

Your Reliable Partner for Cell & Gene Therapy GMP Manufacturing

sctbio

SCTbio is a European global contract development and manufacturing organization for Advanced Therapy Medicinal Products (ATMPs). Founded as a spin-off from SOTIO, member of PPF Group, to directly address the growing demand for cell and gene therapy manufacturing, SCTbio holds over a decade of experience developing best-in-class clinical manufacturing services, development solutions and technologies transfer.



14 years
in cell and gene
therapy field

70+
employees

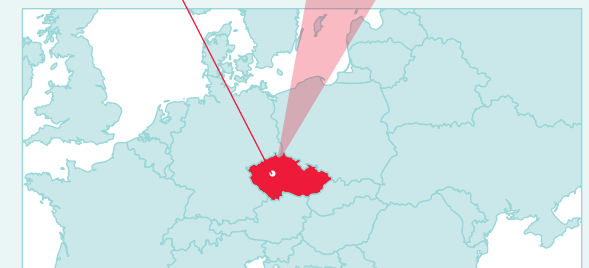


2,000 m²
facility area
including 420 m²
of clean rooms

Located in the heart of Europe

Prague
Czech Republic

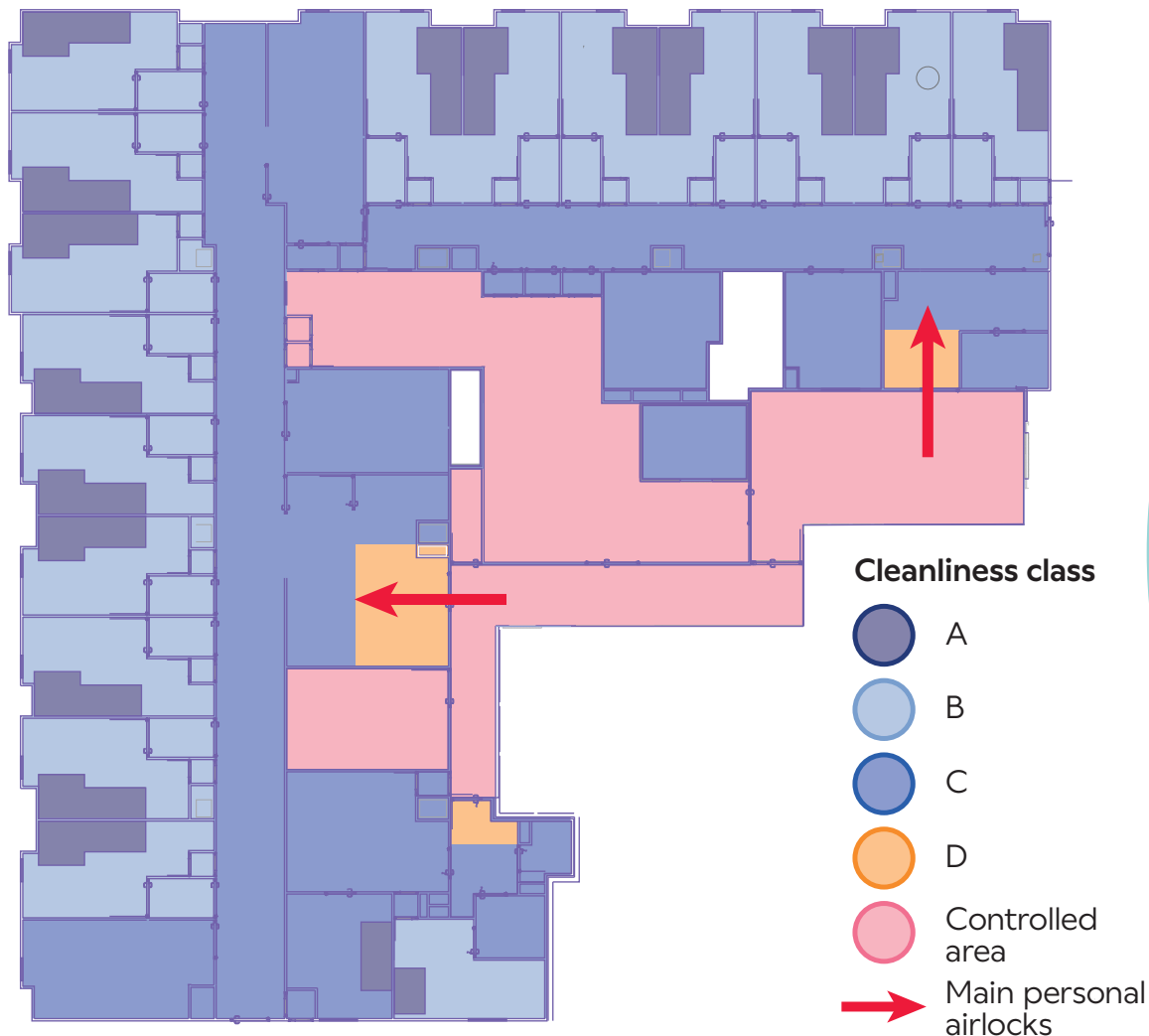
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www.sctbio.com

Cutting-Edge GMP Manufacturing Facility and Capabilities

The company operates a cutting edge GMP manufacturing facility with 420 m² (4,520 ft²) grade A/B/C/D clean rooms classified according to EU cGMP



- Fully segregated clean room facility
- Separated microbiology clean premises 60 m²
- Class B manufacturing suites of 26 m² and 13 m² (ca. 200 m² in total)
- GMO with viral/nonviral origin in different sections without risk of cross-contamination
 - Aseptic fill and finish capabilities
 - Cell culturing and cell banking
- Ability to manufacture different products including GMO with viral/non-viral origin in different sections without risk of cross-contamination
- Class C premises with large cryostorage capacities

Scope of Services

SCTbio has strong expertise in all needle-to-needle GMP operations, including validated apheresis collection sites network, product manufacturing, QC, GMP storage, QA/QP release and worldwide drug products supply

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Scope
of services



cGMP Manufacturing and Quality Control

Production, QC and cell banking methods for autologous or allogenic cell & gene therapy products as well as viral vectors.



Analytical Development

SCTbio has a team experienced in cellular, flow cytometry, molecular as well as microbiology-based methods.



Process Development Capabilities

State of the art laboratories equipped similarly to GMP production.



Logistics Services & Apheresis Collection

Worldwide logistics services of any blood products as well as final drug products in various controlled conditions.



Procurement & Warehouse Management

High value-added services under the GxP practice: product labelling, primary and secondary storage and distribution.



Quality and Regulatory Support & QP Services

Well established quality system in place (Veeva Vault), all services related with release of final drug products within EU, UK and US.

SCTbio offers end-to-end manufacturing and development services to accelerate your cell and gene therapy programs

150

Apheresis
Centers

3,000

collections

24-48h*

lead time

12,000

IMP's
delivered

10+

clinical
studies

* EUROPE: up to 24hrs (destination-dependent); USA: 30-48hrs (transport-dependent)

SCT Cell Manufacturing s.r.o.

Jankovcova 1518/2
170 00 Prague 7
Czech Republic

Contact us

E: partnering@sctbio.com
T: +420 224 174 907
www.sctbio.com

