



A strategy for excellence  
from discovery to the marketplace





## Quality Assistance

- ❏ *Quality Assistance S.A.* is a leading European Contract Research Organisation (CRO) providing the pharmaceutical industry with **all the analytical services** required by **EMA** and **FDA** regulations for the development and marketing of **innovative human medicinal products**.
  
- ❏ *Quality Assistance S.A.* is an expert for the development of analytical methods for
  - Biologics (monoclonal **antibodies**, **ADCs**, recombinant proteins and peptides)
  - **New Chemical Entities** (e.g. protein kinase inhibitors, synthetic peptides, cytotoxics)
  - **Vaccines** (recombinant protein vaccines, synthetic peptide vaccines)
  - Advanced Therapy Medicinal Products (**Cell-Based** MPs and **Gene Therapy** MPs)
  - **Nanomedicine products**





## Quality Assistance

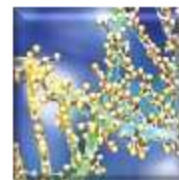
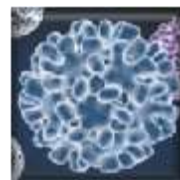
The company holds a unique position on the market with

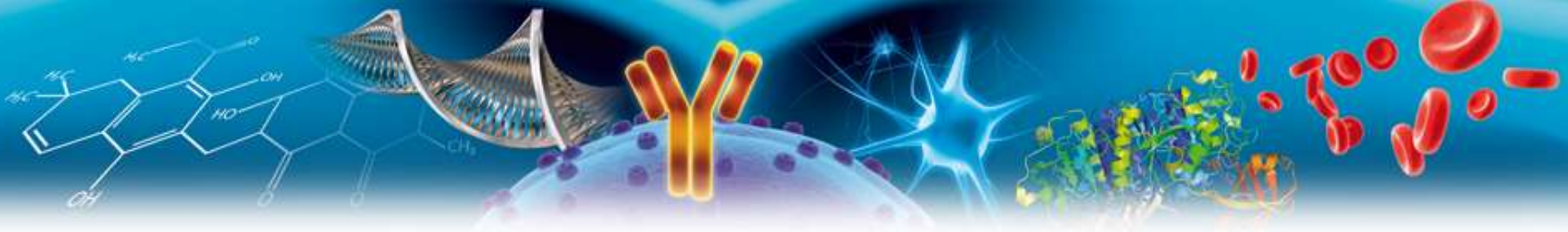
### **All laboratories on one site**

- Bioanalysis (PK/TK/Immuno)
- Bioassays
- Biochemistry
- Chromatography
- Elemental Impurities
- Mass Spectrometry
- Microbiology
- Molecular Biology
- Protein Characterisation

 **145** highly qualified professionals

 Over **30 years'** expertise at the forefront of analytical sciences





## Quality Assistance

Q Our core competencies are

➤ QUALITY (CMC)

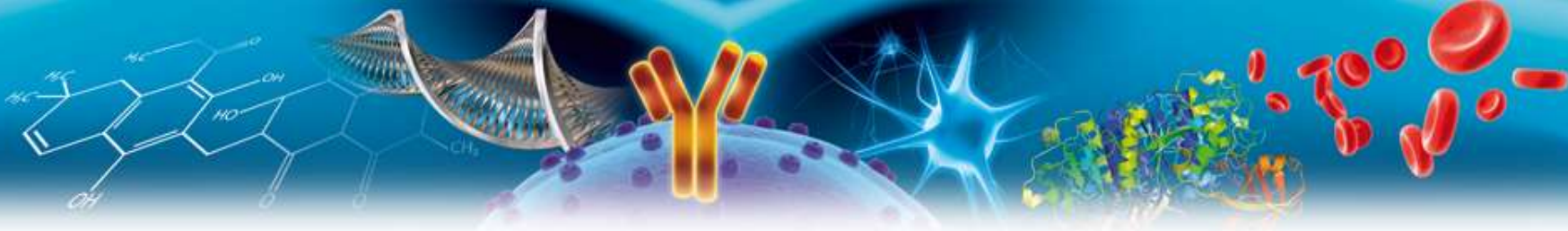
- Q Development and validation of analytical methods
- Q Characterisation
- Q Stability studies
- Q Batch (release) testing

➤ SAFETY/EFFICACY (Bioanalysis)

- Q Development and validation of bioanalytical methods
- Q PK/TK studies
- Q Immunogenicity studies
- Q Biomarker studies

Q The Quality Assistance environment is GMP, GLP and GCLP/GCP compliant.





## 2015 investments in plant, machinery & equipment → ~ 2 M €

Including :

☞ Xevo-G2S Q-TOF – High Resolution Mass Spectrometry (Waters)



☞ UPLC H-Class Bio systems – UV / Fluo / DAD (Waters)

☞ 2D-UPLC system (Waters)



☞ NanoACQUITY UPLC with HDX Automation technology (Waters)



☞ Multi-Angle Light Scattering Detector – MALS Dawn Heleos II (Wyatt)

☞ 2 x ICP-MS 7900 (Agilent)

☞ Flow cytometer – Guava easyCyte 8HT (FACS)

## 2014 investments in plant, machinery & equipment → ~ 1.3 M €

☞ Biacore – T200 (GE Healthcare)

☞ Particle Image Analyzer – FC200S iPAC (Occhio)

☞ Cell Viability Analyzer – Vi-Cell XR12 (Beckman Coulter)

☞ Flow cytometer – Guava (Merck Millipore)

☞ 2D Gel Electrophoresis – DIGE 2D (GE Healthcare)

☞ Charged Aerosol Detector (CAD) –  
Corona Ultra RS (Thermo Scientific)

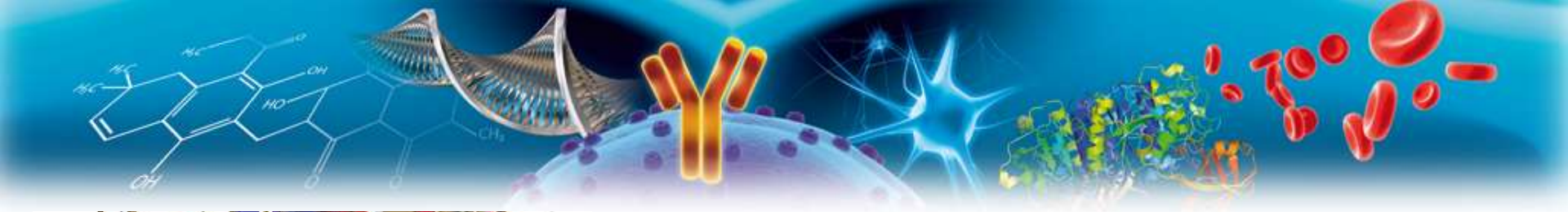
☞ Multi-Angle Light Scattering Detector –  
MALS Dawn Heleos II (Wyatt)

☞ UPLC H-Class Bio System (Waters)

☞ Capillary Liquid Chromatography

☞ & Premises/equipment dedicated to virology





## Internal R&D projects

## Absolute quantification of proteins by ICP/MS

Fast and accurate assay of single proteins by isotope dilution ICP/MS without the need of reference substance



## Protein Aggregation Technical sheet

Characterisation of protein aggregation in biopharmaceutical products



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## Elemental Impurities

Determination of elemental impurities in pharmaceutical products



Respect  
Commitment  
Excellence





Jeudi 24 septembre 2015 – Session 3 – 10h45

🕒 Géry Van Vyncht, Quality Assistance, R&D Departement, Strategy & Innovation

**« Stress testing and physico-chemical  
characterisation of monoclonal antibodies : the  
approach of an analytical CRO »**