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FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI

GMP MANUFACTURING OF CELL BASED MEDICINAL PRODUCTS AND TISSUE PREPARATIONS

Clinical trials using advanced therapy medicinal products (ATMP) require high quality investigational medicinal products manufactured according to European Good Manufacturing Practice (GMP), the "Guideline on human cell based medicinal products" of the European Medicinal Agency (EMA), the German Drug Law (AMG) and the German Ordinance for the Production of Medicinal Products and Active Substances (AMWHV). Therefore, Fraunhofer IZI provides a highly qualified interdisciplinary team, a comprehensive quality assurance system, a pharmaceutical clean room facility that adheres to the newest technical and regulatory standards and last, but not least, a well equipped quality control laboratory. Of particular interest is the separation of the entire facility into several independent clean room suites, which enables the establishment of several specific manufacturing processes for individual products in parallel and independent from other ongoing processes, as well the individual application for a manufacturing authorization according to § 13 AMG. This partition helps to minimise the risk of cross contaminations between the different manufacturing processes. The existing qualified GMP compliant technical equipment and the qualifications of the staff allow the application of a broad and modern spectrum of methods for the isolation, cultivation, cryopreservation and storage of human cells.

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Unique Feature

The partition of the facilities into different suites helps to avoid campaign production. As a consequence the individual cell product of each customer can be provided continuously. The flexible design of the facilities and the comprehensive technical equipment without any specialization to a specific product enables the manufacture and quality control of different autologous and allogeneic medicinal products (e. g. tissue engineered products, stem cell therapeutics, cancer vaccines, gene therapeutics). So it will be possible to fulfil nearly each customer requirement in the field of advanced therapy medicinal products.

Technical Data

The two facilities with a total area of about 750 sqm are designed for sterile manufacturing of cell based medicinal products and tissue preparations. This is reflected by a high amount of class B (ISO 5, class 100) clean room areas. Class A (ISO 4.8, class 100) clean room conditions for work on open cell and tissue products are guaranteed through laminar flow units that are integrated in all class B manufacturing rooms. A cascade of airlocks starting from class D (ISO 8, class 100 000) clean rooms allows a GMP-compliant entry and exit of the facility with a strict separation of material and staff transfer. All critical parameters like air-borne particles, room pressure, laminar airflow, temperature, moisture and the correct function of important technical devices are permanently monitored and recorded by a 21 CFR part 11-/Annex 11 EU-GMP-compliant software solution.

Selected Applications

- Providing investigational medicinal products for clinical trials with advanced therapy medicinal products (e. g. tissue engineered products, somatic cell therapy medicinal products, gene therapeutics) in order to obtain a central marketing authorization by the EMA according to regulation (EC) no. 1394/2007.
- Development of manufacturing processes for cell-based medicinal products (process development) and process validation.
- Development and validation of quality controls for cell-based medicinal products.

Reference Project

- Process transfer/manufacturing of Cvac™ together with the Australian company Prima BioMed Ltd.
- Process transfer/Manufacturing of DCVax® together with the US-companies Northwest Biotherapeutics Inc./ Cognate BioServices Inc.
- Manufacturing of InnovaCB (hematopoietic stem cells from cord blood) together with the Leipzig based biotech company InnovaStem GmbH
- Manufacturing EpiDex™ "autologous skin from hair roots" together with the Leipzig based biotech company euroderm GmbH

Associated Services

- Preclinical GLP safety studies of cell-based products