For a true cell therapy manufacturing partnership, the CDMO of choice is SCTbio

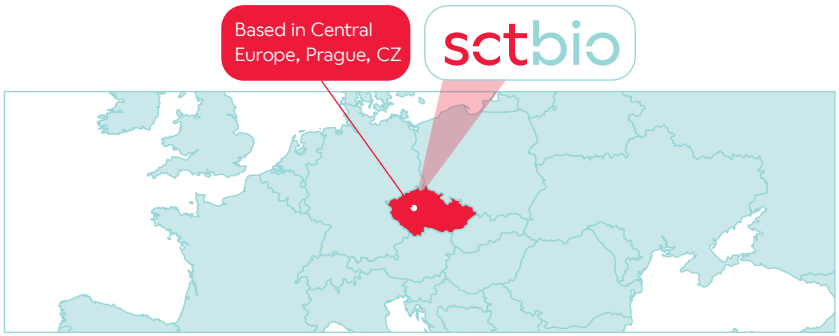
sctbio Member of PPF Group

13 years
in cell and gene therapy field

80+
employees

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

SCTbio is the leader in services, development and cGMP production of cell-based therapies as well as viral vectors. The team provides a full range of services ensuring GMP compliance for the entire life cycle of drug development, including analytical services such as cell-, flow cytometry-, molecular biology- and microbiology-based methods.



Full scope of analytical capability

Microbiology	Sterility test (direct inoculation, rapid BACTEC, membrane filtration or GRAM stain)	Safety first! On the top of the standard safety tests, we can provide rapid and modern approach of sterility testing (BACTEC™) and endotoxin (Endosafe®)
	Endotoxin test (LAL assay or Endosafe®)	
	Mycoplasma test (PCR)	
	Microorganism determination	
d/q PCR	Residual plasmid assay	Detection or precise absolute or relative quantification allows for the identity testing of viral vector samples or ATMPs as well as for impurities detection
	Viral particle quantification	
	Vector copy number	
	Gene expression quantification	
	PERT Assay	
ELISA	Benzonase	ELISA tests allow to determine the state of impurities (residual reagents, host cell proteins, viral particles) in the samples. Additionally, the p24 ELISA provides accurate quantification of viral particles
	BSA	
	HEK293 HCP	
	p24	
Flow cytometry	Identification of various cell populations in whole blood, leukapheresis products and cell cultures	Our flow cytometers allow for the testing of up to 12 colors at once. Highly experienced team can help you to design the panel that will fit unique requirements
	Quasi-quantitative or quantitative enumeration of cell populations	
	Viability and apoptosis assessment	
	Evaluation of activation, exhaustion and senescence of T cells	
	Cell cycle testing	
Hematology analyzer	Complete blood counting	Donor/patient starting materials are highly variable. Extensive analysis at the beginning of the production is useful information before processing any further steps of production
	5 populations differential	
	Viability	
	Fast characterization of CD markers in unmanipulated sample	
Others	Lactate measurement	Monitoring of cell culture growth and physicochemical tests of the drug product
	Glucose measurement	
	Turbidity measurement	
	pH measurement	
Custom-made methods	Potency test	Contact us @ partnering@sctbio.com to discuss your needs in detail
	Culture-based methods	
	Clonogenic assays	

Study case: In-house analytical assays for CAR-T product

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Starting material → **First expansion** → **Transduction** → **Second expansion** → **Product**

Leukapheresis /PBMC

- Lactate
- Hematological analysis / CELL-DYN Sapphire
- Cell population and viability / Flow cytometry (BD LSRFortessa™)

In-process

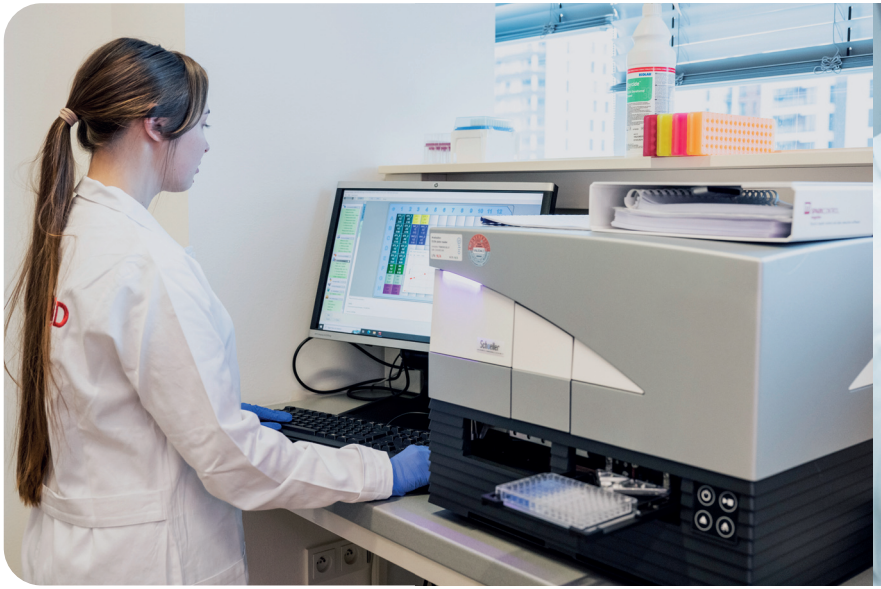
- Cell counting and viability / Nucleocounter® NC-200™

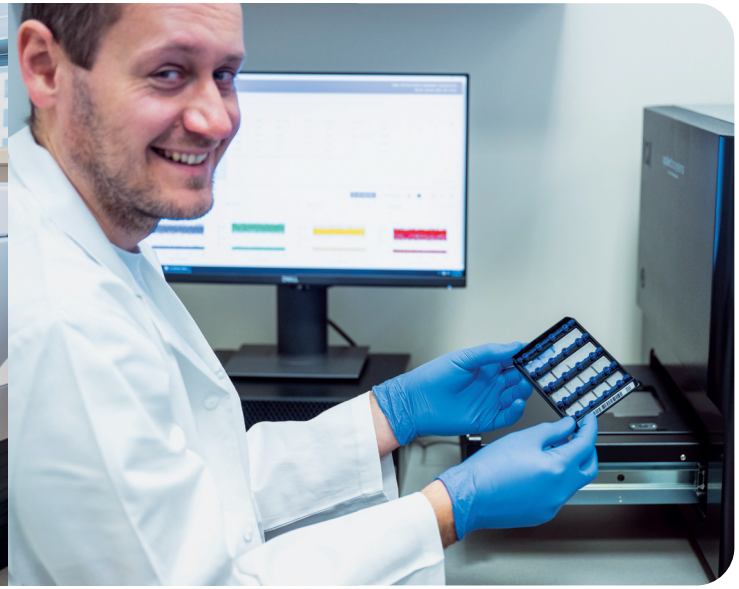
Post-transduction

- T-cell population, viability, CAR expression / Flow cytometry

Expansion

- Customizable flow cytometry panel
- Cell counting and viability / NC-200™





Drug substance / Drug product

Safety:
- Sterility
- Endotoxin
- Mycoplasma
- RCL / RCR / cultivation test* or / PCR
- Viral vector copy number / q/d PCR

Impurities:
- BSA / ELISA
- Benzonase / ELISA
- Residual plasmid / q/d PCR

Identity:
- Gene of interest copy number / q/d PCR
- Expression of the CAR / Flow cytometry
- Viability / Flow cytometry and NC-200™
- Cell count – dose determination

Characterization:
- Cell population / Flow cytometry

Potency / Flow Cytometry:
- Cytokine release assays
- Killing assays
- T-cell activation assays

* RCR/RCL tests are currently outsourced to trusted partners