PHARMACELSUS

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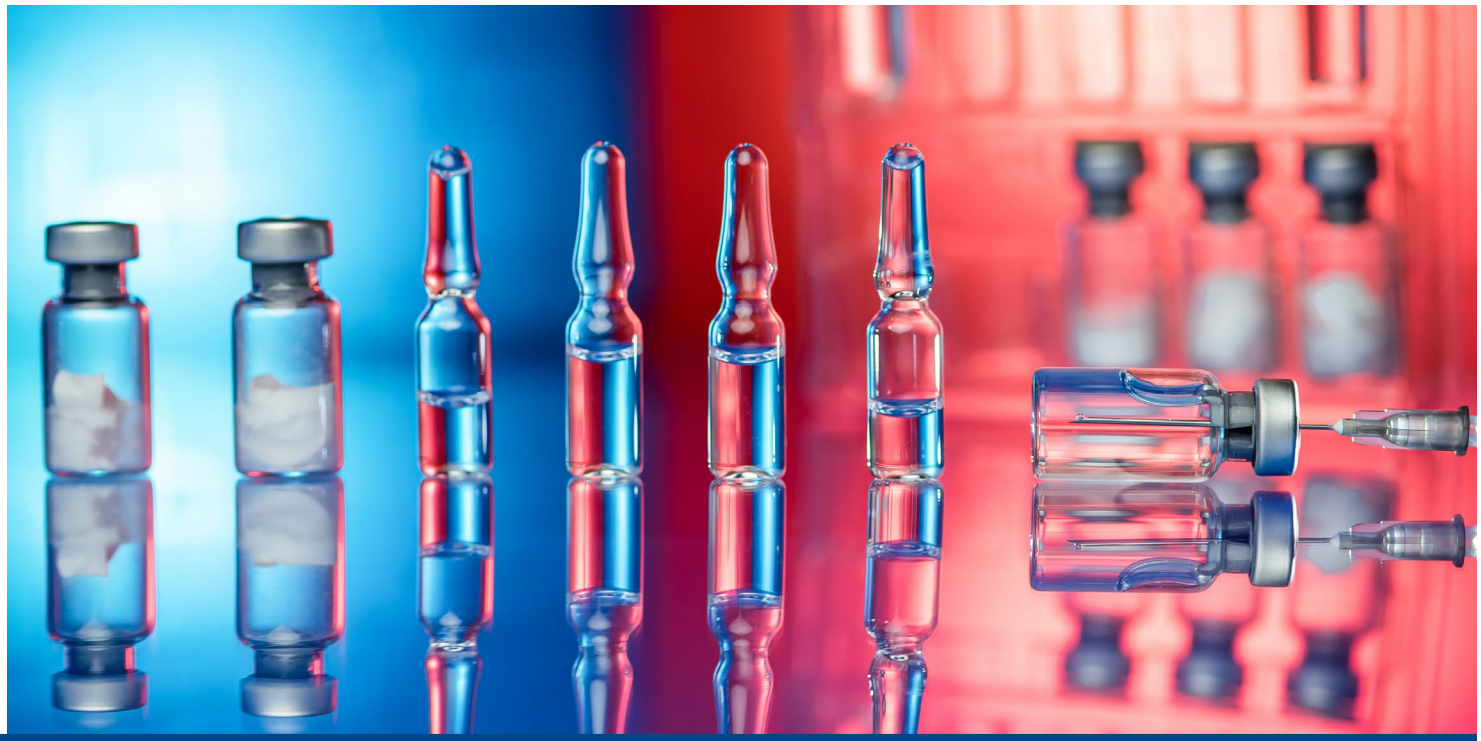
Your Challenges Require Smart Solutions.



Characterization of Biopharmaceuticals

Complexity of Biopharmaceuticals

The molecular complexity of biopharmaceuticals brings about their superior physiological selectivity and activity but puts great demands on their structural and physicochemical characterization. Depending on the biological origin and the conditions of the upstream and downstream processes (USP, DSP) a wide range of possible structural modifications or heterogeneities may occur, including

- Sequence Variations of the Primary Structure
- C-Terminal and N-Terminal Modifications
- Post-Translational Modifications (PTMs), e.g. Met Oxidation, Asn/Gln Deamidation
- Glycation
- Glycosylation/Sialylation/Fucosylation
- Disulfide Shuffling
- Fragmentation
- Dimerization/Oligomerization/Aggregation

Such modifications may potentially impact the biological activity, efficacy and safety of biopharmaceuticals and have to be detected early in their development process, in order to identify critical quality attributes, to optimize USP and DSP, and finally to meet the requirements of the guidelines for biotechnological and biological products published by ICH (ICH Q6B), EMA (Guideline on development, production, characterization and specification for monoclonal antibodies and related products) and FDA (Points to consider in the manufacturing of monoclonal antibody products for human use).

Analytical Portfolio

Comprehensive structural and physicochemical characterization of biopharmaceuticals requires the application of a wide range of analytical principles and methods. Therefore PHARMACELSUS GmbH utilizes a broad spectrum of state-of-the-art instruments with a special emphasis on mass spectro-metry (e.g. Q-TOF or Q-Exactive Plus). Excerpt from our analytical portfolio for biotherapeutica (e.g. antibodies, antibody derived fusion proteins, therapeutic peptides and proteins or protein-drug-conjugates).

- Molecular Weight Determination (Intact Molecules, Reduced mAB Chains)
- Peptide Mapping MS/MSn for Amino Acid Sequence Confirmation
- Peptide mapping UV for Protein Identity Confirmation
- Identification of Post-Translational Modifications (PTMs) like Oxidation, Deamidation, Glycation
- Identification of N-Terminal/C-Terminal Heterogeneities
- Disulfide Bridge Analysis
- Glycosylation Site Determination
- Structural Analysis of Glycans
- Physicochemical Properties and Purity (cIEF, cGE, HPLC)
- HCP Detection and Identification by MS/MSn
- Aggregation analysis (SEC-HPLC)
- Analysis of ADCs (e.g. Coupling Efficiency)

Characterization and beyond

A close cooperation between PHARMACELSUS GmbH and the cGMP sites of GBA Pharma GmbH allows a straightforward advancement of selected characterization methods with the aim of applying them as quality control (QC) methods under cGMP. This may include

- Method Development and Optimization (non-GMP)
- Method Validation (cGMP)
- Method Transfer (cGMP) or
- Batch Release of Biopharmaceuticals (cGMP)
- Stability Studies (cGMP)

Choosing PHARMACELSUS GmbH as your contract research organisation means to decide for a

- Europe-based company that is an integral part of GBA GROUP PHARMA. Within GBA GROUP PHARMA we cover the entire life-cycle of medicines, including preclinical testing, clinical trial supply management, central laboratory, GMP release testing, a global GMP-compliant logistics network as well as QP services for EU market release
- Market leader in the early stage characterization of molecules in vivo, ex vivo and based on bio-assay (GLP and non-GLP)
- Highly motivated team of scientists, pharmacologists, veterinarians and technical personnel with a passion for quality and about 20 years of experience.

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