QUINTA-ANALYTICA s.r.o., Pražská 1486/18c, Praha 10 – Hostivař, 10200 Czech Republic

A Brief Introduction

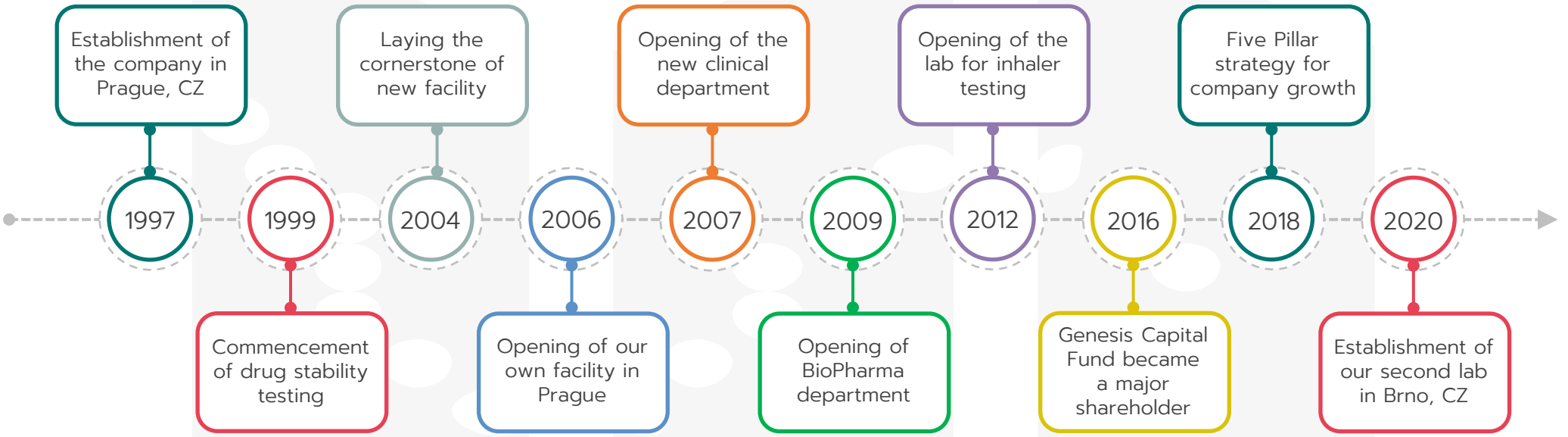
Since 1997 QUINTA-ANALYTICA has been providing clients a full suite of top-class services and support in the world of pharma. That dedication continues today as we offer a broad range of analytical, clinical and QA services across all stages of the drug life cycle, helping to get products to the market in a fast and reliable way.

- Founded in 1997
- Located in Prague and Brno, CZ with a key affiliate in Russia.
- 200+ experienced professionals
- EU-GMP/GLP/GCP approved and US-FDA inspected
- On-site clinical unit and BioA lab
- Clientele in EU, USA, Asia and Russia
- Annual turnover of approximately €12M

QUINTA ANALYTICA

Quinta's History

Some of the major milestones along our journey.



QUINTA ANALYTICA

Business and Operations

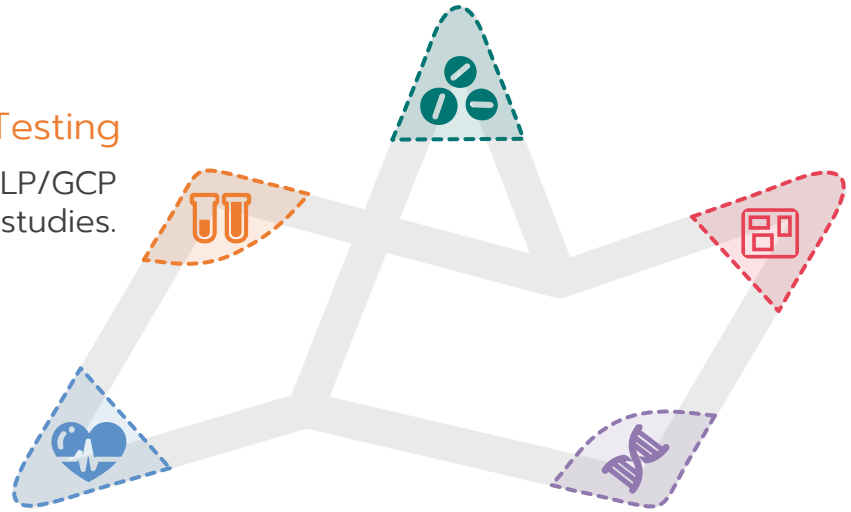
Our five pillars provide a complete end-to-end solution, following the life cycle of the product.

Pharmaceutical Analyses

GMP pharma analyses and testing, method validation, quality control and more.

Bioanalytical Testing

Complete solution for GLP/GCP compliant preclinical/clinical studies.



Analytical R&D

Development of analytical methods, impurities research, degradation studies, trace analyses, and more.

Clinical Trials

Our in-house Clinical Unit has been operating since 2007, with over 250 BA/BE/PK studies completed.

BioPharma Analyses

Complex analytical services for large molecules in GxP environment, including analytical support to pre-clinical/clinical studies.

QUINTA ANALYTICA

Pharmaceutical Analyses

We offer cGMP pharmaceutical analyses and testing for both human and veterinary drugs.

Quality & Release

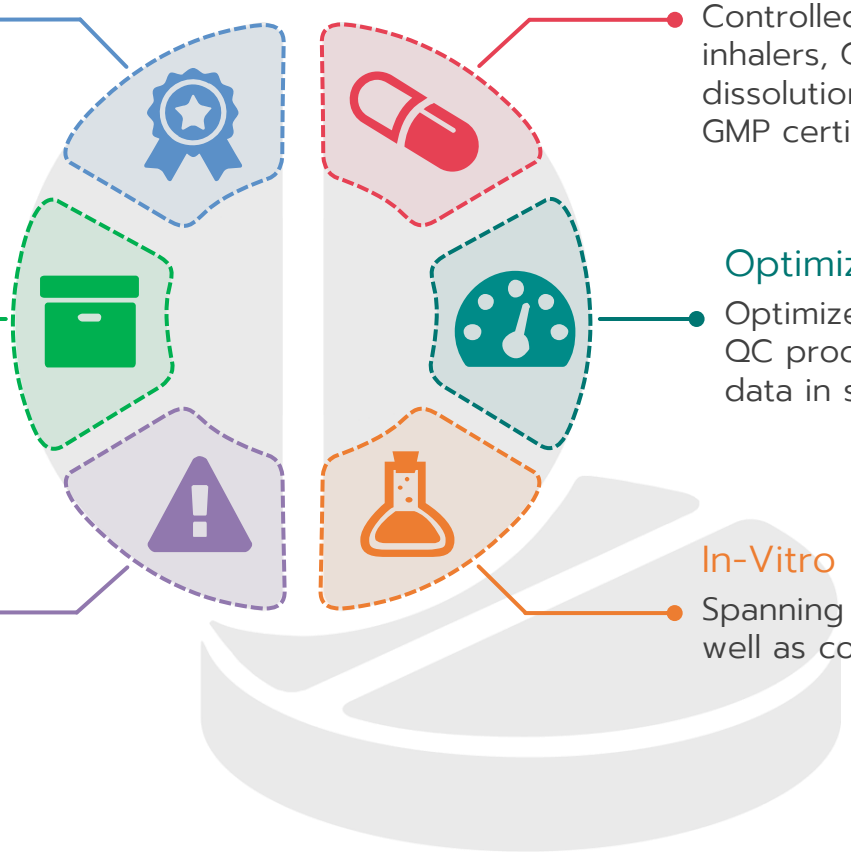
Substances/ drug products/ excipients for both pharmaceutical and veterinarian products, including imports from 3rd countries and batch release by QP.

Stability

ICH Stability studies on drug substances/dosage forms, freeze/thaw and shipping studies, retain samples warehousing.

Highly Potent Substances

Completely autonomous zones to test Hormones, Cytostatics, Sterile products and Antibiotics.



Analyses

Controlled substances, dry powder inhalers, Q3D elemental impurities, dissolution studies, regulatory reports, GMP certification.

Optimization and Validation

Optimized and validated analytical QC procedures to obtain reliable data in short time at reasonable cost.

In-Vitro Studies

Spanning both classic in-vitro study as well as comprehensive IVIVC studies.

QUINTA ANALYTICA

Analytical R&D

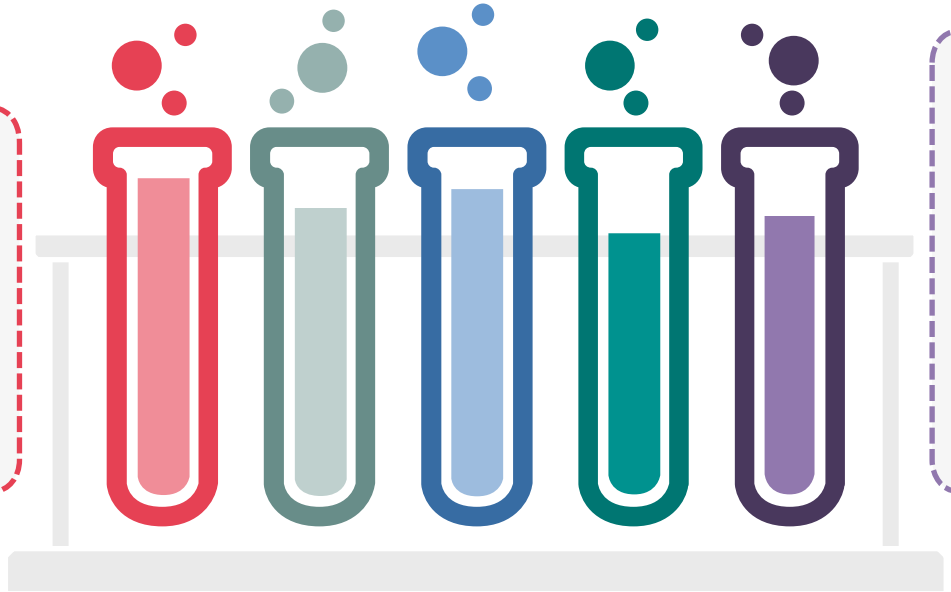
Using our analytical expertise and state-of-the-art equipment we support clients during their drug development and registration stages following the latest trends in analytical chemistry.

Identification and determination of structures of impurities using a combination of GC/LC-MS.

Analytical method development and optimization for both API and FDF - HPLC, GC/LC-MS, dissolution, PSD etc.

Synthesis of reference materials including the full characterization of the structure, determination of potency and issuance of the analytical certificate.

Accelerated stability and FDS (forced degradation studies) an instrument for the evaluation of analytical methods that aspire to be "stability-inducing".



Separation and identification of individual components of a formulated drug product via deformulation studies

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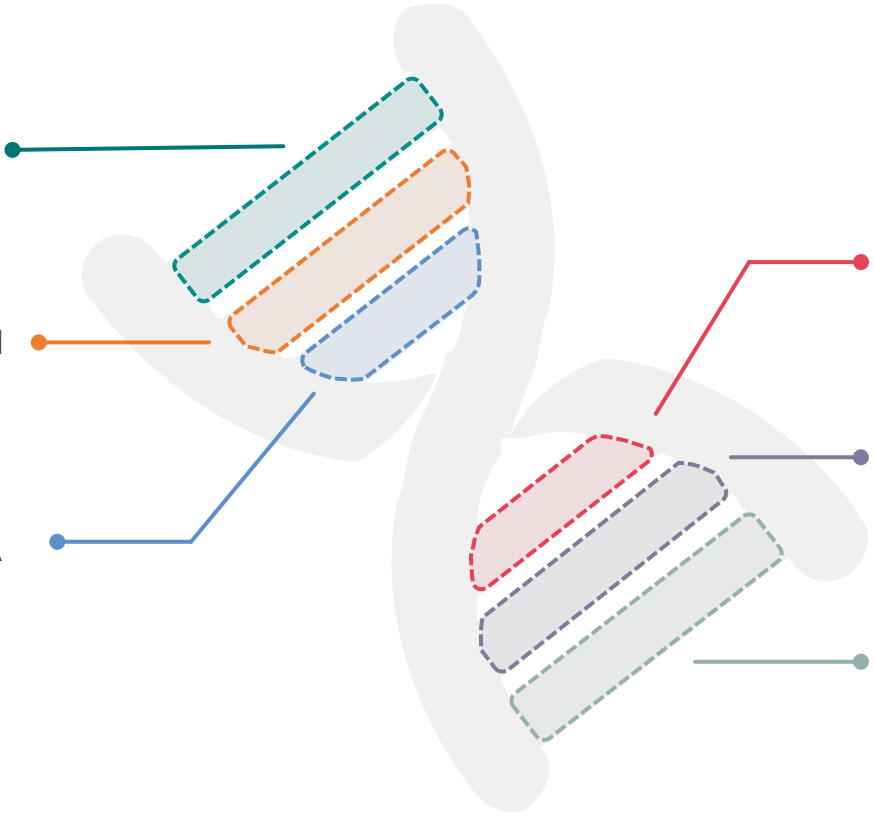
BioPharma Analyses

Analytical & Bioanalytical solutions for large molecules - from short peptides to biosimilars.

Characterization and protein purity analyses based on the ICH-Q6B regulations

Evaluation of immunochemical properties of protein medicinal products

Quantification in biological material using LC-MS and ELISA methods, under GxP environment.



Identification of proteins and peptides in mixtures using 2D LC-MS/MS

Post-translational modifications (PTMs) detection and characterization

Complex analytical services for large molecules in GxP environment, including analytical support to (pre)clinical studies.

QUINTA ANALYTICA

Clinical Trials and Evaluation

Comprehensive services for bioanalytical, bioequivalence, pharmacokinetic and pharmacodynamic studies
Phase I studies on healthy volunteers.

- Since 2007, our in-house clinical unit has been operating in compliance with GCP.
- Phase I offers 60 beds (incl. emergency care) with capability to run parallel studies.
- Operating in English, Russian and Czech, with a capacity of ~40 studies per year.
- Over 16,000 healthy volunteers with the ability to recruit new candidates quickly.
- Clinical reports in CDISC format available
- Resident medical staff licensed in clinical pharmacology, internal medicine, oncology, diabetology, anesthesiology, intensive care.
- Expertise of resident personnel enhanced by 200+ external staff (dermatology, hematology, diabetes, inhalers & more).
- Difficult sample handling and complex dosage forms including injectables.
- Bioanalyses performed by our own in-house GLP lab.
- Auxiliary activities for full service solutions for non-EU customers.

Bioanalytical Testing and PK Analyses

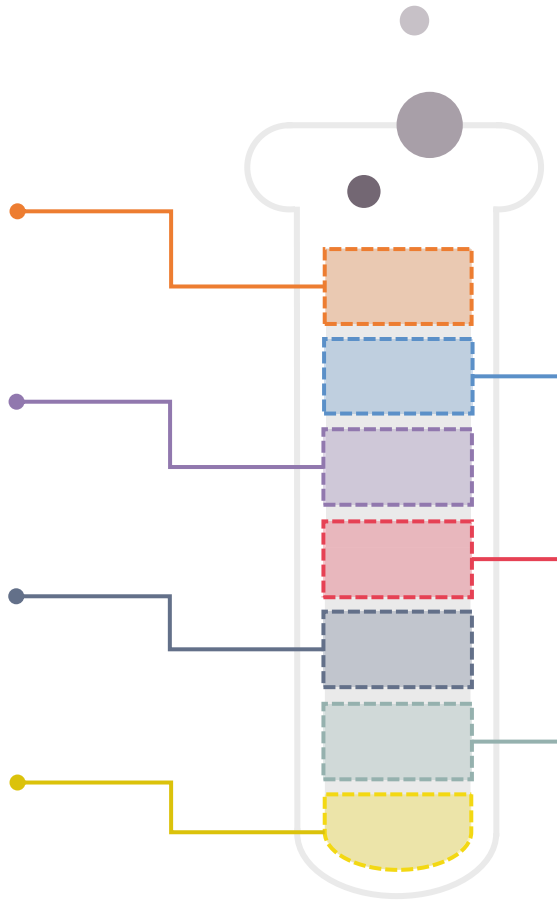
With a complete integrated solution for GLP/GCP compliant preclinical/clinical studies, our Bioanalytical Lab has successfully participated in over 550 clinical studies.

Preclinical PK & toxicokinetics
Design of the studies, bioanalytics, PK assessment, reporting.

Human & Animal pharmacokinetics
Complete studies with various biological matrices (e.g. blood plasma, serum, urine, feces, cerebrospinal fluid).

Structure of metabolites
Determination of chemical structures and isolation from biological matrices.

Method development & validation
Dedicated team of experts, with close to 300 in-house validated methods.



Biostatistics
Non-compartmental and statistical analysis of acquired data

Metabolites
Determination of chemical structures of metabolites and their isolation from biological matrices

State-of-the-art
Eight LC/MS/MS instruments (capacity up to 3,750 samples/day), hybrid quadrupole-orbitrap MS, ELISA, ICP-MS

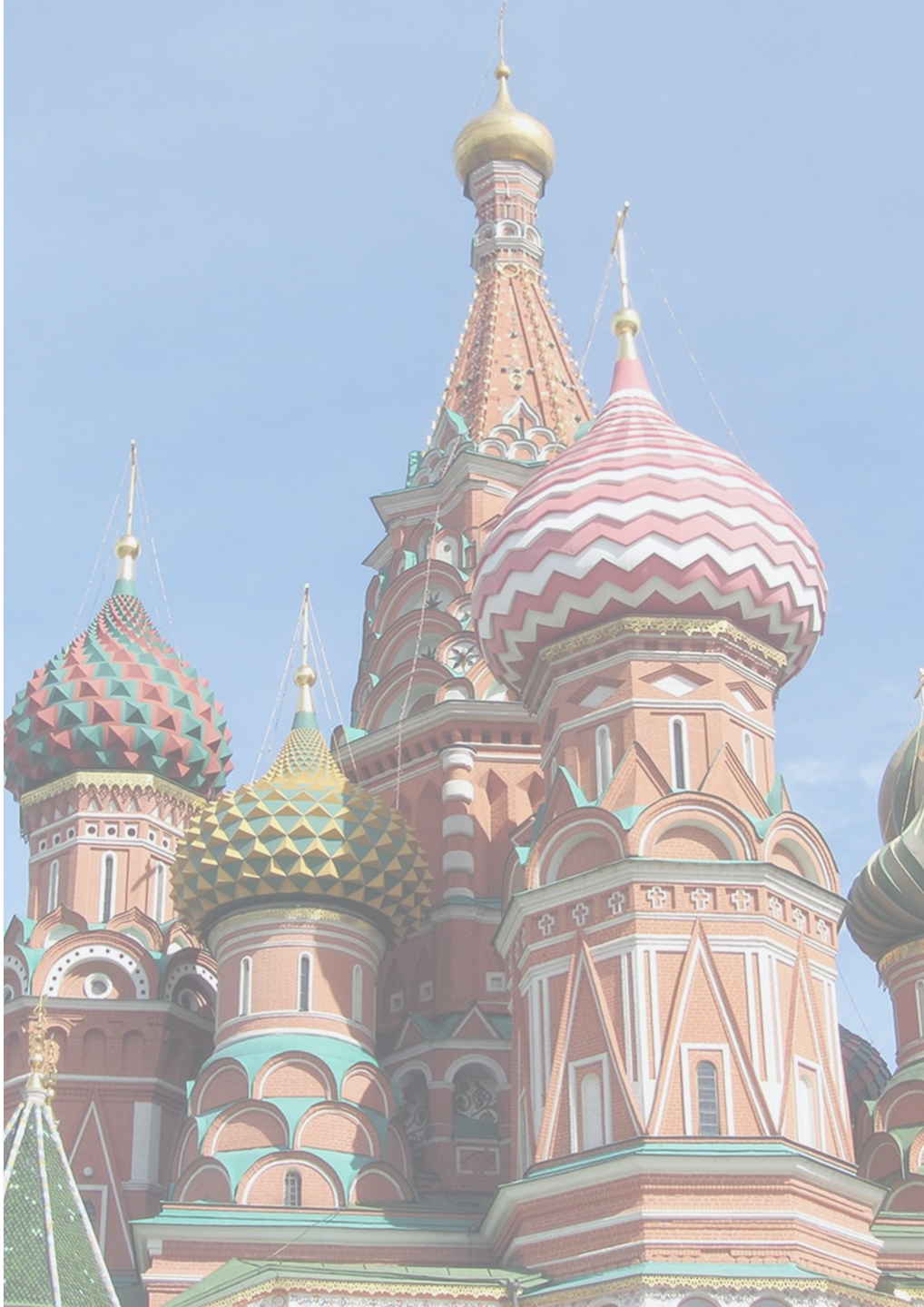
QUINTA ANALYTICA

Business in Russia

From Preclinical to Phase IV studies

In addition to our Czech facilities we have a joint-venture CRO located in Russia (Yaroslavl). Following European working procedures, while also adhering to specific Russian legislation, we open the door to registering your generic products in Russia.

- Full clinical management, monitoring, quality assurance
- Pharmacokinetics and statistical expertise (350+ data sets & molecules)
- Quinta-Analytica's Quality System implemented assuring full adherence to EU standards
- Own BA/BE clinical site with 44 beds
- Regulatory strategy consultancy
- Russian LEC approval



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Additional Services

We offer complex services related to pharmaceutical development and manufacturing activities.

API SOLUTIONS

Broad portfolio of active ingredients from reliable, established manufacturers, guaranteed by our expertise.

REGULATORY AFFAIRS

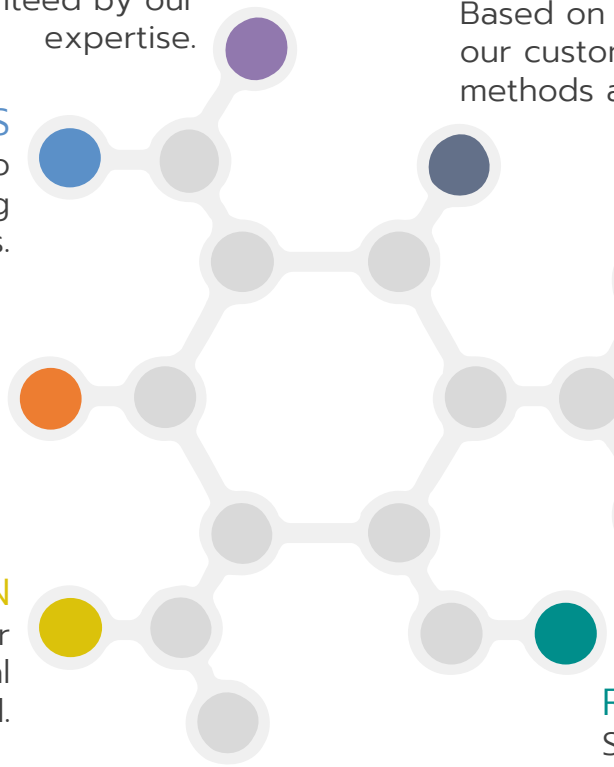
Expertise in helping to compile dossiers and drug registration processes.

MONITORING OF STUDIES

Oversight of subjects' health and correctness of treatments during clinical studies.

IMPD COMPILATION

Expertise in the preparation of your IMPD for smooth and fast trial approval.



NITROSAMINES

Based on isotopically labeled standards, our customizable in-house detection methods are available immediately.

GMP PACKAGING / LABELLING

Secondary packaging and labelling to meet regulations for your stability/clinical testing.

PHARMACOVIGILANCE

Monitoring of daily routine to detect unrecognized adverse events, plus assess and ensure drug safety.

RLD SOURCING & QP RELEASE

Sourcing of RLD to be used in clinical studies and QP release activities for IMPs

QUINTA ANALYTICA

Fully certified and providing top-class services
in the pharmaceutical industry globally for over twenty years.
We'll never let you down.

GET IN TOUCH TODAY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