



# Recombinant Proteins

**Richter-Helm** has extensive experience in the cGMP production of recombinant proteins produced in microbial expression systems.

From strain establishment up to API production, **Richter-Helm** offers a variety of services to its clients:

## Development of production strains

- Own high yield expression systems
- Freedom to operate
- Suitable for GMP

## Process development

- In-depth knowledge of soluble and insoluble protein expression
- Fermentation development up to 15 L (batch and fed-batch) scale
- Experience of various refolding strategies
- Complete downstream process development

## Cell banking (Master and Working Cell Bank)

- Production in cleanroom category A in B
- Up to 500 Vials MCB and WCB
- Quality control and documentation according to cGMP

## cGMP production

- Fermentation: up to 1500 L batch and fed-batch fermentation
- Downstream processing: common cell separation techniques, high pressure homogenisation, continuous and discontinuous centrifugation, various filtration techniques, various refolding strategies, various chromatography techniques including preparative HPLC applied
- Aseptic processing: sterile bulk filling

## Full analytical services

- Analytical method development
- Analytical method validation acc. to ICH guidelines
- Accomplishment of stability studies acc. to ICH guidelines
- Characterisation of reference standards
- QC testing and release
- Broad range of bioanalytical methods established in-house
- Broad range of biological assays established in-house
- Divers methods established for analysis of process related impurities

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