



Noorwegenstraat 4
9940 Evergem - Belgium
+32 (0)9 241 56 40
lab@anacura.com



What we do

We provide insight in your drug development journey

AnaBioTec provides **analytical solutions** for your **product development & filing** from pre-clinical to market.

Based on our extensive experience we focus on the analytics that matters & help you to connect the dots for your product across all aspects of your analytical needs.

Pre-Clinical & Clinical

- Method & assay development
- Forced degradation
- Method qualification
- Method validation
- Release
- ASAP stability studies
- ICH stability studies
- Process control
- Comparability
- Process characterization
- Reference standard management
- Trending

Market

- Release
- Stability
- Trending
- Comparability
- Investigations

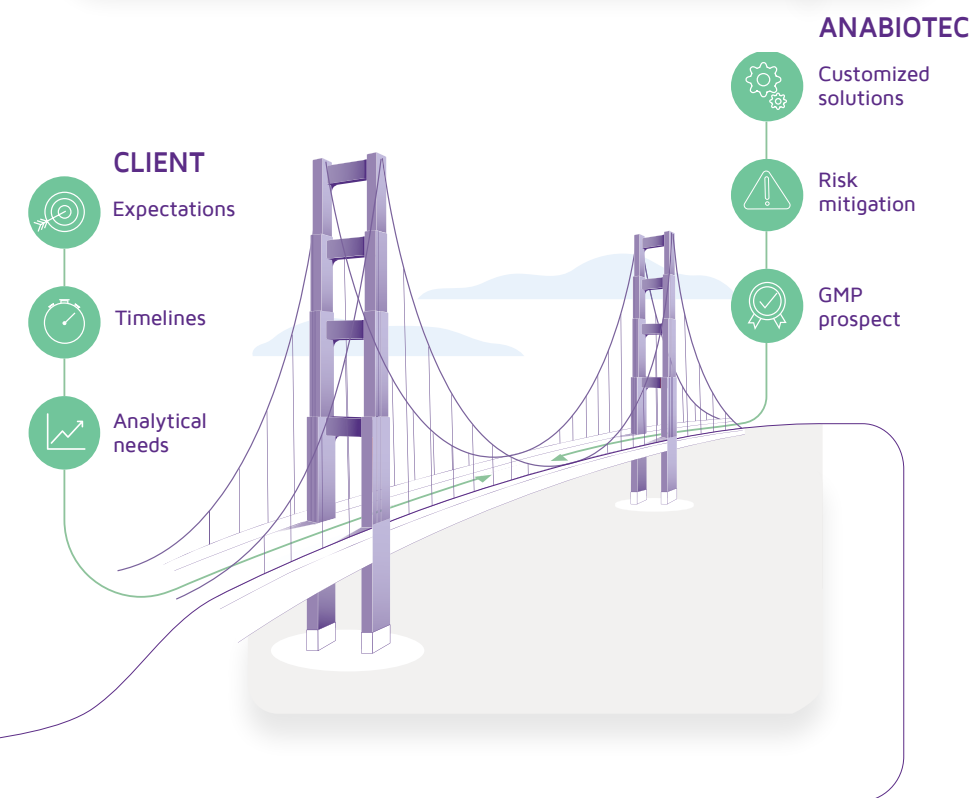
- IND
- IMPD

- BLA
- NDA
- MAA

Where we make the difference

Valued by our customers

- Flexible resource assignment assuring on time delivery
- Effective communication as part of our efficient project management
- Pro-active & knowledge driven advise to mitigate risks & anticipate next phases in drug development



Where we make the difference

What's in our portfolio

AnaBioTec exhibits an extensive experience with **DS**, **complex** formulations/mixtures, **liposomal** products, **low solubility** products, microspheres & **derivatised** products.

- Peptides
- mAbs
- Oligonucleotides
- Plasmids
- Small Molecules
- Derivates
- Vaccines
- mRNAs
- Stem Cells
- Car-Ts
- PBMCs

"Open mind for a different view; great expertise and dedication brought our out-of-the box approach to in-time batch release. Thanks for thinking with us!"

Brigitte Burm, CMC Project Director at ISA Pharmaceuticals



Small Molecule Solutions



Biologics Solutions



Cell & Gene Therapy Solutions

Testing capabilities

Chromatography/ Electrophoresis

- HPLC & UPLC (UV/DAD/CAD/MS/ELSD/FLD)
- Gas chromatography (GC)
 - liquid & headspace
 - FID & TCD
- Capillary electrophoresis (CE)

Physico-chemical testing

- XRD
- Differential scanning calorimetry
- Karl Fischer Volumetric
- Karl Fischer Coulometric (with/without VAP)
- Hardness
- Disintegration
- Friability
- Solubility
- Color

Mass spectrometry

- LC-MS, High Resolution
- LC-MS, Single Quad

Particles, particulate matter

- Appearance
- Turbidimetry
- Laser diffraction
- Light obscuration

Spectroscopy

- FT-IR
- UV-VIS

Dissolution

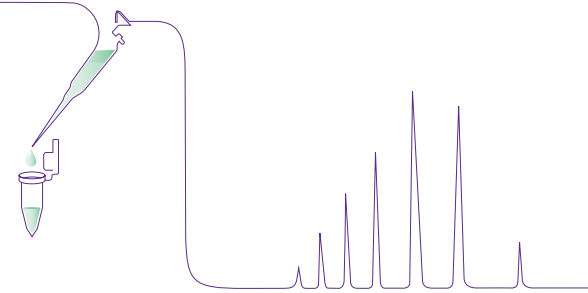
- USP type 1 (baskets)
- USP type 2 (paddles)
- QC (real-time & accelerated)
- Biorelevant

Microbiology

- Water activity
- Sterility
- Endotoxines

Wet chemistry

- Osmolality
- pH
- Density
- Viscosity
- Heavy metals
- Sulfated ash
- Titration



Testing capabilities

Identity & purity

- Molecular weight
- Size distribution
- Charge variants

- Glycosylation profile
- Disulphide bridges
- Drug-to-antibody ratio (DAR)

Impurities

- Degradation
- Physical modifications
- Chemical modifications

Quantity

- Total protein content
- In matrix (serum, CSF)

Potency

- Immunoassays
- Enzymatic assays
- Cell-based assays

General quality

- Appearance
- pH
- Osmolality
- Particulate matter
- Moisture content

Process impurities & contaminants

- Host-derived (HCPs, DNA)
- Downstream / culture-derived
- Residual solvents / chemicals / biochemicals / inorganic salts

- Medium components
- Mycoplasma
- Sterility
- Endotoxins

Testing capabilities

Characterization

- Multiplex testing (8 colors) by FACS
- Primer & probe design
- Electro-chemiluminescence (MSD)

Identity

- Single / multiple protein markers
- Absence of markers
- Protein secretion
- Gene expression
- Flow cytometry

Purity

- Percentage of dead cells & undesired cells
- Ratio viability
- Expression of markers

Potency

- Biomarkers
- ELISA
- Gene expression by RT-qPCR
- Enzymatic assays
- Flow cytometry
- Mixed lymphocyte reaction (MLR) assay

Quantity

- Cell viability
- Cell count
- mRNA/DNA concentration

General quality

- Appearance
- pH
- Osmolality
- Subvisible particles

Process impurities & contaminants

- Host-derived (HCPs, DNA)
- Downstream / culture-derived
- Residual solvents / chemicals / biochemicals / inorganic salts

- Medium components
- Mycoplasma
- Sterility
- Endotoxins

