

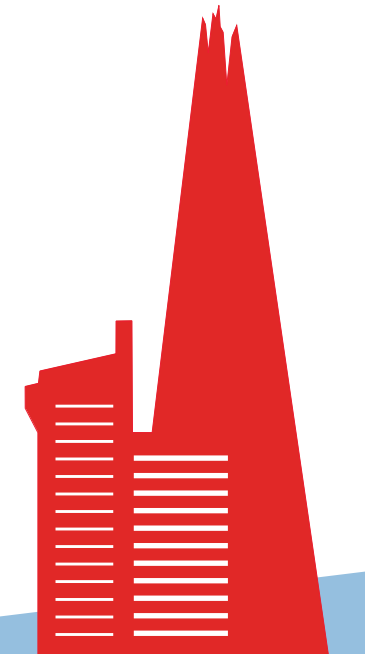


National Institute for
Health Research

World-leading facilities and expertise:

NIHR BRC Advanced Therapy Manufacturing (GMP) Platform

Producing innovative, investigational cell and gene
therapy products for early phase clinical trials



Research and Development Department incorporating the Biomedical Research Centre
at Guy's and St Thomas' NHS Foundation Trust and King's College London

Uniquely placed world class expertise and services for first in human studies

The Advanced Therapy Manufacturing (Good Manufacturing Practice (GMP)) Platform at the National Institute for Health Research (NIHR) Biomedical Research Centre (BRC) at Guy's and St Thomas' NHS Foundation Trust and King's College London is a research platform designed to provide a flexible and secure environment for the production of Advanced Therapy Medicinal Products (ATMPs) (Cell and Gene Therapies & Tissue Engineered Products) for first in human clinical studies, and early phase clinical trials.

Being co-located on the 15th floor of Guy's Hospital with the MHRA Phase I Clinical Research Facility (CRF) and the BRC's Flow Cytometry and Immune Monitoring Platforms provides an unique environment for ATMP studies to be undertaken. This unique co-location enables us to manufacture and administer ATMPs to patients within one site, and deliver trial endpoints.



Fully flexible, state of the art facilities

The GMP Platform has a proven track record in adapting methodologies and approaches from research into ATMP.

With state of the art equipment and facilities and world class expertise our GMP Platform operates a number of concurrent cell and gene therapy production campaigns.

The use of isolator technology facilitates flexibility in production activities that require open aseptic conditions.

The GMP Platform has three fully equipped suites for advanced therapies, including two for the use of viral vectors for genetic modification of cells. The third suite is designed for cell therapies.

We also offer liquid nitrogen cryostorage facilities for ATMPs.





Expert personnel in a fully licensed environment

With our world leading experts in the field of GMP, we are in position to support each study with dedicated teams of production and quality control, led by Heads of Advanced Therapy Production and Quality and Qualified Persons specialising in ATMPs.

▼ Licences

Medicines and Health Products Regulatory Agency (MHRA)

▶ MIA (IMP) Licence

Cell or gene therapies for use in clinical trials are manufactured under an MIA (IMP) Licence (Manufacturers Authorisation for Investigational Medicinal Products).

▶ Specials Licence (MS)

We hold an MS licence for the manufacture and supply of unlicensed ATMPs for human use outside of clinical trial settings.

Human Tissue Authority (HTA)

We are authorised for these licensable activities:

▶ Procurement

▶ Donor Testing

▶ Processing of Tissues & Cells





World leading ATMP technology

Our GMP Unit is home to unique first in the UK equipment such as the MACS Quant Tyto Fluorescent Activated Cell Sorter from Miltenyi Biotec, which enhances our GMP manufacturing processes enabling higher specifications in terms of potency, efficacy and purity of cells.

For precision medicine this heralds a new era in clinical treatment, enabling delivery of new advanced therapies. Current examples of our work include the manufacture and supply of patient-specific ATMPs for clinical trials in Head & Neck Cancer and recipients of Liver & Kidney Transplants.

Our state of the art equipment enables the production of personalised cell and gene products for use in clinical trials, and includes:

- ▶ Sepax S2 cell processor
- ▶ CliniMACS Prodigy cell processor
- ▶ SynGenX cell processor



Conducting your research within our world class facilities

To discuss carrying out your research within our GMP Unit and to find out how our facilities and expertise can add value to your research please contact us by email at atmp@gstt.nhs.uk

Our location

BRC GMP Unit, Guy's Hospital, 15 Floor,
Tower Wing, Great Maze Pond, London SE1 9RT

Our website

Visit our web pages to find out more about our work at www.guysandstthomasbrc.nihr.ac.uk/research-platforms

