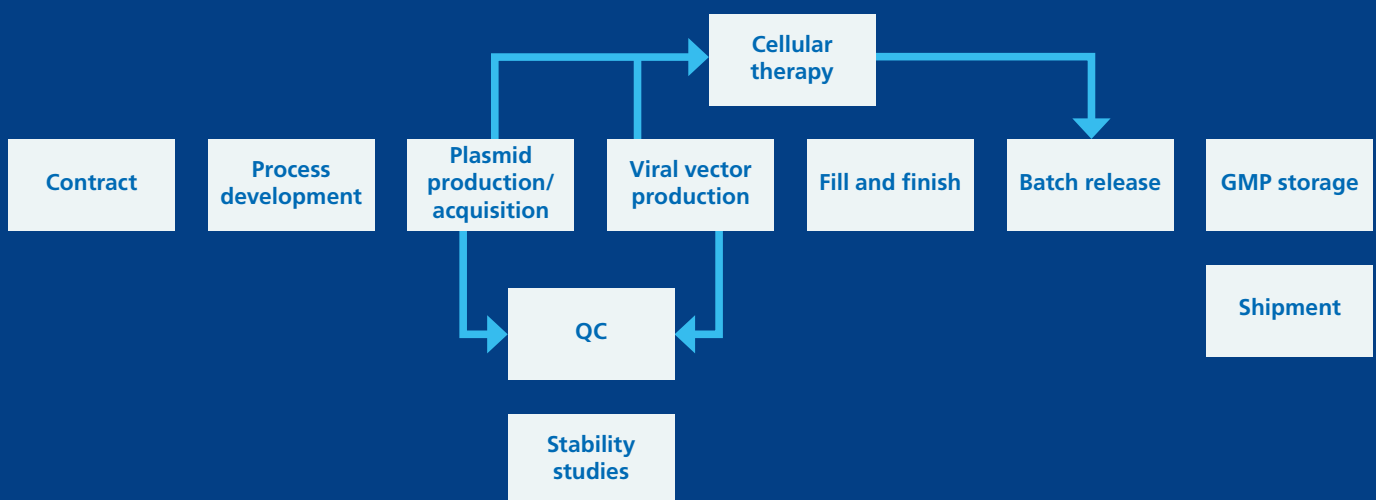


# Steps of manufacturing

Take a look at our step-by-step process below and please get in touch to find out more about pricing and lead times.

NHSBT can provide a full end-to-end supply chain that has the added benefits of:

- Working with a single organisation under an overarching quality management system and project management process
- A complex supply chain made simpler
- Streamlined timeline to clinical trial



# Why choose us?

## Experience

- Over 20 years' manufacturing GMP-plasmids
- Extensive track record supporting partners worldwide
- Part of established NHS infrastructure providing stability and assurance

## Value

- Charge on a cost recovery basis
- Affordable prices

## Support

- Expert guidance - bridging the gap from pre-GMP to GMP
- Bespoke service offered to meet your individual needs
- Flexible, collaborative, and approachable team

## Convenience

- Range of scale facilitating early-stage therapies

## Contact us:



**Email:** [enqcbc@nhsbt.nhs.uk](mailto:enqcbc@nhsbt.nhs.uk)

**X:** [@NHSBT\\_CMT](https://twitter.com/NHSBT_CMT)

**Website:** [nhsbt.nhs.uk/cmt](https://nhsbt.nhs.uk/cmt)





**NHS Blood and Transplant** saves and improves lives by providing a safe, reliable and efficient supply of blood and associated services to the NHS in England. We are the organ donor organisation for the UK and are responsible for matching and allocating donated organs. We rely on thousands of members of the public who voluntarily donate their blood, organs, tissues and stem cells.