

Your Partner for Product Development from Bench to Market!
Our Expertise – Your Benefit

Cell Banking and Strain Characterization Services

Cell banking of recombinant strains is the initial step in providing biological products for clinical development and commercial manufacturing. Rhein Biotech GmbH is an experienced partner in strain development, production, release and characterization of microbial cell banks.

Rhein Biotech has an EU-GMP license for microbial cell bank production and GMP release testing. Cell bank characterization is performed according to OECD-GLP in compliance with the ICH guidelines.

Our cell bank services meet all EU regulatory requirements to support CMC files for *Hansenula*-derived vaccines and biopharmaceutical products.

Rhein Biotech has unique expertise which includes:

- EU-GMP production of Master Cell Bank (MCB) and Working Cell Bank (WCB)
- Microbial characterization
- Genetic characterization
- Product characterization
- End of production cell line characterization (EOPC)

Rhein Biotech - Partnership in Product Development!



Office, Laboratories and Production Building

Process Development
Pilot Facility and EU-GMP certified Production
Classified Areas of Grade D, C, and A (Isolator)
Molecular Biology, Immunology and Cell Culture
Analytics and Microbiology
OECD-GLP certified Laboratories

Please contact Business Development

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Cell Banking and Strain Characterization Services

Production (GMP)

- **GMP Cell Bank production**
 - Evaluation of growth characteristics
 - Growth media optimization
 - EU-GMP production of Master Cell Bank (MCB) and Working Cell Bank (WCB)

Release (GMP)

- **Microbial characterization**
 - Viability
 - Purity
 - Identity

Characterization (GLP)

- **Genetic characterization**
 - Copy number determination of the integrated plasmid
 - Identity of the recombinant plasmid
 - Proof of integration of plasmid
 - Determination of the integration locus of the plasmid
 - Proof of mitotic stability
- **Product characterization**
 - Purity
 - Identity
 - Stability