



STUDIES

Searching for study planning experts to identify the most promising candidates right from the beginning?

We support your **NBE** or **biosimilar** project with the following packages:

- ✓ COMPARABILITY OR BIOSIMILARITY STUDIES
- ✓ DEVELOPABILITY STUDIES
- ✓ LEAD & CLONE SELECTION
- ✓ STABILITY STUDIES
- ✓ REGULATORY GUIDANCE

→ www.biofidus.de/studies



BIOLOGICS

You need a **CRO** with a holistic set of analyses for a comprehensive characterization of your **mAb** or **AAV**?

Let our experts advise you to find the most suitable solution for your analytical challenge.

- ✓ STRUCTURAL CHARACTERIZATION
- ✓ FUNCTIONAL CHARACTERIZATION
- ✓ SAFETY ASSESSMENT
- ✓ STABILITY ASSESSMENT
- ✓ IMPURITY ANALYSIS

→ www.biofidus.de/biologics



POPULAR ANALYTICAL SERVICES

We built a **One-Stop-Shop** with a comprehensive set of analytical methods to streamline your drug development.

- ✓ PROTEIN SEQUENCING
- ✓ N-AND O-GLYCOSYLATION
- ✓ PTM CHARACTERIZATION BY MASS SPECTROMETRY
- ✓ SURFACE PLASMON RESONANCE (SPR)
- ✓ IMPURITY ANALYSIS
- ✓ CAPILLARY ELECTROPHORESIS (CE)
- ✓ CELL-BASED ASSAYS
- ✓ NUCLEIC ACID ANALYSIS
- ✓ PROCESS- AND PRODUCT-RELATED IMPURITIES
- ✓ SERUM AND PLASMA ASSAYS

→ www.biofidus.de/popular-analytical-services/



WE ARE FOCUSED ON YOUR REQUEST TO ACCELERATE YOUR DEVELOPMENT.

BIOFIDUS AG
 info@biofidus.de
 Morgenbreede 1
 33615 Bielefeld
 Germany



WHO WE ARE

Biofidus is your CRO of choice for fast and reliable solutions for most complex analytical challenges. We support international clients from start-ups to big pharma throughout the whole biologics development cycle, from early-stage research to preclinical and clinical studies.

- ✓ **VAST EXPERIENCE (MOLECULES & METHODS)**
- ✓ **ONE-STOP-SHOP FOR COMPREHENSIVE ANALYTICAL ASSESSMENTS**
- ✓ **1:1 GUIDANCE DIRECTLY FROM EXPERT TO EXPERT**
- ✓ **EXCEPTIONAL SPEED AND DATA QUALITY**
- ✓ **COMPETITIVE PRICING**



PORTFOLIO OVERVIEW LIST OF ANALYSES

PRIMARY STRUCTURE

- Amino acid sequence, N- & C-terminal truncation by LC-ESI-MS/MS
- Amino acid content after protein hydrolysis by LC-MS incl. determination of extinction coefficient
- Peptide mapping by LC-UV and LC-ESI-MS/MS
- Molecular weight determination by LC-ESI-MS

AMINO ACID MODIFICATIONS

- N- and O-glycosylation, glycation, oxidation, deamidation, isomerization, amidation, acetylation, pyroglutamate, phosphorylation, sulfation, PEGylation, cysteinylolation, glutathionylation etc.
- Drug-to-antibody ratio (DAR) for ADCs
- Analyzed by multi attribute methods (MAM) such as peptide mapping by LC-ESI-MS/MS and molecular weight determination by LC-ESI-MS

CHARGE HETEROGENEITY

- Ion exchange chromatography (IEX)-UV and -MS (cation and anion exchange chromatography, CEX/AEX)
- Capillary zone electrophoresis (CZE) and capillary isoelectric focusing (cIEF)
- Gel based isoelectric focusing (IEF)

GLYCOSYLATION ANALYSIS

- Released N- & O-glycans by HILIC-FLD-MS, MALDI-TOF, and HPAEC-PAD
- Site-specific N- and O-glycopeptide analysis by LC-ESI-MS/MS (incl. occupancy)
- Glycosylation analysis on intact protein or subunits by LC-ESI-MS
- Neutral monosaccharides and sialic acids by HPAEC-PAD

SIZE HETEROGENEITY, PURITY, AGGREGATION, PARTICLES

- Size exclusion chromatography (SEC-UV)
- Capillary gel electrophoresis (CGE)
- SDS-PAGE
- Visible and subvisible particles by DLS, AUC, AF4, LO and MFI (partner laboratory)

HIGHER ORDER STRUCTURE

- Disulfide analysis by LC-ESI-MS/MS
- Analysis of free thiol groups by fluorescence measurement
- Secondary and tertiary structure by CD, FTIR and HDX-MS (partner laboratory)
- Thermal stability by DSC and DSF (partner laboratory)
- Intrinsic fluorescence

BIOACTIVITY STUDIES

- Binding and kinetic assays using surface plasmon resonance (SPR)
- Enzyme-linked immunosorbent assay (ELISA)
- Cell-based assays (ADCC, ADCP, CDC, reporter gene assay, cytokine release assay, proliferation and apoptosis assay)

GENOME AND VECTOR CHARACTERIZATION

- Integration site analysis by whole genome sequencing (amplification-free)
- Gene copy number determination and structural analysis of tandem integrations by whole genome sequencing (amplification-free)
- (Mono-)Clonality assessment by whole genome sequencing (amplification-free)

- Targeted sequencing of integrated genes of interest
- Vector characterization of highly similar vectors or vectors with repetitive elements by rapid sequencing (amplification-free)
- Analysis of highly repetitive or complex regions of interest by amplicon sequencing
- Oligo and polyA length characterization by LC-MS

AAV ANALYSIS

- Empty/full ratio determination by ELISA/UV/Vis, HPLC/UPLC, or TEM
- Genome integrity analysis and sequence verification by long read sequencing
- Analysis of chimeric genome fusions and genome duplications
- ITR characterization
- Identification and quantification of host cell DNA and host cell protein impurities by NGS, qPCR, ELISA and LC-MS
- Capsid protein characterization including PTMs by LC-ESI-MS/MS
- VP stoichiometry analysis by LC-MS and western blot

SPENT MEDIA AND OTHER SMALL MOLECULE ANALYSIS

- Amino acids, dipeptides, vitamins, polyamines, organic acids, nucleotides, and fatty acids by LC-MS
- Sugars by HPAEC-PAD
- RNA and DNA-content
- Polysorbate 20/80 by LC-MS, Surfactants by GC-FID
- Growth factors
- Neurotransmitters

HOLISTIC BIOANALYSIS

THE CRO FOUNDED TO PROVIDE FAST AND RELIABLE SOLUTIONS TO THE MOST COMPLEX ANALYTICAL CHALLENGES.