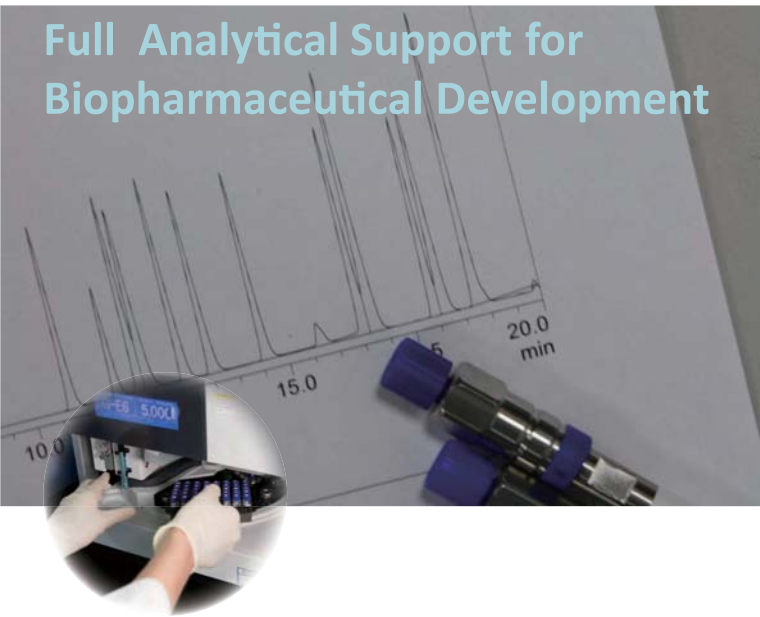


From Discovery to Manufacturing

Full Analytical Support for Biopharmaceutical Development



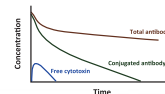
Analytical Solutions to Antibody Drug Conjugate (ADC)

HPLC/LC-MS/Immunoassay/Immunocapture

For Lys- or Cys- linked ADCs

Detailed Characterization

- Payload distribution
- Drug-to-antibody ratio (DAR)
- Drug conjugation site
- Full characterization of antibody

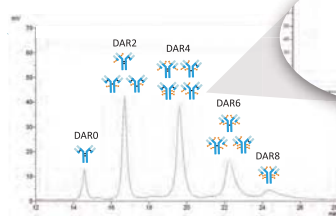


Bioanalysis

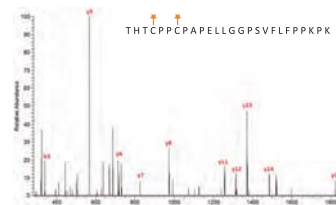
- PK profiles for free cytotoxin & total/conjugated antibody
- Payload distribution in serum/plasma

Cys- linked ADCs

LC-UV/Intact Mass Analysis



Conjugation Site Identification



Analytical & Bioanalytical Services for Biopharmaceuticals

Mithra has proven expertise and experience in meeting international standards to assist pharmaceutical development from discovery, CMC preparation, registrations, manufacturing to clinical levels.

Cell Line Development

- Amino Acid Sequence
- MW, Glycan, Charge Profile

Process Development

- Structural Characterization
- Comparability Studies
- Impurity Analysis

Preclinical/Clinical Development

- PK/PD Bioanalysis
- Immunogenicity Assessment

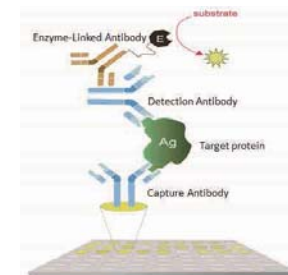
Manufacturing

- QC Release Testing
- Stability Test
- Impurity Analysis

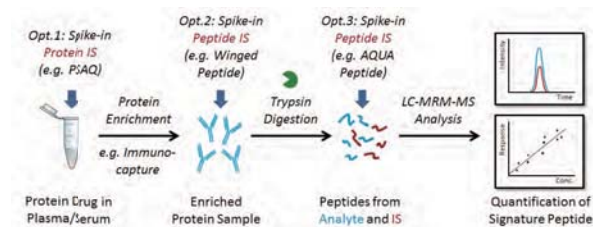
Hybrid Solutions for Bioanalysis

Therapeutic proteins are quantified by ligand binding assay (LBA) or LC-MS/MS for

- pharmacokinetic study
- immunogenicity assessment during preclinical and clinical research.



Ligand binding assay (LBA)

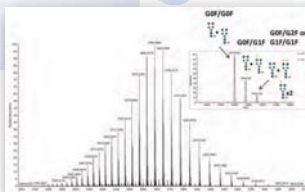


Full Characterization Plan for Biologics

With profound expertise in biological products diverse in monoclonal antibodies, growth factors, antibody drug conjugates (ADC) and a variety of other proteins, our services include primary structure characterization, terminal sequencing, PTMs identification, disulfide bond assignment, carbohydrate structure analysis and peptide mapping for biosimilar comparison or lot-to-lot QC, and degradation/impurities profiling.

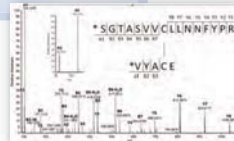
Molecular Weight Determination

- ▶ Intact mass
- ▶ Reduced/deglycosylated form



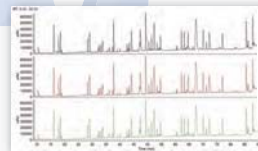
PTM Identification

- ▶ Disulfide bond and mismatch
- ▶ N-term pyroglutamate
- ▶ C-term Lys clipping
- ▶ Oxidation/deamidation



Peptide Mapping

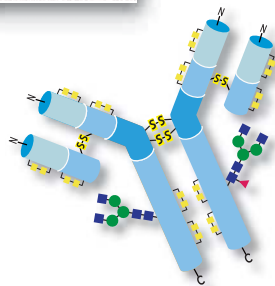
- ▶ Lot-to-lot QC
- ▶ Variant analysis
- ▶ Comparability studies
- ▶ Similarity studies



Amino Acid Sequence

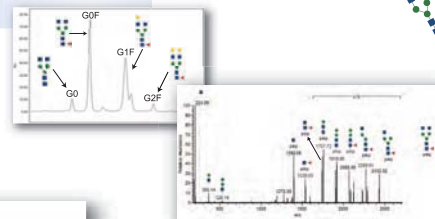
- ▶ N-term, C-term sequence
- ▶ Full sequence analysis
- ▶ De novo sequencing

```
XVSVLTVLHQDWLNGKXXXXXXXXXALPAPIEK
XXXXXXXXXXXXXXXXXXXXXKCKVSNKALPAPIEK
RVSVLXXXXXXXXXNGKEYXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXLNKEYKCKVSNKXXXXXXXX
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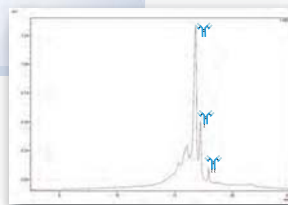
Glycan Analysis

- ▶ Carbohydrate structures
- ▶ Glycan profile
- ▶ Glycopeptide quantification
- ▶ Glycosylation sites



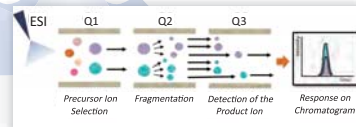
Product-related Impurities

- ▶ IEX, SEC, RP-HPLC
- ▶ Truncated forms



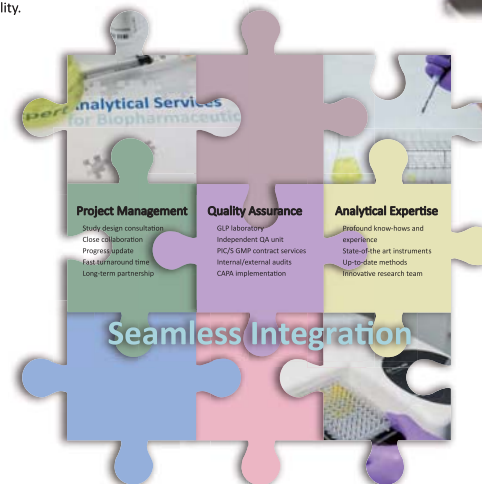
Process-related Impurities

- ▶ HCP & Protein A
- ▶ Residual antibiotics



Your Brilliant Choice of CRO Partner

Mithra Biotechnology Inc., the first Contract Research Organization in Taiwan since 1988 offers integrated and multi-dimensional CRO services including full characterization plans for biologics in accordance with ICH Q6B, and bioanalytical services for chemical drugs and biologics. Our GLP laboratory is equipped with state-of-the-art analytical instruments including UPLC-MS/MS, LC-MS/MS, nanoflow LC-HRMS, ICP-MS and ELISA systems for sensitive and high throughput drug quantification in various biological matrices. A great variety of comprehensive methods have been developed and validated for contract research, as well as SOPs been established and applied to ensure the result being delivered to its highest quality.



Project Management

Study design consultation
Close collaboration
Progress update
Flexibility and time
Long-term partnership

Quality Assurance

GLP laboratory
Independent QA unit
PIC/S GMP contract services
Internal/external audits
CAPA implementation

Analytical Expertise

Profound know-how and experience
State-of-the-art instruments
Up-to-date methods
Innovative research team

Seamless Integration



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