Development from a Cord Blood Bank to a Contract Development and Manufacturing Organization (CDMO) for ATMP

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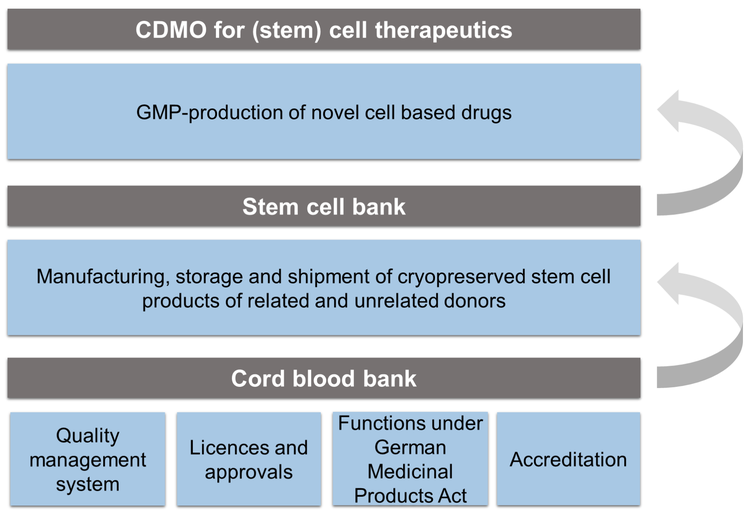
Background

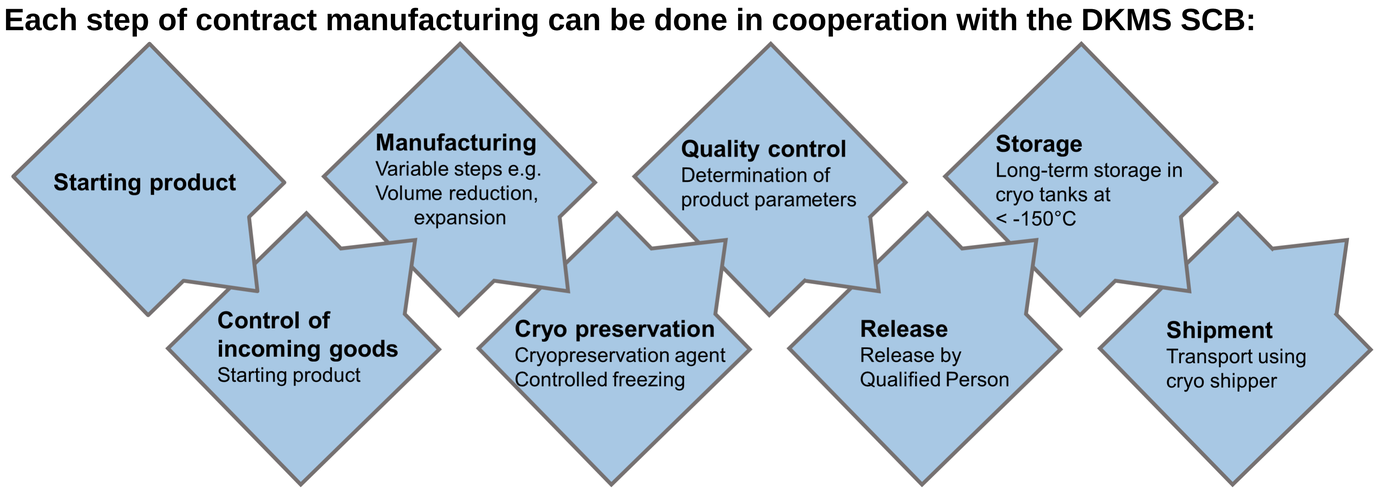
DKMS is an international non-profit organization. To date DKMS provides > 12.5 million registered donors and has facilitated > 125,000 stem cell transplantations, giving patients a second chance at life. Beside 7 international donor centers DKMS is operating in stem cell collection, genotyping, donor search and matching, clinical studies, research and stem cell therapies. DKMS Stem Cell Bank offers equipment, quality management, expertise in regulatory affairs, personnel, specific know-how and experience in ATMP processing and testing based and developed in the field of cord blood banking. With this prerequisites services can be offered to institutions striving for process transfer and development for clinical studies and subsequent production upscaling.

DKMS Stem Cell Bank – from CBB to CDMO

DKMS Stem Cell Bank (DKMS SCB) evolved from a pure public cord blood bank to a stem cell bank by acquiring the manufacturing license and approval for the world's first allogeneic undirected cryopreserved PBSC product. This represents the basis for further development into a CDMO.



Each step of contract manufacturing can be done in cooperation with the DKMS SCB:



Manufacturing

Equipment:
- Clean room class C
- Isolators (clean room class A)
- Equipment for volume reduction, cell cultivation, and controlled freezing

Environmental and process monitoring:
- Total and viable particles
- Temperature and relative humidity
- Aseptic process simulation

Storage and Shipment

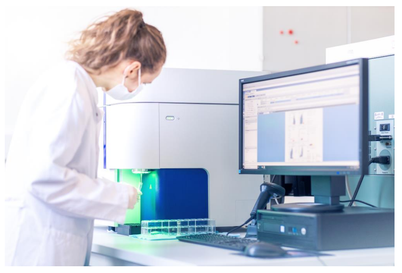
- Storage capacities at <-150°C, -80°C and -20°C
- Shipment in qualified cryo shippers

Staff

- Expertise and knowledge for development of new processes
- Know-how to realize customized solutions
- Well trained, highly experienced staff
- Key staff positions, laboratory staff, quality management, project and process management, GMP-IT

Quality Control

Methods:
- AB0/Rh typing
- Cell count and viability
- Blood count
- Microbial contamination
- Flow cytometric analysis
- Light and fluorescence microscopy
- Mycoplasma detection
- Proliferation assay
- Potency assay
- qPCR methods
- Bacterial endotoxins



Legal Requirements

- German Medicinal Products Act
- EU-GMP directive
- Manufacturing authorization for different stem cell products
- Licenses (Paul-Ehrlich-Institut)
- FACT/netcord accreditation

Pharmaceutical Quality System

- Risk management
- Contamination control strategy (CCS)
- Deviations, root cause analysis, corrective and preventive actions (CAPA)
- Supplier qualification
- Qualification and validation

Pilot Project

Manufacturing and quality control processes for mesenchymal stromal cells from umbilical cord (c-MSC) were transferred from academy to DKMS SCB. The process is currently under validation in accordance with GMP requirements. Application for manufacturing authorization was completed.
Next step is implementation of a inline facility for upscaling of MSC production.

Conclusion

DKMS SCB is a CDMO for cell therapeutics including manufacturing and quality control. Key factors for a successful process transfer include the definition of requirements by both client and CDMO as well as close communication among all parties involved throughout each phase of project. DKMS SCB offers know-how, state-of-the-art technical equipment and experienced staff to cooperation partners in the GMP-regulated environment.

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