

# Process Development and R&D

The Process Development and R&D team offers expertise and services to support the development of ATMPs from early R&D stages to GMP-readiness.



## Research and Discovery

- Proof of Concept
- Mode of Action
- Feasibility Studies

## Analytical and Process Development

- GMP-readiness
- Scale-up/out
- Automation

## Our mission

- Your success: fully committed to helping you to achieve your aims in the most efficient way and to the highest quality. Your success is our success.
- Your satisfaction: determined to provide you with the best end-to-end customer experience through tailored support, clear communication and the personal touch. We are on your side.

## Our team

- A highly competent, friendly and passionate group of scientists, with a broad range of scientific and technical skills to help you develop your cell therapy product
- 86% hold a Master degree or above, 40% hold a PhD
- Expertise in a broad range of disciplines including:
  - Cell and gene therapy - 25 years of experience in cell therapy
  - Cellular, molecular and developmental biology (including human iPSCs)
  - Immunology
  - Statistical analysis
  - QbD and PAT principles
  - Project management
  - Scientific writing

## Our services

From concept to bench top, our team can help you with:

### R&D

- Consultancy, strategic advice, project evaluation, gap analysis
- *In vitro* proof of concept, mode of action, feasibility studies

From bench top to clinical manufacturing, our team can help you with:

### Analytical development

- Product characterisation, phenotyping and functional assays, cell-based assay, biochemical assays
- Assay design, development and optimisation, GMP-readiness, technical transfer to Quality Control

### Process development

- Process design, development, optimisation and monitoring, GMP-readiness, technical transfer to Production
- Process and product characterisation, identification of CQA, CMA and CPP, scale-up, scale-out, automation

