SBMC's Pilot Production Facility

Scale your biomedical innovation in our GMP cleanrooms

Smart BioMaterials Consortium (SBMC) offers a state-of-the-art Pilot Production Facility at the High Tech Campus Eindhoven, the Netherlands. Our cleanrooms are designed to help innovators bring biomaterials and medical implants from prototype to clinical use — without the cost and delay of building their own GMP environment.

Why shared cleanrooms matter

- Immediate access to GMP-compliant space (ISO 6/7)
- Flexible rental, short- or long-term, aligned with customer needs
- Cost-effective: invest in your product, not in infrastructure

General (technical) description

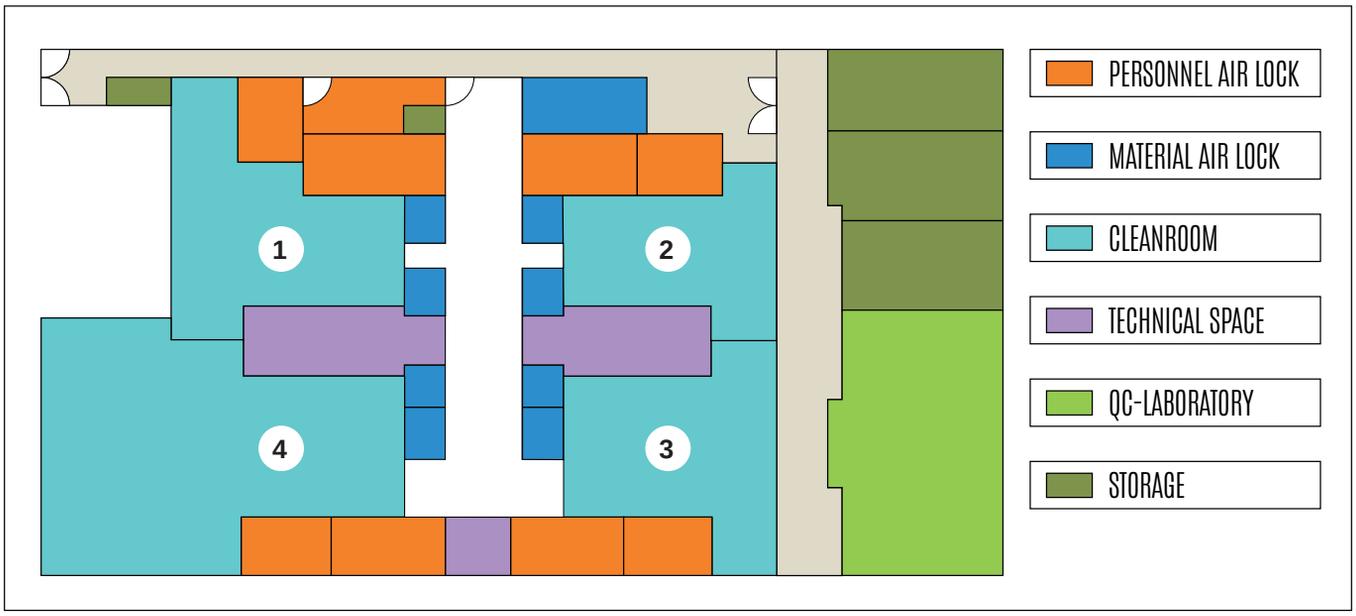
The SBMC cleanroom facility is situated in a multi-tenant building on the High Tech Campus in Eindhoven, The Netherlands. The facility includes a cleanroom area, storage areas (23 - 30 m^2) and QC laboratory. The cleanroom area (see floorplan next page) consists of a central, non-classified corridor, which is accessible for personnel via a consecutive shared gowning area, and for materials and/or equipment via a shared material air lock. From the central CNC corridor all cleanroom areas can be accessed. Each of the four cleanroom production areas is reached via two dedicated consecutive personnel air locks.

A technical room is located between two adjacent cleanrooms, providing space for equipment that should not be placed in the cleanroom production area. Cleanrooms 1 and 4, and 2 and 3 can be directly connected when desired. Cleanroom production areas are temperature controlled, and relative humidity is monitored.

Room specification

Cleanroom area and applicable GMP grade	ISO class according ISO14664-1	Air changes per hour	Pressure
Non-classified	n.a.	> 5	+5 Pa (± 2.5 Pa)
PAL to GMP Grade D	ISO 8	> 10	+20 Pa (± 2.5 Pa)
PAL to GMP Grade C	ISO 7	> 20	+35 Pa (± 2.5 Pa)
MAL to GMP Grade C	ISO 7	> 20	+35 Pa (± 2.5 Pa)
GMP Grade C (cleanroom 2 and 3)*	ISO 7	> 30	+45 Pa (± 2.5 Pa)
GMP Grade C (cleanroom 1 and 4)*	ISO 6	> 70	+45 Pa (± 2.5 Pa)

*At rest



Air handling

Fresh air for the cleanrooms is supplied by one central HVAC system. For the central corridor, the personnel airlocks and material airlocks, this fresh air is directly led into the rooms via terminal filters. For the cleanroom production areas, the fresh air is fed into the plenum area above each cleanroom production area. The air is cooled in each plenum and recirculated into the cleanroom using fan filter units with terminal HEPA filters.

Utilities and fixed equipment

Cleanroom 1 (58m²) is equipped with: 2 fume hoods with Argon 5.0, Nitrogen 5.0, and compressed air.
Cleanroom 2 (43m²) is equipped with: 1 fume hood with Argon, Nitrogen 5.0, and compressed air.
Cleanroom 3 (53m²) is equipped with: 1 fume hood with Argon, Nitrogen 5.0, and compressed air.
Cleanroom 4 (112m²) is equipped with: 2 fume hoods with Argon, Nitrogen 5.0, and compressed air.

Additional connection to gases can be constructed to the utility panels in the ceiling of each cleanroom production area. For gases other than Argon 5.0 and Nitrogen 5.0, an appropriate source and solution can be assessed. Additional air extraction from process equipment was foreseen in the cleanroom design, and can be constructed specifically in accordance to customer requirements.

Environmental monitoring

SBMC uses a standalone validated Rotronic Monitoring System. Differential pressure is continuously monitored in all cleanroom areas. Temperature and relative humidity are monitored in the cleanroom production areas, QC-laboratory, and the storage areas.

Access control

Access to the airlocks leading into the cleanroom production areas and storage area is restricted by using badge readers.

Services

SBMC offers services including gowning, pest control, cleanroom cleaning, waste management, environmental monitoring and bioburden monitoring.

Additional resources at SBMC

Alongside the cleanrooms, SBMC provides access to its development laboratory equipped with advanced tools for biomaterials and tissue engineering R&D, including:

- Confocal & epifluorescence microscopy
- Electrospinning (Vivolta EC-CLI)
- Scanning Electron Microscopy (SEM + EDX)
- Tensile tester, rheometer, automated pipetting robot
- Biocompatibility & tissue processing workflows
- Quality Management as a Service (QMaaS) for compliance

More than a facility: part of Cureon

Our cleanrooms are located in Cureon, the MedTech & BioTech innovation center at High Tech Campus Eindhoven. Cureon connects SBMC's Pilot Production Facility with a thriving regional ecosystem:

- Access to universities, hospitals, and research institutes
- Funding opportunities for SMEs and consortia
- Shared infrastructure, talent, and innovation partners all in one place

More info

- smartbiomaterials.nl
- bd@smartbiomaterials.nl

Scan the QR code

- Take a 360° tour of the cleanrooms: https://smartbiomaterials.nl/services/pilot-production-facility/explore360/