

# 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.



**12 years**  
in cell and gene  
therapy field

**80+**  
employees

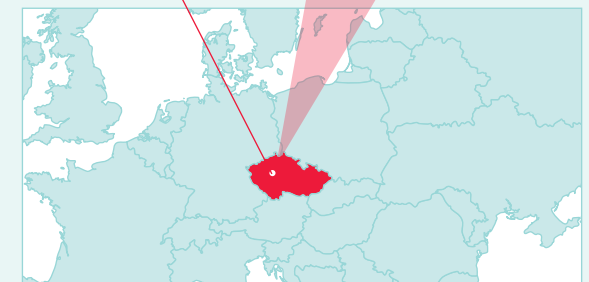


**2,000 m<sup>2</sup>**  
facility area  
including 420 m<sup>2</sup>  
of clean rooms

**Located in the heart of Europe**

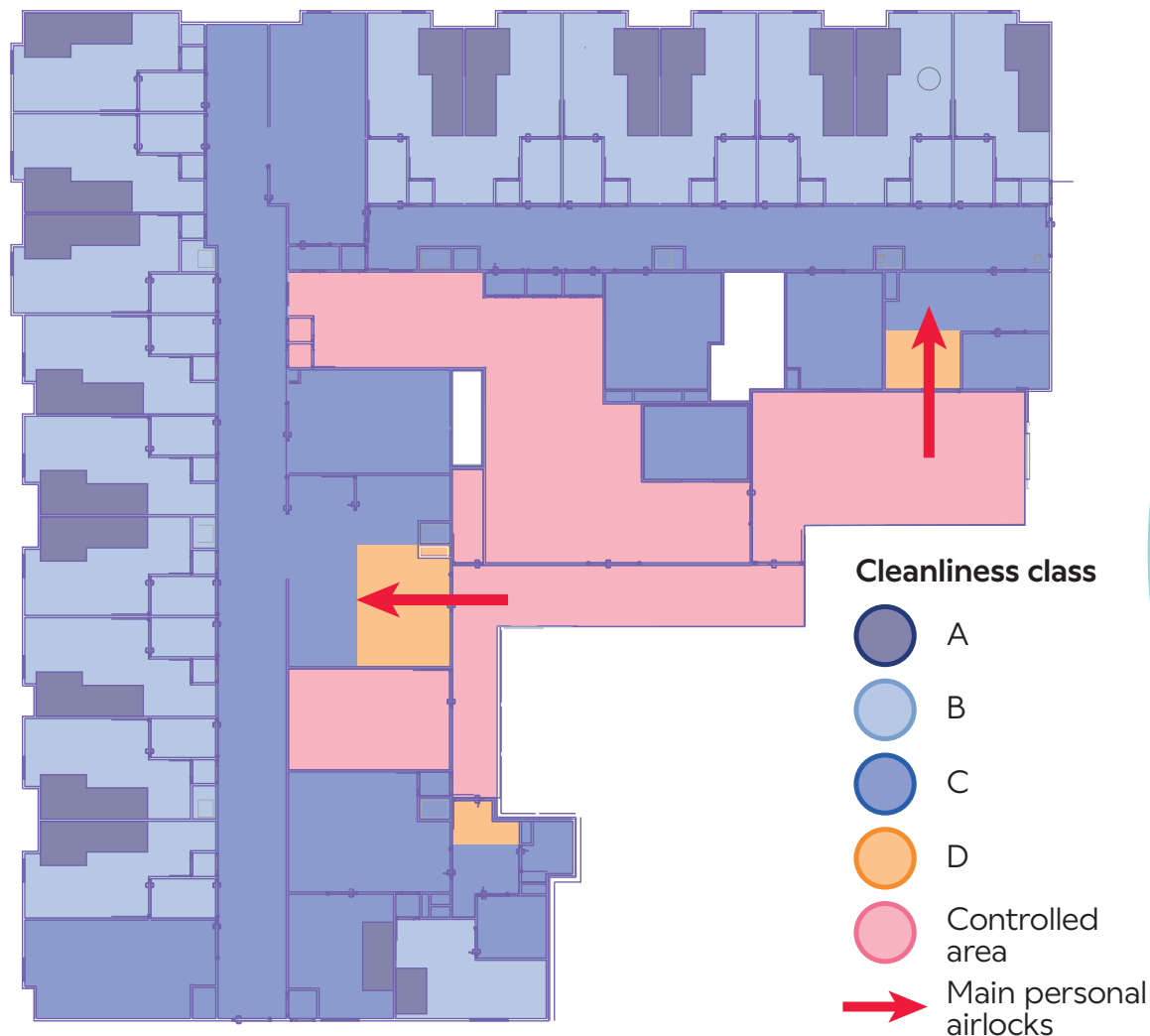
Prague  
Czech Republic

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# Cutting-Edge GMP Manufacturing Facility and Capabilities

The company operates a cutting edge GMP manufacturing facility with 420 m<sup>2</sup> (4,520 ft<sup>2</sup>) grade A/B/C/D clean rooms classified according to EU cGMP



- Fully segregated clean room facility
- Separated microbiology clean premises 60 m<sup>2</sup>
- Class B manufacturing suites of 26 m<sup>2</sup> and 13 m<sup>2</sup> (ca. 200 m<sup>2</sup> 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

**30-70h**

lead time

**12,000**

IMP's  
delivered

**10+**

clinical  
studies

**SCTbio a.s.**

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