QUALITY ASSISTANCE
Contract Research Organisation

Your one-stop shop for analytical services

Quality Assistance is a **leading CRO** that provides **analytical services** to the pharmaceutical industry. *Quality Assistance* offers a comprehensive range of analytical services required by EMA and FDA regulations.

Quality Assistance occupies a **unique position in the CRO market** by providing all the analytical services required by EMA and FDA regulations **on one site.**

All laboratory facilities are **GMP certified.**

All laboratories on one site

With **over 40 years of expertise** at the forefront of analytical sciences, *Quality Assistance* offers essential services to the pharmaceutical industry, and has developed a comprehensive offering for the **characterisation of the quality attributes of ATMPs related to safety, purity, process and product impurities and potency.**

We will work hand-in-hand to achieve the success of your ATMP!

ANALYTICAL SERVICES

Analytical development and robustness assessment

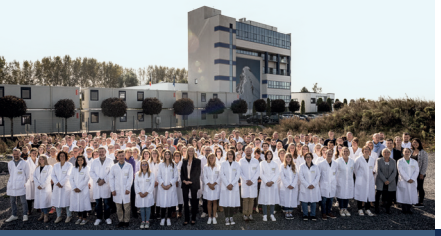
Development, qualification, validation, and transfer of methods
according to protocols compliant with ICH, FDA and EMA regulations

Stability studies

DS/DP characterisation & QC Testing
Customised testing
Batch testing
Bioassays expertise

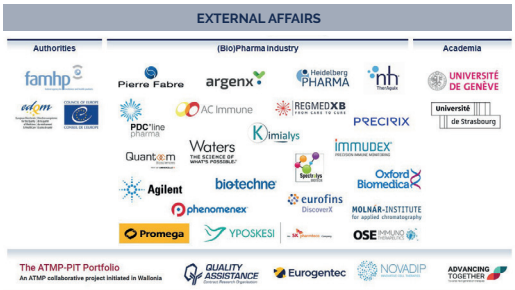
Clinical and non-clinical studies
Biomarker quantification
Immunogenicity testing

Access our scientific library



Quality Assistance constantly strives to provide **full and reliable analytical support** for innovative medicines. In addition to its contracted R&D activities, it deploys a **strong in-house R&D and Innovation strategy**. Dedicated experts perform **regulatory, scientific, and technological monitoring** which they then translate into **projects to acquire new analytical skills** in order to address clients' needs and challenges.

These internal R&D projects are either led autonomously or in collaboration with public or private partners, labs, suppliers or clients.



The ATMP-PIT Portfolio
An ATMP collaborative project initiated in Wallonia

ADVANCING TOGETHER

***Quality Assistance* participates in an Innovation Partnership in ATMPs of 81 million euros.**

This groundbreaking project is led by BioWin and the Service public de Wallonie of Belgium. It brings together 26 partners for 12 work packages covering all the links in the ATMP value chain and addresses:

- particular areas of scientific research with high development potential,
- various aspects of preclinical and clinical research,
- innovative approaches to production process design and control.

***Quality Assistance* is thrilled to contribute to two critical work packages:**

- **CARACT'EXO:** In partnership with Novadip, we're leading the development of innovative analytical tools for exosome analysis.
- **GUIDEPRO:** We're collaborating on a project coordinated by Eurogentec to develop a methodology to produce guide RNAs for CRISPR therapeutic gene editing.

BIOWIN | Wallonie Relance

Our clients rely on *Quality Assistance* to accelerate Time to Market.

We design **customised solutions**, define analytical protocols, as well as develop and validate specific new analytical methods **for each client project.**

Our comprehensive range of analytical services is **fully GxP compliant.**

	NON-CLINICAL	CLINICAL	POST-REGISTRATION
	DEVELOPMENT, VALIDATION & APPLICATION OF ANALYTICAL METHODS		
GMP	DS/DP characterisation		
GMP	Preliminary stability studies	Forced degradation studies	Photostability / (In-use) Stability studies
GMP	DS/DP batch analysis (release testing)		
GLP	PK/TK sample analysis Formulation/buffer analysis	GCLP: PK sample analysis Biomarker analysis	
G(C)LP	Immunogenicity		

	CELL-BASED THERAPIES	GENE-BASED THERAPIES
Safety Detection and quantification	• Endotoxins • Mycoplasma detection (by qPCR based method) • Adventitous virus detection (by qPCR based method)	• Microbiology • Container closure system integrity • Leachables
Identity Profiling	• Single and multiplexed assay biomarkers expression • Secreted biomarkers • Cell morphology	• Genome identity • Genome sequencing • Viral vector serotyping
Purity Detection and quantification	• Viability/Apoptosis • Cell phenotype • Cell differentation state • Biomarkers expression	• Replication competent viral vectors • Viral aggregates • Full/empty capsides
Impurities Detection and quantification	• Ancillary products • Residual inorganic, chemical, contaminants • DMSO detection and quantification • Soluble growth, differentiation factors	• Plasmid isoforms • Residuals (solvents, elemental impurities, salts, proteins, DNA and RNA), benzonase. • Process contaminants
Potency Functionality	**Detection of Biomarkers / Biological active substances** **Functional protein expression** • Translation/Expression • Secreted biomarkers proteins • Paracrine effects **Evidence of function and MOA** • Proliferation • Activation/cell signaling • Differentiation • Cytotoxicity/apoptosis **In vitro assay potency**	• Infectious vector titers • Vector particucle concentration • Total protein • Capsid concentration