

Cellex Group

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Cellex Group: a leading and complete service provider for the manufacture of cellular immunotherapy products

With expertise, capabilities, and capacity in abundance, the Cellex Group is an experienced facility worldwide for allogeneic bone marrow, peripheral blood stem cell and other cellular blood components, and is now growing to become a complete service provider for cellular immunotherapy products.

CAR-T cells are highly promising immunotherapies for the targeted treatment of leukemia, lymphomas and multiple myeloma. T cells are isolated from the blood of patients, engineered to produce chimeric antigen receptors (CARs) on their surface, expanded and re-infused into the patient, where the CAR-guided T cells home in on and eliminate cancer cells.

"Although it may at first sound relatively simple, the current CAR-T manufacturing process and supply chain are hugely complex, with each step potentially taking place in a different country," said Gerhard Ehninger, CEO of the Cellex Group. For example, after harvesting blood from a patient in an Italian hospital, the blood may be transported to Germany for isolation and extraction of T cells. The isolated cells are then transduced with an appropriate viral vector and expanded into the final immunotherapy product—a procedure that may be completed either on the Cellex site or, after T cells have been frozen and transported to a pharmaceutical manufacturing plant, often in the USA. Either way, once the immunotherapy product has been manufactured, it must be frozen again, transported and re-imported into the European Union and then returned to the Italian hospital for administration to the patient (Fig. 1).

"Up to 12 different working groups can be involved in the entire immunotherapy process from initial harvest to administration of the final product, each step time-dependent and subject to national good manufacturing practice (GMP) and cross-border customs requirements," explained Carla Kreissig, CEO of Cellex Manufacturing Transports and Logistics GmbH (CMT), which specializes in cellular immunotherapy manufacture and supply chain management. "Any delay could jeopardize product integrity and patient treatment."

The Cellex portfolio is able to offer unique services to any biopharma or research organization involved in complex cellular products

Gerhard Ehninger, CEO,
Cellex Group

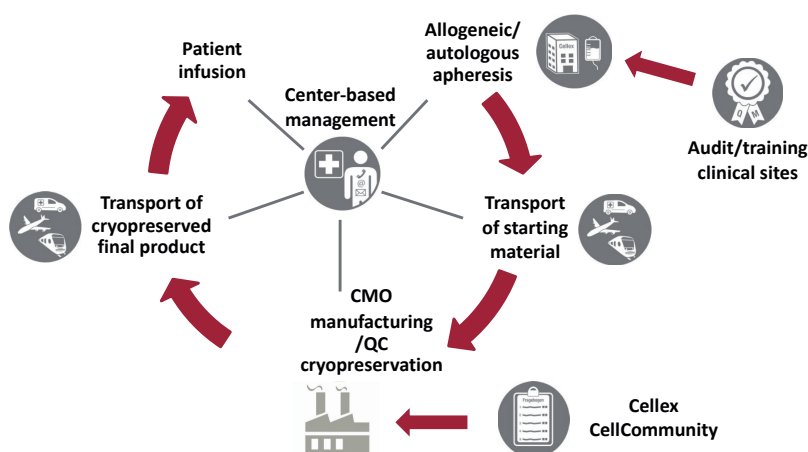


Fig. 1 | The Cellex Group. From apheresis, transport, cell selection and genetic modification, automated production, cryopreservation and cryo-storage, the Cellex Group is a full service provider for the manufacturing and transport of complex cellular products and provides software tools, tailored to customer needs. QC, quality control.

Vast experience and high-quality facilities

Fortunately, the Cellex Group has all steps covered, with long-established capability and expertise for each stage of the process. Cellex has 20 years' experience in stem cell and bone marrow harvesting, and is the most experienced facility worldwide for allogeneic bone marrow, peripheral blood stem cell and other cellular blood components. Moreover, CMT has established more than 15,000 square feet of dedicated clean rooms, extensive experience in cell selection and genetic modification, automated production, cryopreservation and cryo-storage knowhow, as well as processes for specialist transportation that operate worldwide.

CMT is also able to draw on its CellCommunity of healthy unrelated donors to set up and demonstrate consistent product production while also providing biopharma companies and academic institutions with pharmaceutical-grade cells for research purposes and clinical studies. Furthermore, CellMo (Cellex Molpe IT Solutions GmbH) has developed proprietary IT solutions to efficiently manage the entire manufacturing process from start to finish; the integrated software tool enables the mapping of the multistage GMP-compliant manufacturing process, line of scheduling, exchange of all relevant data and documents, and import/export management.

All-round partner for cellular products

CMT has deep process development, quality, manufacturing and logistics expertise and provides its services to several international leading biotech companies and research organizations, while CellMo provides software tools, tailoring them to customer needs.

"The Cellex portfolio is able to offer unique services to any biopharma or research organization involved in complex cellular products," said Ehninger. "Whether it's planning and coordinating stem cell donations and clinical trials, cell selection, transduction and expansion followed by cryopreservation, cell logistics and worldwide transport of delicate cell and blood products, the development of new therapies to combat cancer, or management software, Cellex has the expertise, capabilities, experience and capacity to provide tailor-made international supply-chain management solutions that will more than meet your specific needs."

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