Global Cell and Gene Therapy Services Overview

Celerion's molecular and cellular capabilities to GLP/GCP standards allows the support of a wide range of studies from immune modulating drugs and vaccines to vector-based gene therapies and cell-based test articles. Our bioanalytical cell biology expertise speeds up the understanding of pharmacological and immunological interactions to support accelerated drug developments and de-centralized clinical trials. The close connection of Celerion's clinical research unit with the bioanalytical department allows unprecedented access to the human matrix which is vital for timely method validation of many assays.

Available platforms include:

1) Cellular Immune Response - ELISPOT

Immune monitoring and biomarker screening with high-throughput ELISpot testing. T-Cell monitoring capabilities and world-leading ELISPOT expertise which allows:

a. T-cell mediated immune response at a single cell level for pre-clinical (GLP) and clinical (GCP) studies
b. Antigen determinant mapping with overlapping peptides
c. Measurement of cytotoxic T-cell responses
d. Measurement of B-Cell responses
e. The ability to combine multiple assays on the same cell pool, such as ELISpot combined with Intracellular Cytokine Staining or mRNA expression analysis

Celerion has pre-qualified many ELISpot assays which allow for a significantly faster validation process with the study-specific antigens. This accelerates the development process for cell and gene therapies and vaccines alike.

2) Molecular Testing – PCR

High throughput molecular biology testing for vector shedding and bio distribution studies. Celerion's purpose-built laboratory facilities accommodate the timely delivery of the following analyses:

a. Vector shedding analysis for gene therapies in compliance with current regulations and fast turnaround
b. Biodistribution to support GLP studies
c. Transgene expression analysis using RT-PCR

3) Flow Cytometry

High-throughput multicolored flow cytometry is a powerful platform that supports the drug development of cell, gene and immuno-therapies. Some of the endpoints Celerion supports are:

a. Immune-phenotyping of immune cells
b. Receptor occupancy assessment
c. Assessing functional characteristics of immune cells
d. Kinetic and characterization of cell-based therapeutics

4) Capacity

Celerion's state-of-the-art cellular and molecular division was purpose- built to support the increased demand for new modalities in mind. We have qualified assays, validated analytical platforms and trained available staff in order to quickly start your project and deliver on demanding timelines.

5) Compliance

Celerion has significant regulatory experience in bioanalysis, and all laboratories are compliant to GCP and GLP to support pre-clinical and clinical studies. In addition, CLIA compliance can be added on a per-assay basis.

Celerion's decades of regulatory experience, scientific excellence and laboratory investments enable the perfect partnership for an accelerated development of these complex therapies. All assays can be validated to the required standards in order to support these clinical or pre-clinical endpoints.

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