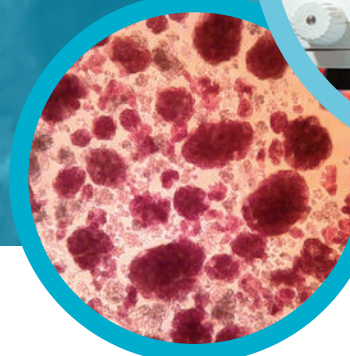
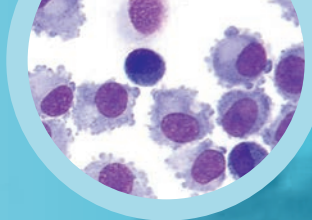


Newcastle Biomedicine Clinical Platforms:

Cellular Therapies Facility





About

The Newcastle Biomedicine Cellular Therapies Facility is an MHRA-licensed clean room complex designed specifically for the production of cellular therapies. It is one of the biggest facilities of its kind in Europe and is a recognised UK centre for translational research, with substantial experience of manufacturing cellular therapies and delivering cell therapy clinical trials.

The facility is available for use by external universities, hospitals and companies – please contact us to discuss your project.



Case Study One:

Limbal Stem Cells

Limbal stem cell deficiency (LSCD) is a painful, blinding disease of the eye caused by the loss or dysfunction of limbal stem cells (LSC). Professor Francisco Figueiredo (Consultant Ophthalmologist) has successfully treated eight consecutive patients with total unilateral LSCD using LSC autografts, resulting in significant improvements in visual impairment and pain scores in all cases. A small limbal biopsy is taken from the patient's healthy eye and expanded *ex vivo* on human amniotic membrane in the Facility. A larger study involving 24 new patients is underway to evaluate the long-term safety and efficacy of cultured human LSC for the treatment of patients with unilateral total LSCD.

“ This Facility is absolutely unique and, without it, I would not have been able to grow the stem cells for transplantation into patients and restore their sight.”



Professor Francisco Figueiredo
Consultant Ophthalmologist

Case Study Two:

Tolerogenic Dendritic Cells for Rheumatoid Arthritis

Professor John Isaacs (Consultant Rheumatologist and Professor of Clinical Rheumatology) and Dr Catharien Hilkens (Reader in Immunotherapy) are using the Facility to derive tolerogenic dendritic cells (ToIDC) for a Phase I clinical trial in patients with rheumatoid arthritis. Autologous ToIDC are derived *ex vivo* from monocytes using immunomodulatory drugs and are introduced arthroscopically into the knees of patients to investigate the safety, feasibility and acceptability of the therapy.

“ Cellular therapies are at the cutting edge of modern medicine and Newcastle is at the heart of their development.”



Professor John Isaacs
Consultant Rheumatologist

Case Study Three:

Haematopoietic Stem Cell Transplants

The Cellular Therapies Facility has over 25 years experience in the production of haematopoietic stem cells for transplantation and offers a Regional Transplant Service. Around 140 transplants are processed in the Facility each year for adult and paediatric haematology, immunology and oncology patients in Newcastle's hospitals.

Staff Expertise

The Facility's Director is Professor Anne Dickinson who is Professor of Marrow Transplant Biology at Newcastle University and has a wealth of experience in the application of cellular products for clinical use.

Professor Dickinson is supported by a team of highly qualified personnel, including Quality Assurance Managers, Production Managers and Quality Control Managers, HPC-registered biomedical scientists and a Qualified Person for product release.

The Facility's staff offer a range of services, including Investigational Medicinal Product Dossier (IMPD) development, support in writing grant applications, GMP training, liaison with the MHRA and can undertake IMP and ATMP manufacturing on your behalf.



Technical Specification

The Cellular Therapies Facility is run by Newcastle Biomedicine, a partnership between Newcastle University and the Newcastle upon Tyne Hospitals NHS Foundation Trust. The main GMP clean rooms are based at the International Centre for Life in central Newcastle, while the sister clean room facility is based at the Royal Victoria Infirmary, Newcastle.

MHRA Manufacturing Authorisation: MA(IMP)/MA(MS) 17136
HTA License No: 11122

The Facility provides high specification room space, equipment infrastructure and air-handling capabilities that, when combined with the process management requirements of EU GMP, will ensure cellular therapies are produced for safe use in human applications.

There are two modular suites with a total of nine GMP Grade B labs supported by two GMP Grade C preparation labs. GMP Grade A environments are provided by Class II Microbiological Safety Cabinets, with integrated non-viable particle monitoring.

Clinical Integration

Commercial or academic partners wishing to use the Cellular Therapies Facility are also able to access other scientific and clinical research facilities provided by Newcastle University. This includes preclinical and clinical imaging modalities, clinical trial design services and a Clinical Research Facility with inpatient and outpatient facilities. These state-of-the-art facilities are run by dedicated staff experienced in all phases of clinical research.

The University and Trust together have an excellent track record of recruiting patients into clinical trials, as we receive fantastic support for our work from the local population. The Newcastle upon Tyne Hospitals NHS Foundation Trust is committed to providing the best possible healthcare from two large hospitals in the city – the Royal Victoria Infirmary (RVI), including the Great North Children’s Hospital, and the Freeman Hospital. The Institute of Transplantation, based at the Freeman Hospital, contains dedicated beds for cell therapy trials – another example of Newcastle’s forward thinking in cell therapy research.

The Cellular Therapies Facility offers a range of services to support your project from its early stages through to clinical trials and marketing authorisation.

We welcome enquiries from external universities, hospitals and companies.

Please contact us to arrange to visit the Facility and to talk about your cellular therapy project.

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www.ncl.ac.uk/ctf