Rentschler Biopharma

Bioprocess Development

Cell Line and Process Development
Formulation and Analytical Development

Passion for Performance

Rentschler Biopharma provides you a comprehensive expertise in the development of bioprocesses for therapeutic proteins. We are specialized in mammalian cell culture. With our experience and our proven track record of a wide variety of proteins, we support you through all stages of the life cycle of your product.

For cost-efficient processes we develop cutting-edge cell lines with excellent growth and productivity characteristics or we transfer your own cell line. We implement or optimize reliable cell cultivation and purification processes with optimal product quality and yield.
We develop analytical methods for protein characterization and together with our partner Leukocare we provide advanced formulation development.

Cell Line Development

Expertise

- CHO cell lines for cGMP manufacturing
- Commercially available, animal component free media
- Proprietary technology platform TurboCell™
- For all types of recombinant proteins
- For new biologic entities and biosimilars

TurboCell™ expression platform

- Well-characterized cGMP Master TurboCell™ (CHO-K1) cell line
- Vector construction based on site-directed integration of genes
- Recombinase-mediated cassette exchange (RMCE) procedure
- Development for up to 10 candidates in parallel
- Established and scalable cGMP process for antibodies
- Research material supply within 7 weeks from pools, within 11 weeks from clones
- Monoclonal antibody (mAb) levels up to 3g/L

Benefits

- Robust and scalable CHO cell lines
- Predictable product quality of pool and clone material
- Efficient multiple candidate screening
- Fast supply for early manufacturability studies
- Royalty and license free

Process Development

Expertise

- Application of various mammalian cell lines for the expression of recombinant proteins
- Statistical design approaches (DoE)
- Platform and customized processes
- Transfer and optimization of clients' processes
- Scale-up and transfer to manufacturing scale
- Process characterization, scale-down modeling and validation

Upstream Process Development (USP)

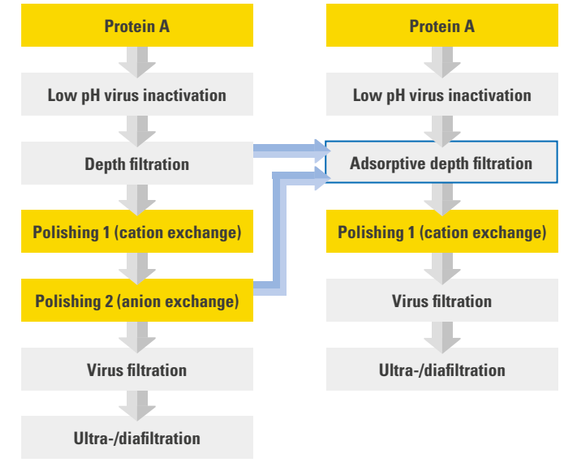
- Fed-batch, continuous and perfusion
- High cell density and high titer processes
- Media platform and feeding strategies
- Robust generic cell culture process
  - Standard bioreactor conditions
  - Commercial media and commercial feeds
- Non-cGMP production up to 250 L

Downstream Process Development (DSP)

- Various chromatographic and filtration methods
- Method definition and buffer concepts
- Virus inactivation and removal steps
- Flexible generic purification platform
  - For mAbs and Fc fusion proteins
  - Three or two chromatographic steps
- Protein modification, e.g. PEGylation

Benefits

- Reliable and reproducible processes
- Long-term experience with a broad range of proteins and technologies
- Cost and time-saving generic platforms
- Customized concepts for complex proteins
- Excellent scalability in manufacturing scales



Flexible generic mAb purification platform with three or two chromatographic steps depending of the degree of impurities

Formulation Development

Strategic Alliance with Leukocare AG

Advanced formulation development exclusively by Leukocare

LEUKOCARE BIOTECHNOLOGY

Expertise

- In addition to industrial standard formulations, Leukocare develops superior formulations based on its Stabilizing and Protecting Solutions (SPS®) formulation technology platform
- Improved stability of therapeutic proteins in dry and liquid formulations, including highly concentrated drug products
- Meets current and emerging demands in the increasingly competitive and cost-sensitive healthcare market

Benefits

- Advanced formulation maximizes product potential
  - Provides optimal direct benefit to patient, physicians, payers
  - Maintains efficacy and safety of products during storage
  - Extends patent lifespan
- Improved cost efficiency in product planning and development
  - Optimizes planning (especially timing the start) of clinical trial programs
  - Early adoption of an advanced formulation in clinical trials can avoid the need to repeat them and simplify compliance with regulatory agencies
- Improved cost effectiveness of market implementation logistics
  - Container systems, packaging, transportation, storage and handling by pharmacists, physicians and patients

Analytical Development

Expertise

- Development and qualification of analytical methods
- cGMP compliant method transfer and validation
- Standard and sophisticated methods for biopharmaceutical testing parameters

Benefits

- Method selection and design according to client preferences
- Fast and flexible implementation
- Robustness and reliability
- Broad spectrum of cell based assays
- Experience with a wide variety of molecules including highly-glycosylated proteins and biosimilars

Analytical Methods

Content	Identity	Purity/Impurities	Potency	Translational modifications	Physico-chemistry
• UV determination • Chromatographic methods • Colorimetric methods • ELISA	• Amino acid analysis • Protein sequencing • Peptide mapping • Mass spectrometry • Electrophoresis • Isoelectric focusing • UV-VIS, IR and fluorescence	• Electrophoresis • Chromatographic methods • Peptide mapping • Mass spectrometry • Process related impurities (HCP, Protein A, Insulin/IGF, DNA) • Microbiological assays	• Cell-based assays • Non-cell based assays • Biacore™ molecular interaction analysis	• Glycan analysis • Sialic acid • Glycation • Deamidation • Oxidation • Disulfide shuffling • Modified N- and C-termin	• Various physico-chemical testing, e.g. color, clarity/opalescence, osmolality, viscosity

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