SYMBIOSIS
THE ANALYTICAL COMPANY

FACT SHEET

SYMBIOSIS – The Analytical Company – is the newly created business division of Biopharm GmbH offering services and solutions for biopharmaceuticals and classical pharmaceuticals. SYMBIOSIS integrates the extensive experience and expertise of Biopharm GmbH in analytical services of more than 25 years combined with a customer-focused approach driven by excellence in **process, communication** and **quality**. GMP and GLP certified we operate according to the highest quality assurance standards.

PROCESS
Applying the right approach and accelerating your product time-to-market

SOLUTIONS

SYMBIOSIS solutions are customer-driven sets of analytical methods designed to meet regulatory requirements. SYMBIOSIS solutions are designed to accelerate drug product development and to provide analytical support throughout drug product life cycles. An extensive range of methods combined with our expert knowledge provides accurate analysis and consistent results in accordance with GMP and GLP requirements.

- Analysis of drug substances and drug products of bio-pharmaceuticals and classical pharmaceuticals
- Stability testing according to ICH/FDA guidelines, incl. storage
- Release testing
- Development and validation of analytical methods in accordance with ICH/FDA guidelines
- Comparability testing (incl. Biosimilars/Biobetters)
- Safety testing

COMMUNICATION
Project visibility and flexibility for changing market needs and regulatory requirements

SERVICES

SYMBIOSIS offers an extensive set of analytical methods for a wide range of substances from small molecules to antibodies.

SYMBIOSIS supports you through all stages of the development life cycle of your product from discovery to market.

Identity
- Amino acid analysis
- Protein sequencing (N- and C-terminal)
- Peptide Mapping
- Mass spectrometry (MALDI TOF MS)
- Western blot
- Isoelectric focussing (IEF)
- Spectrometry (UV-VIS, IR, Fluorescence)

Content
- RP-HPLC
- Protein determination (CBB, BCA, UV)
- ELISA
- Titrimetry
- Sialic acid determination

Purity
- SDS-PAGE gel electro-phoresis
- Capillary gel electrophoresis
- Thin layer chromatography
- Size exclusion chromato-graphy (SEC)
- Ion exchange chromato-graphy (IEC)

Impurity
- ELISA for host cell proteins (HCP)
- Q-PCR for residual DNA
- Phage determination
- Determination of process related impurities
- Silicone oil determination by IR spectrometry

Functionality/ Potency
- Bioassay
- Dissolution testing

Safety
- Bioassay
- Immunogenicity

Physicochemical
- Colour
- Clarity/Opalescence
- Visible particles
- Osmolality
- Optical rotation
- pH
- Residual moisture (Karl Fischer)
- Loss on drying
- Melting point
- Resistance to crushing

POTENCY TESTING – BIOASSAYS

SYMBIOSIS provides a dedicated one-stop-service from bioassay development to GMP batch release, helping to accelerate your testing programs.

Our bioassay experts can assess a wide range of mode of action including:

- Cytotoxicity
- Proliferation
- Differentiation
- Apoptosis
- Angiogenesis
- Neutralising antibodies

Our capabilities include:

- Development of scientifically sound and cost effective cell banks qualified for your bioassay
- Validation of potency assays according to ICH/FDA guidelines
- Establish criteria for critical reagents and define specifications of reference materials required for measuring relative potency
- Cell bank storage and stability programs

SYMBIOSIS can perform virus based assays (biosafety level S1 and S2) according to Gentechnikgesetz (GenTG), Infektionsschutzgesetz (IfSG) as well as Tierseuchenerreger-verordnung (TierSeuchErV).

QUALITY
Accurate analysis,
consistent results
in compliance with GMP/GLP

SAFETY – IMMUNOGENICITY TESTING

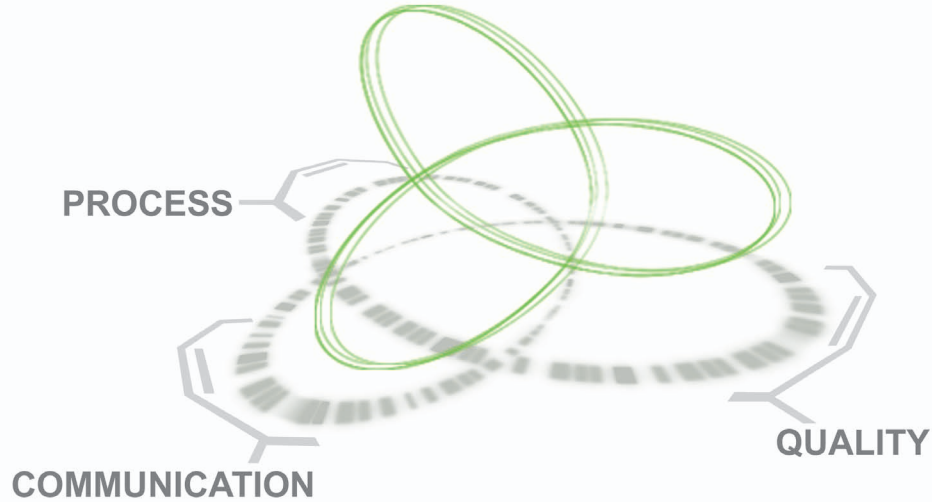
SYMBIOSIS performs immunogenicity testing to detect anti-drug antibodies (ADA/NADA) of recombinant proteins, antibodies or of your product.

Development and validation of immunoassays for the measurement of anti-drug antibodies and neutralising antibodies (ADA/NADA) is one of the core competences of SYMBIOSIS.

SYMBIOSIS offers several approaches to immunogenicity assessments to ensure that the most sensitive, rugged and reliable techniques are employed.

To thoroughly assess the immunogenic potential of your drug SYMBIOSIS applies a four-step immunogenicity testing strategy:

- Screening
- Confirmatory
- Titer assessment
- Cell-based neutralising antibody detection



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