



Newcastle Bio-Manufacturing Facility

For cGMP Production of Stem Cells

About the Facility

The Newcastle Bio-Manufacturing Facility was designed and built to enable the production of stem cells and derived cellular products to a clinical standard. The facility provides high specification room space, equipment infrastructure and air-handling capabilities that when combined with the process management requirements of EU cGMP, will ensure biologics are produced for safe use in human applications.

The facility was designed as a two suite model to enable the separation of work involving somatic and embryonic stem cells. Commercial clients will have exclusive access to up to seven separate Grade B (Class 100, ISO grade 5) and two Grade C (Class 10,000, ISO grade 7) rooms together with additional space for QA/QC and storage. Expert Quality Assurance and Control staff are available at the facility.

Facility Floorplan



7 Equipped Grade B Rooms ~ 1000 sqft.

Support Facilities

- GrC** 2 Grade C rooms ~ 400 sqft.
- CA** Change Areas
- SR** Store Room (secure access, 100 sqft.)
- CS** Cryostore Room (secure access, 100 sqft.)
- off** Write Up Office

Key Equipment in Grade B Production Rooms

- Class II Microbiological Cabinet
- CO₂ Incubator
- Refrigerated Centrifuge
- Inverted Microscope

Other Equipment

- Store Room: +2°C to +8°C fridge
- Cryostore Room: 2 x 240L Liquid nitrogen transfer vessels
- 1 x nitrogen vapour storage dewar

Typical Grade B (Class 100, ISO grade 5) Room Spec

Area – 130-190 sqft.

Air handling

- Grade B (Class 100, ISO grade 5)
- Critical area grade A in clean air Cat II microbiological cabinet

Equipment infrastructure

- Binder CO₂ incubator
- Refrigerated centrifuge
- Leica inverted microscope
- KNF vacuum pump
- VWR micropipettes (0–1 ml range)
- Integra pipette controller

Room finish

- Vinyl finish to walls and ceiling
- Bonded vinyl flooring

Services infrastructure

- Mobile benches
- CO₂ supply points
- Fuse spurs (emergency power wired)

IT Infrastructure

- Double communication points – RJ45 Cat 6 cabled

Additional Facilities

- Two Grade C (Class 10,000, ISO grade 7) preparation rooms (120 and 200 sqft.) with air-controlled pass through hatches to Grade B (Class 100, ISO grade 5) corridor
- Temperature controlled storage with dedicated -80°C, -20°C and +2°C to +8°C
- Controlled cryogenic storage room
- Exclusive write-up office
- Quality Control microbiology laboratory on-site

Additional Features

- Secure access to a fully serviced Bio-Manufacturing Facility with utility costs included
- Ongoing support provided through the dedicated facility EU cGMP QA Manager, EU cGMP QC Microbiology Technician and EU cGMP Production Technician
- Access to additional equipment and services within Newcastle University e.g. comprehensive FACS capability
- Ready to move-in facility circumventing the need for investment in the expensive building, air-handling and equipment infrastructure needed to produce stem cells to EU cGMP
- Available with flexible terms on either a short term 'campaign' basis or for a longer fixed period
- Excellent opportunity to build partnerships with internationally recognised stem cell scientists and clinicians working under the auspices of NESCI (North-East England Stem Cell Institute)
- Strategic route through which the client can establish a UK/European base for the production of biologics to EU cGMP standard and to access new markets

For further information,
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Facility Documentation & Regulatory Compliance

The facility has complete and accessible VMP (Validation Masterplan), IQ (Installation Qualification Protocol) and OQ (Operational Qualification Protocol) documentation.

A HTA (Human Tissue Authority) licence is in place ensuring that the facility is compliant with the EUTCD (EU Tissues and Cells Directive). The EU Tissues and Cells Directive creates a common framework that ensures high standards in the procurement, testing, processing, storage, distribution and import / export of tissues and cells across the EU community. The Directive is primarily concerned with assuring the safety and quality of tissues and cells used within the therapeutic tissue bank sector.