Newcastle
Bio-manufacturing Facility
FAQs

Q. Where is the facility?

A. Within the Bioscience Centre at the International Centre for Life in the city of Newcastle Upon Tyne, UK.

Q. How many production rooms does the facility contain?

A. There are up to 7 Grade B (Class 100, ISO grade 5) production rooms available to commercial clients and 2 Grade B (class 100, ISO grade 5) rooms ring-fenced for academics. These rooms are supported by 2 Grade C (Class 10,000, ISO grade 7) prep rooms.

Q. What storage space is available with the facility?

A. There is room space just outside the Graded air environment of the bio-manufacturing facility for use as 'Release' and 'Quarantine' stores. Additionally there is a dedicated cryogenic room and cold storage within the facility.

Q. What equipment is provided within the facility?

A. Each production room has a Class II Microbiological Safety Cabinet, [these provide a Grade A (Class 100, ISO grade 5) air environment for cell handling] a CO_2 incubator and a microscope. Mobile benching, chairs and a set of micropipettes are also provided in each room. Centrifuges are available.

Q. Are there support staff in the facility & what do they offer?

A. The facility is supported by 2 full-time and 1 part-time cGMP trained personnel i.e. a QA & Facility Manager and a cGMP QC microbiology technician, both with extensive industry experience and a cGMP cell culture technician respectively.

Q. Is the facility accredited by the appropriate regulatory bodies?

A. The Facility has applied for a HTA (Human Tissue Authority) licence to ensure compliance with the Human Tissue (Quality & Safety for Human Application) Regulations 2007 and hence the EU Tissues & Cells Directive (EUTCD). In applying, the facility is now deemed to possess a licence and is free to operate with human cells and tissues.

Q. Is there access to scientists & clinicians active in the cellular therapy arena?

A. Yes, the Bio-manufacturing Facility is overseen by NESCI (The North East England Stem Cell Institute) which includes scientists and clinicians in the region who are active in the cellular therapy field. NESCI is a collaboration between Durham and Newcastle universities and the Newcastle Hospitals NHS Foundation Trust. The BMF itself is owned and operated by Newcastle University, who have contracted Cels to carry-out marketing services for the facility.

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Q. How is the facility monitored & maintained?

A. Entrance to the facility is fully controlled by use of proximity card readers, with readers provided at the entrance to the change areas and the Cryostore. The air handling for the facility is managed through a BMS (building management system) managed by the International Centre for Life. Individual room pressures are constantly monitored through an automated system; this software also provides continual monitoring for non–viable particles in the Class II Microbiological Safety Cabinets. The CO_2 incubators are monitored for temperature, humidity and CO_2 levels and fridges and freezers are monitored via a radio based system.

Facility maintenance is managed via the QA office and utilises a number of sources, including the International Centre for Life and specialist companies for lab equipment and the air handling system. An emergency call out system is in place for out of hours emergencies.

Q. How do you deal with information confidentiality?

A. All information provided by the Client will be stored (as copies only) within locked filing cabinets and marked as 'CONFIDENTIAL'.

Q. What IT facilities exist & are these secure?

A. The facility is fully equipped with Cat VI cable which links back to a hub room operated by Newcastle University. Ordinarily these will be integrated in to the University network: a dedicated server with back up has been deployed for managing all aspects of data storage required by users of the facility. This server resides within the University network and is fully protected by University systems. On occasions where this is deemed not appropriate by Clients, scope exists for the Client organisation to install a dedicated server on a private network linked to the facility.

Q. Is there access to equipment/services outside the facility?

A. There will be access to additional equipment/services onsite and on the Newcastle University campus, on commercial terms e.g. FACS analysis.

Q. Are there analytical service capabilities close to the bio-manufacturing facility that can be accessed by clients?

A. Yes, there are a number of university departments that provide analytical services to external commercial organizations. Details of these services are available upon request.

Q. Is there access to secure write-up facilities?

A. Yes, a secure, confidential write-up office is provided by the facility. In addition, on-site services including boardrooms, meeting and conference rooms, catering and video-conferencing are all commercially available.