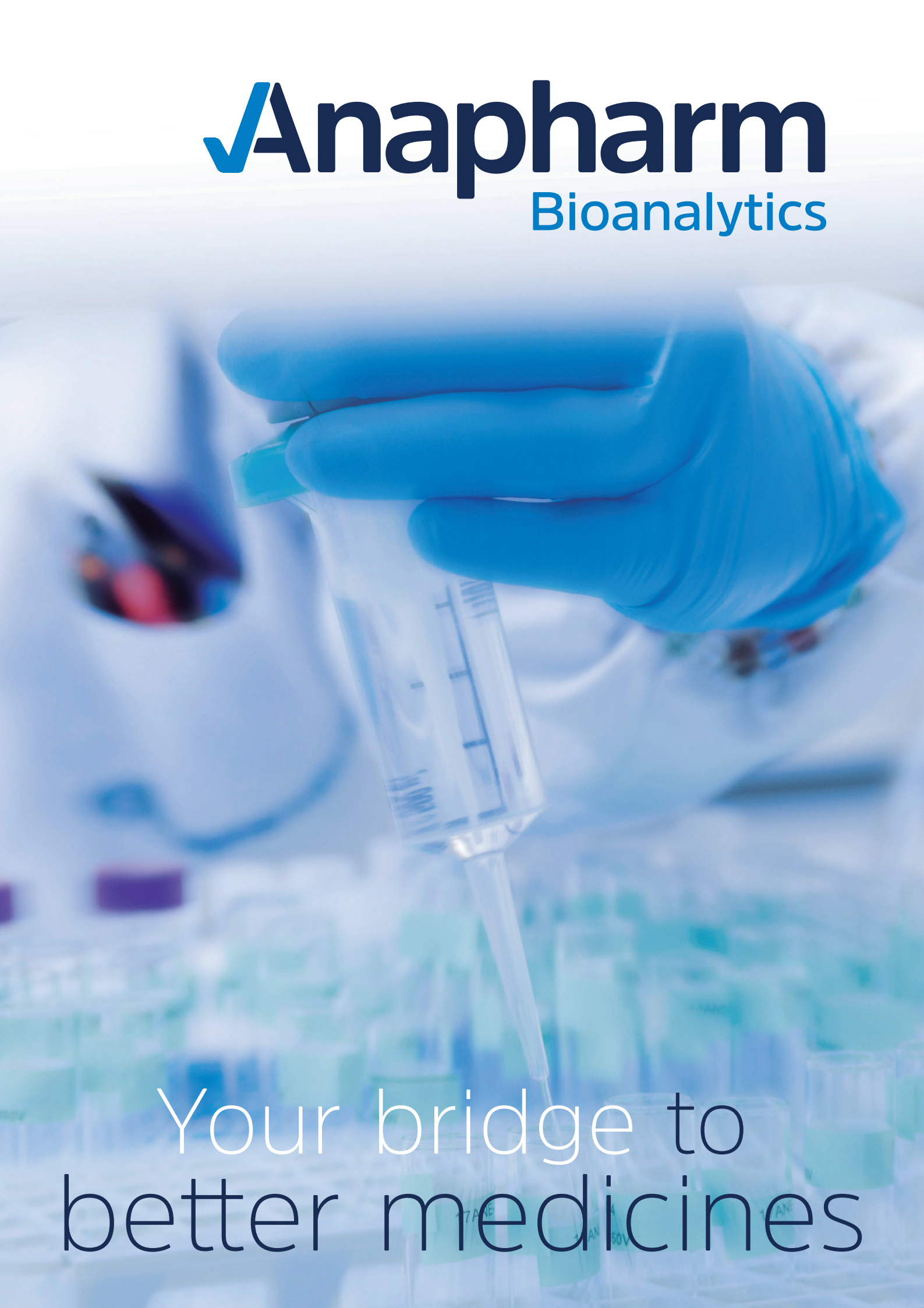
Anapharm
Bioanalytics



Your bridge to better medicines


Plasma
Aliquot 1
ETH

At a Glance

Anapharm Bioanalytics is a client-oriented, GLP-certified, FDA-inspected, GCP-compliant and ANVISA-certified bioanalytical contract research organization (CRO) offering comprehensive high quality bioanalytical services to the pharmaceutical, biotechnological and generic industry worldwide.

INDUSTRY LEADER

We offer 30+ years of experience in analytical method development, validation and sample analysis of both small and large molecules in a variety of biological matrices, using state-of-the-art LC-MS/MS and Ligand Binding Assay (LBA) technology platforms.

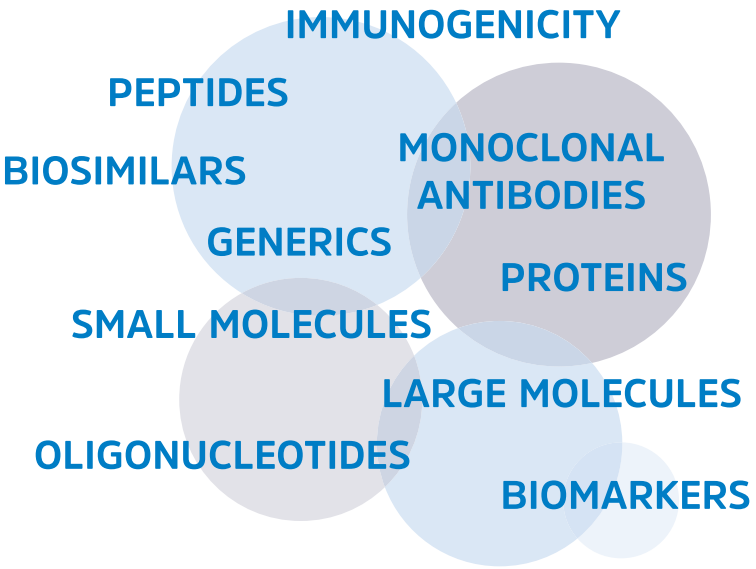
PHASE I-III & BIOEQUIVALENCE

Our global reach allows us to provide full service outsourcing solutions to conduct preclinical, Phase I-III clinical trials, PK/PD and BA/BE studies for registration worldwide, as well as non regulated discovery projects.

500+
bioanalytical methods

1,300+
studies performed

250,000+
samples per year



Services

SMALL MOLECULE BIOANALYSIS

A team with more than three decades of experience in bioanalysis and specialized in LC-MS/MS provides outstanding expertise to lead you through the development of any small molecule drug candidate.

- New Chemical Entities (NCE)
- Generics
- Biomarkers

LARGE MOLECULE BIOANALYSIS

We offer an array of Ligand Binding Assays (LBA) and LC-MS/MS technology platforms tailored to support development programs of biologics from early preclinical through Phase I-III clinical stages.

- Peptides
- Proteins
- Monoclonal Antibodies
- Biosimilars
- Oligonucleotides
- Biomarkers

COMPREHENSIVE LC-MS/MS & LBA BIOANALYTICAL SERVICES

METHOD DEVELOPMENT & VALIDATION

Analytical method development and validation of proprietary assays, as well as method transfer, optimization and cross-validation of sponsor-supplied methods.

SAMPLE ANALYSIS

Quantitative sample analysis of small and large molecules for clinical and non-clinical studies in a variety of human and animal biological fluids and tissues.

IMMUNOGENICITY

Immunogenicity testing for anti-drug-antibodies (ADA) safety assessment following a tiered approach including ADA screening and positive ADA confirmation.

BIOMARKERS

Targeted biomarker assay development, validation and measurement in non-clinical and clinical samples.

GENERICS

An extensive portfolio of 500+ assays is readily available to support bioequivalence, bioavailability and drug-drug interaction studies.

REGULATORY AFFAIRS

Our team will help you during the marketing authorization procedure by addressing all queries received from health authorities worldwide to ensure a smooth regulatory filing.

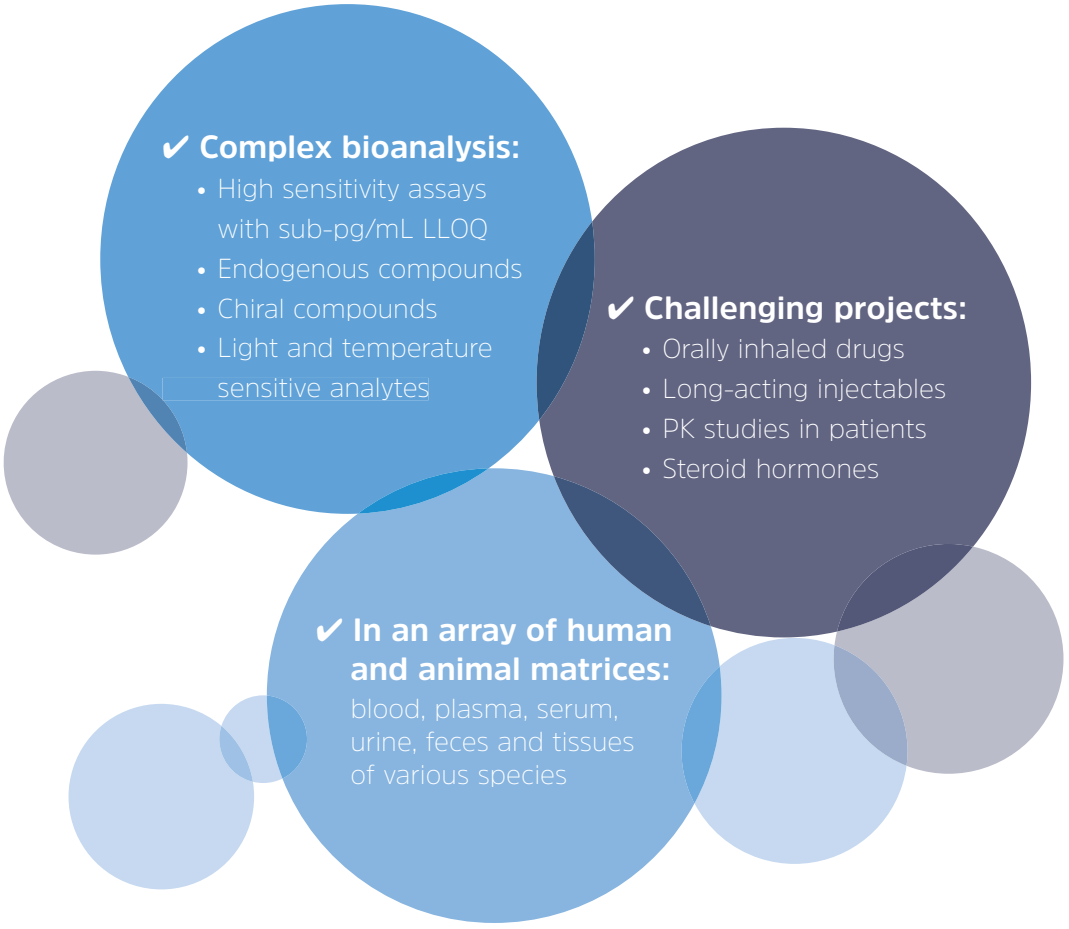
FROM EARLY PRECLINICAL THROUGH PHASE I-III STUDIES UNTIL REGULATORY APPROVAL

Whether your drug candidate is a new chemical entity, a new biologic, a generic or a biosimilar, we shall guide you from early discovery through non-clinical and clinical stages until successful regulatory approval is attained.

EARLY DEVELOPMENT	CLINICAL DEVELOPMENT	DRUG APPROVAL
• Discovery • Preclinical	• Phase I, Phase II, Phase III • PK/PD - BA/BE	• Regulatory Approval • Safety & Surveillance

EXPERTISE IN COMPLEX BIOANALYSIS

We offer broad experience in challenging projects involving complex bioanalysis in a variety of biological matrices.



Main Strengths

Our dedicated staff ensures that all our studies meet Sponsor's requirements with regards to quality, performance, reliability and timelines.

High Quality Standards

A strong quality culture is second nature at Anapharm Bioanalytics and is a key factor in ensuring a solid quality system in compliance with international guidelines.

1

Extensive Experience & Solid Know-How

A team of experts with more than 30 years of experience in the bioanalytical field delivers robust assays and reliable data to support preclinical and clinical phases.

2

Outstanding Regulatory Track Record

Our impeccable reputation and the inspections undertaken by EU Health Authorities, FDA and ANVISA ensure a smooth dossier registration procedure worldwide.

3

Client Oriented

We aim to exceed clients' expectations. For this reason, our highly trained staff is committed to your project from the very first minute until its finalization, in order to help you achieve your long-term goals.

4

We Meet Your Deadline

Our high throughput capacity and committed staff provide us with the necessary flexibility to offer competitive timelines for method development, validation and sample analysis.

5

Worldwide Regulatory Support

Our clients benefit from the vast experience and fast assistance of our scientists in responding queries from health authorities in North & South America, Europe, Africa, Middle East, South East Asia, Australia and Japan.

6

Team & Experience

Highly trained scientists with over 30 years of experience by LC/MS-MS and over 15 years of experience by Ligand Binding Assays (LBA) in bioanalysis ensure maximum level of expertise and quality standards to support our clients at any stage of drug development.
Each of our senior staff has more than 10 years of proven bench experience.

Leading bioanalysis since the 1980's

Recruitment of highly qualified scientists

Intensive **training** of personnel (including sample handling, sample extraction, run set-up, data processing and reporting)

Maximum level of **expertise** and **quality standards**

Each study has an assigned study director in charge, who leads a team of experts dedicated to your project.

We ensure direct and easy communication with the study director throughout the project in order to meet your individual requirements and provide you with fast assistance and timely updates.

The knowledge, experience, attention to detail and dedication of Anapharm Bioanalytics' staff have created an effective and enriching work environment.

The relationship with our clients is essential to us; we want you to feel confident about our work.

Facilities, equipment & software

Anapharm Bioanalytics offers a state-of-the-art laboratory, equipped with the most advanced High Performance Liquid Chromatography Mass Spectrometry (LC-MS/MS) and Ligand Binding Assay (LBA) technology platforms, tailored to meet all scientific, regulatory and quality requirements in support of the drug development efforts of the pharmaceutical industry.

✓ 13 LC-MS/MS instruments:

- 3 x Sciex Qtrap 6500/UPLC
- 2 x Sciex Qtrap 5500/UPLC
- 2 x Sciex API 5000/UPLC
- 6 x Sciex API 4000 triple quadrupoles

✓ MSD - Meso QuickPlex SQ120

✓ ELISA with the following readouts:

- Colorimetric
- Chemiluminescence
- Fluorescence

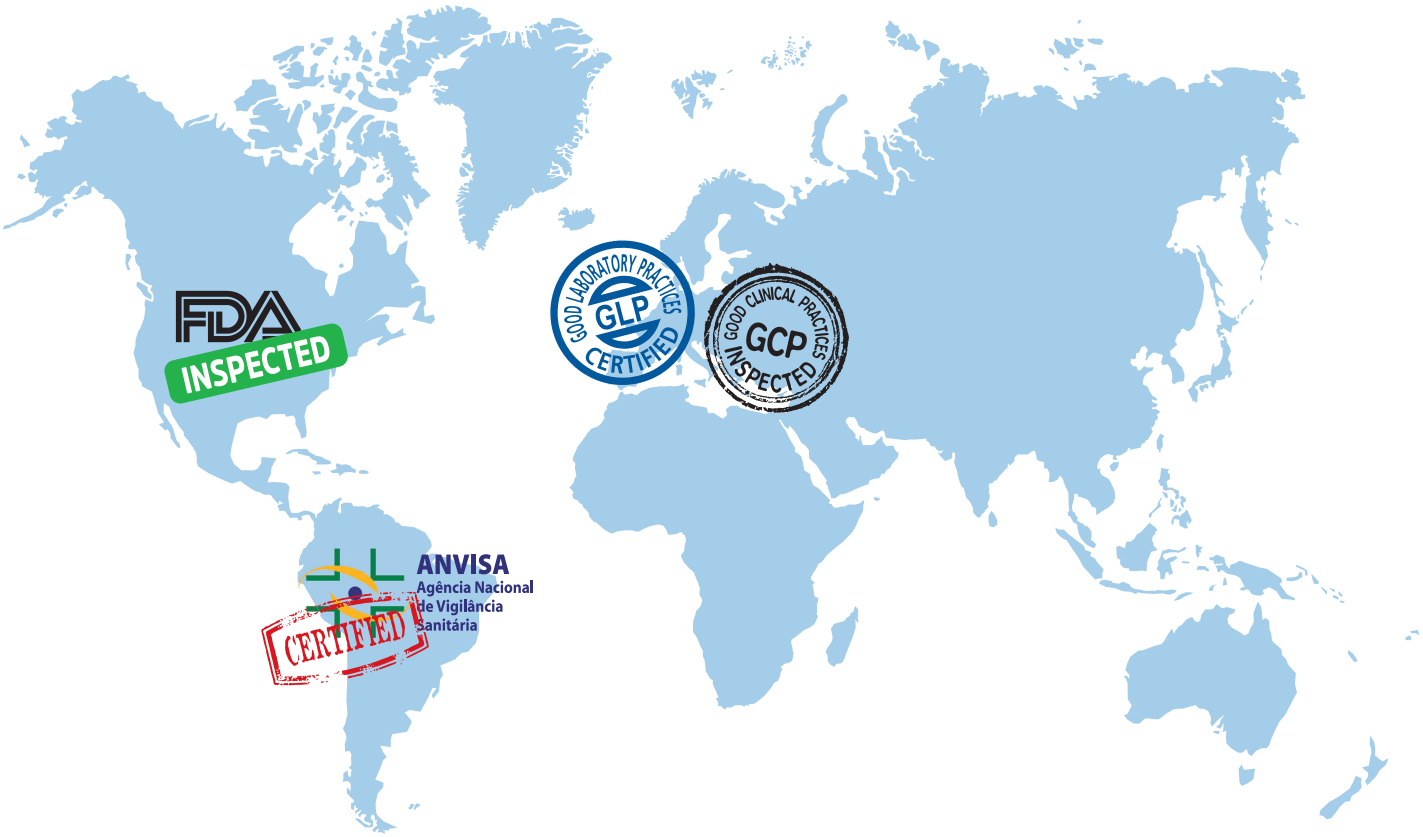
LABORATORY FACILITIES & SOFTWARE

- ✔ 1,500 m² of GLP laboratory space with controlled access.
- ✔ Laboratory Information Management System (LIMS).
- ✔ 4°C, -20°C & -80°C refrigerators and freezers monitored 24/7.
- ✔ Storage capacity for 300,000+ samples and reliable sample tracking.
- ✔ On-site GLP archives with restricted access, controlled environment and fire protection.
- ✔ Robotics sample handling and extraction technology.
- ✔ Multi-purpose laboratory for special projects, such as processing of light sensitive samples.
- ✔ Reference standards room with restricted access.
- ✔ Emergency electrical supply.
- ✔ Two Uninterrupted Power Supply units (UPS).

Quality Assurance

GLP-CERTIFIED, FDA-INSPECTED, GCP-COMPLIANT AND ANVISA-CERTIFIED

Anapharm Bioanalytics has a robust quality system to ensure delivery of consistent, reproducible and reliable data required for international registration.



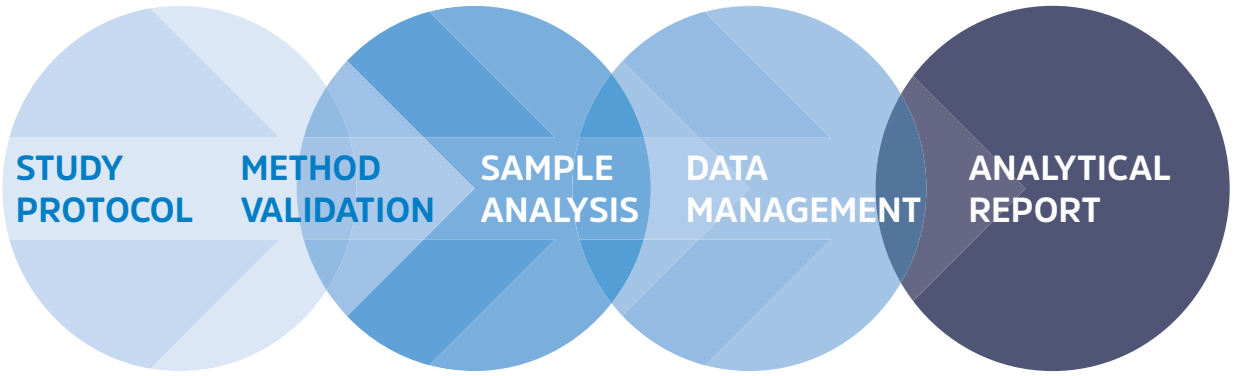
Quality is of utmost importance at Anapharm Bioanalytics. All analytical work and processes are conducted in accordance with Standard Operating Procedures (SOPs) in strict compliance with Good Laboratory Practices (GLP) and Good Clinical Practices (GCP). These SOPs are constantly updated to comply with international regulatory requirements.

Led by a Quality Assurance Director with over 20 years' experience in the field, Anapharm Bioanalytics has its own independent Quality Assurance Unit (QAU), that ensures strict compliance with applicable guidelines and integrity of study data by continuous monitoring, process improvement and staff training.

Over the past years, Anapharm Bioanalytics has established itself as a world-class provider of bioanalytical services for international registration.

Quality Assurance

The QAU is an integral component of every study, and systematically monitors each one of them from analytical protocol and method validation, through experimental work in sample analysis, data management and final analytical report. In addition, the QAU conducts process-based and facility audits.



The continuous inspections undertaken by Health Agencies as well as audits from pharmaceutical and biopharmaceutical companies, together with the efforts of our Quality Assurance Unit, contribute to constantly improving the level of quality, integrity and compliance achieved at Anapharm Bioanalytics.

19+
regulatory inspections

100+
sponsor audits

As a leading provider of bioanalytical services we aim to become a valued partner for your product research, development and registration.

www.anapharmbioanalytics.com

Anapharm Bioanalytics

C/ Encuny 22, 2nd floor
08038 Barcelona - Spain
Phone: +34 93 223 86 36
contact@anapharmbioanalytics.com