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

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# A Brief Introduction

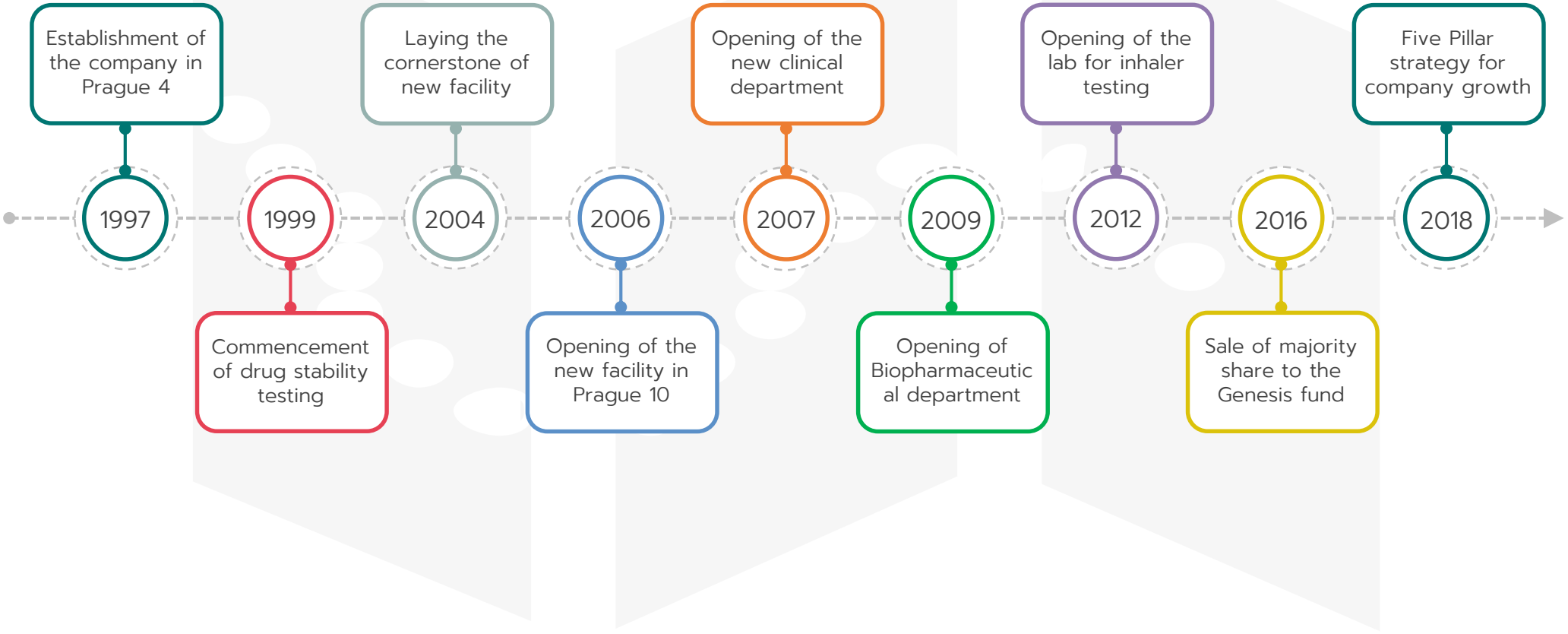
Since 1997 QUINTA-ANALYTICA has been providing clients a full suite of top-class services and support in the world of pharma. That dedication continues today as we offer a complete line of analytical solutions across all stages of the drug life cycle, helping to get products to the market in a fast and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

- Founded in 1997
- Located in Prague, Czech Rep.
- 170+ experienced professionals
- 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 €11M

QUINTA ANALYTICA

# Quinta's History

Some of the major milestones along our journey.



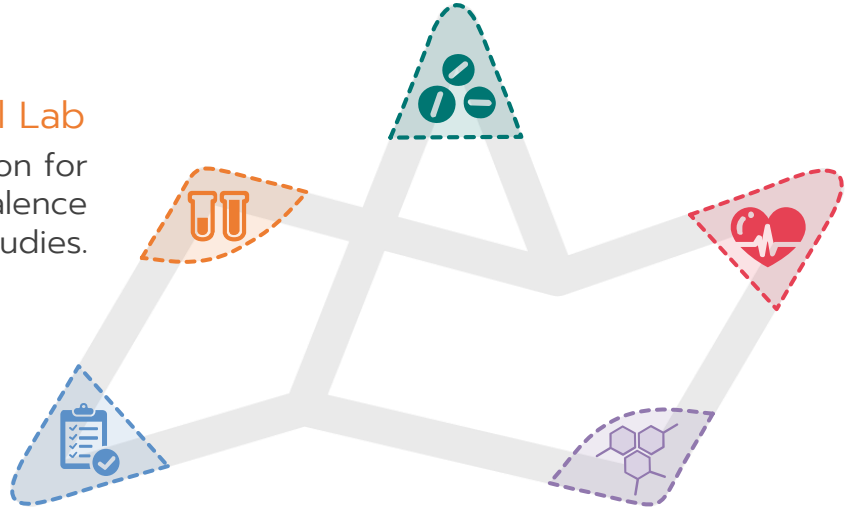

QUINTA ANALYTICA

# Business and Operations

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

## Pharmaceutical Testing

Research and development, analysis and testing, quality control and more.



## Bioanalytical Lab

Complete integrated solution for GLP/GCP compliant bioequivalence studies.

## Clinical Trials

Our in-house Clinical Unit has been operating since 2006, with over 200 BA/BE/PK studies completed.

## APIs Solutions

Essential components from reliable and approved manufacturers, guaranteed by Quinta.

## Formulation

Design and optimization of formulations for various FDFs to achieve desired characteristics.

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# Pharmaceutical Testing

We offer research and development, analysis and testing, quality control and more.

## Quality & Release

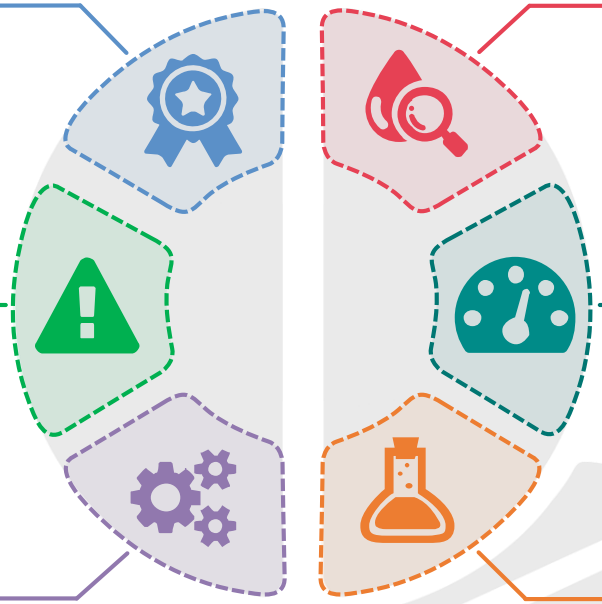
Substances and drug products for both pharmaceutical and veterinarian markets, including imports from 3rd countries and batch release by QP.

## Stability

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

## Methodology

Development of methods for quality testing of process materials, drug substances and dosage forms



## Analyses

Highly potent products, controlled substances, dry powder inhalers, Q3D elemental impurities, in-vitro equivalence studies, regulatory reports, GMP certification.

## Optimization and Validation

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

## Research and Development

Identification of impurities, investigation of complaint samples, accelerated stress studies, small scale syntheses and formulation development, extractables and leachables.

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# Clinical Trials and Evaluation

Comprehensive services for bioanalytical, bioequivalence, pharmacokinetic and pharmacodynamic studies

Phase I studies on **healthy volunteers** and/or **patients**

- From 2006 our in-house clinical unit has operated 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.
- Fully licensed in clinical pharmacology, oncology and internal medicine.
- All clinical staff are regularly trained in ILS and ALS, including mock patient scenarios.
- Difficult sample handling and complex dosage forms including injectables.
- Bioanalyses performed by our own in-house GLP lab.

QUINTA-ANALYTICA is a proud
Phase I Site Partner of IQVIA (formerly Quintiles)

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IQVIA™

# Clinical Trials and Evaluation

Collaboration with Clinical Physiology Unit (equipped by Emergency Unit)

Centre for Research on Diabetes, Metabolism and Nutrition, Department of Internal Medicine

Research area in experimental diabetology, endocrinology and nutrition.

Insulin sensitivity, secretion measures , Functional endocrinology testing, Tissue microdialysis, biopsies and preparations, Arterio-venous balance studies

In-patients and outpatients visist.

Patients/volunteers recruitment.

Equiped with 3 monitored beds, indirect calorimeter and ergometer, laminar flowbox, incubator.

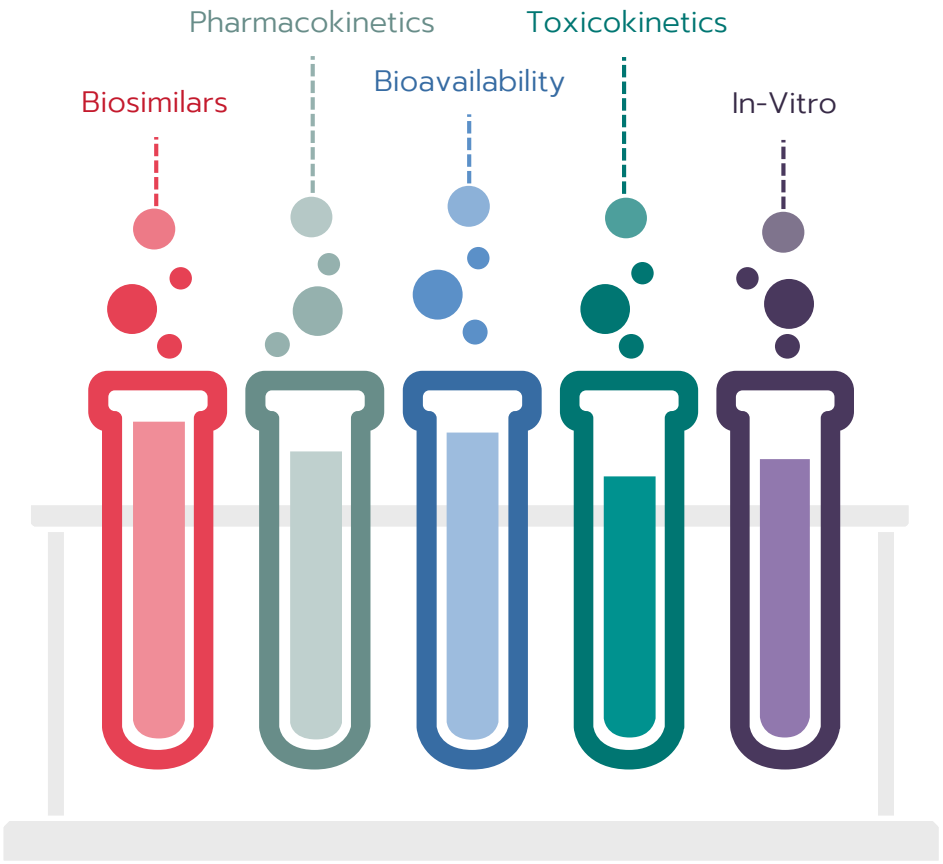
All clinical staff are regularly trained in ILS and ALS, including mock patient scenarios.

Amorphine test, high MUFA diet, BCAA and whey secretion test, methionine test, excersive physiology of functional electrical stimulation.

Partnership and collaboration with Diabetes and Obesity, Department of Charles Universit, Department of Anaesthesia and Intensive Care Medicine.

# Bioanalytical Lab

Complete integrated solution for GLP/GCP compliant bioequivalence studies.




Our Bioanalytical Lab has successfully participated on over 500 clinical studies (including pharmacokinetic and statistical evaluations) with pharmaceutical companies in Europe, North America, India and Asia.

We have developed more than 250 bioanalytical methods, and all were created and validated in compliance with GLP/GCP rules, in our certified and state of the art lab equipped with eight LC/MS/MS instruments (capacity up to 3,750 samples/day), by our own highly trained and skilled staff.

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# Bioanalytical Expertise

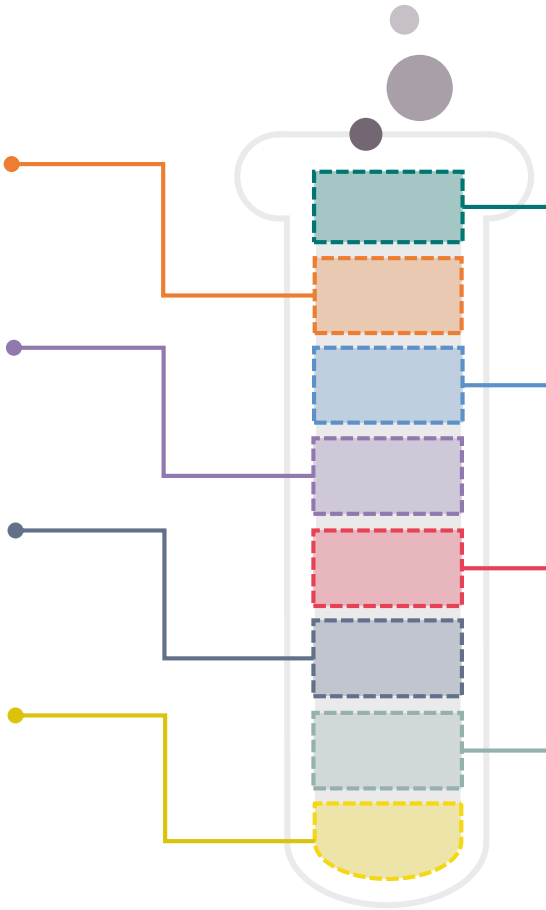
Dedicated state of the art laboratories for both small and large molecules (incl. Biosimilars).

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

### Human & animal pharmacokinetics
Complete studies with various biological matrices.

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

### Method development & validation
Dedicated team of experts, with over 250 in-house validated methods.



### Analytical support for PK Studies
Peptide and protein quantification in plasma and urine, formulation analysis.

### Activity and potency
Cytotoxicity, cell-proliferation assay.

### Protein purity
Related impurities, formulation excipients, aggregates, residual nucleic acids.

### Protein characterization
Intact molecular weight, isoelectric point, charge state distribution, primary sequence, amino acid profiles, post-translational modifications, affinity profiles.

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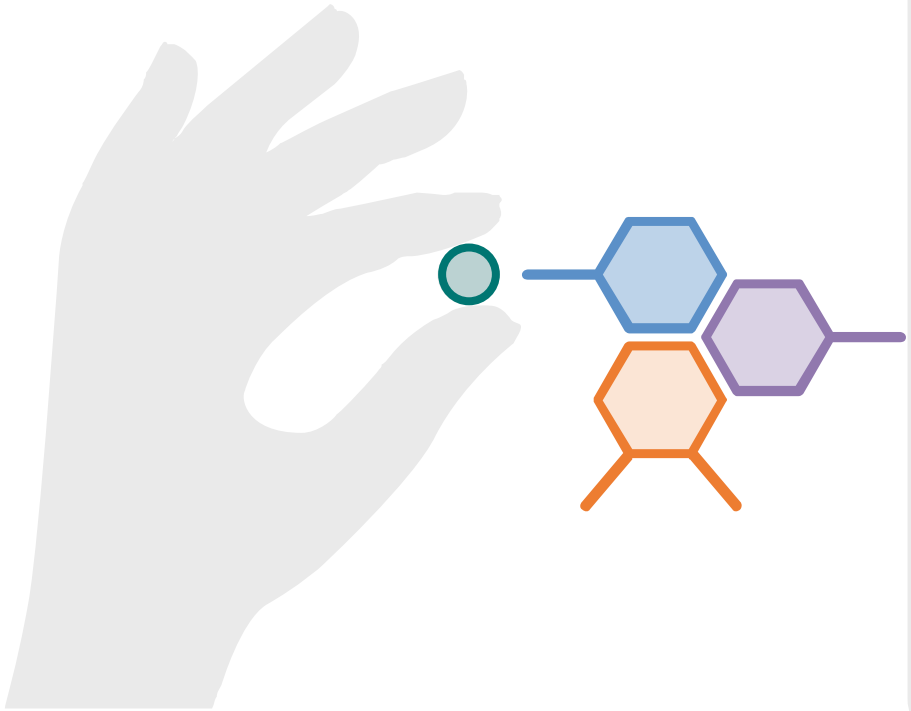
# Formulation

Our advanced expertise optimizes delivery performance and product stability.



QUINTA-ANALYTICA can design the ideal formulation for various FDFs to optimize drug delivery performance and product stability.

**FDF development**

- Preformulation – Research study (intrinsic chem& phys. properties
- Lab development - formulation design and proposal of suitable packaging
- Stability studies – accelerated and long-term stabilities
- Troubleshooting – improvement of parameters (stability, BA of API etc.)

**Cooperation with manufacturing site (GMP compliant)**

- Pilot production – technology transfer into pilot size
- Clinical batches – support in preparation of MBR and Product spec.
- Standard production – tech.transfer to standard mnfg size; supervision; validation protocol & report

# API solutions

Essential components from reliable and approved manufacturers, guaranteed by Quinta.

## Manufacturers' base

We carefully preselect reliable partners with a solid portfolio of both commodity and niche APIs.

## GMP qualification

Inspection of production facility and GMP systems by our own QP can be done on customer's behalf.

## Product Pipelines

In addition to commercial APIs we monitor the development pipelines and can recommend robust candidates for your Paragraph IV or Patent Exp. launches.

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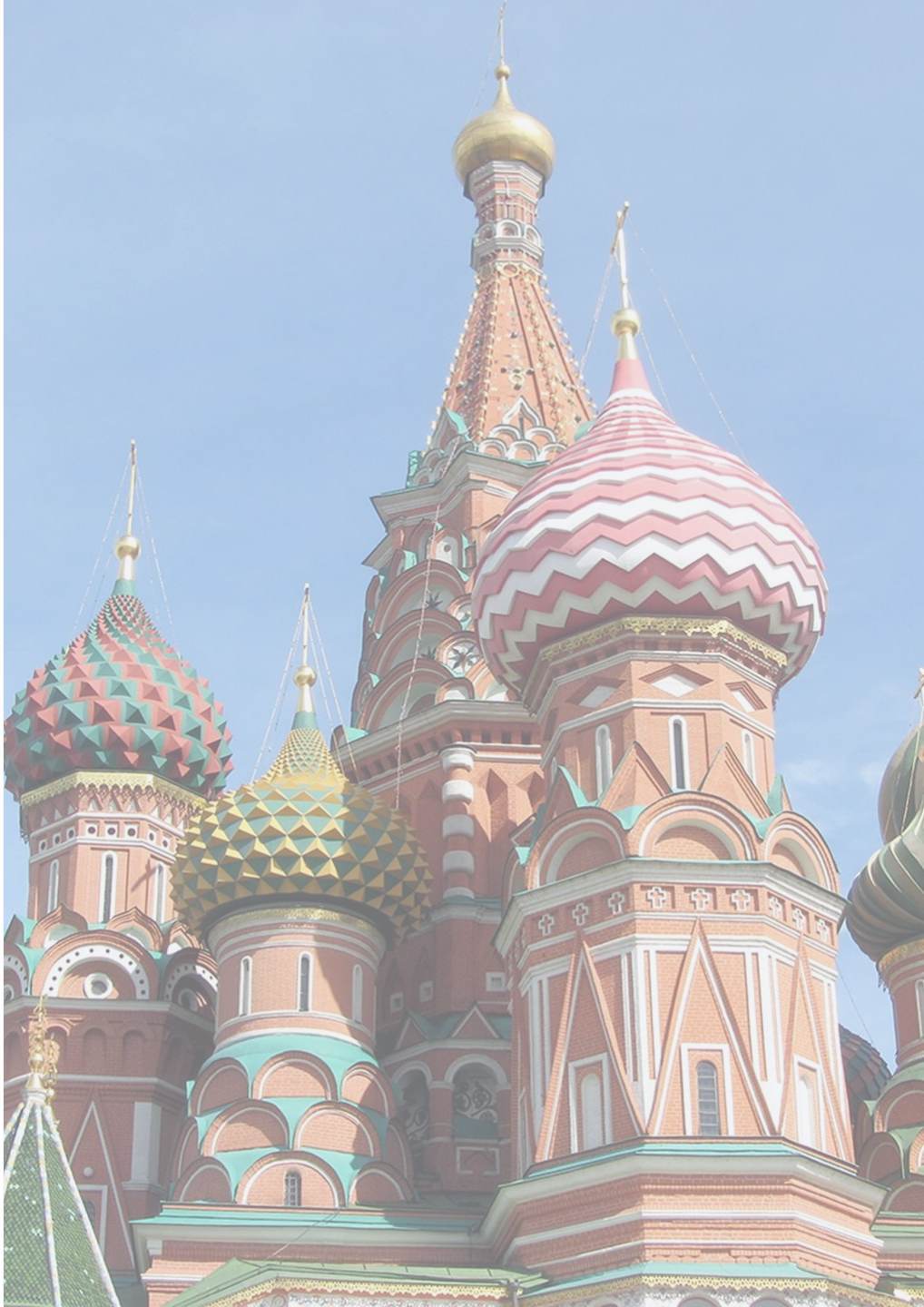
# Business in Russia

In addition to our Prague facilities we have a joint-venture laboratory located in Russia. Following European working procedures while also adhering to specific Russian legislation, we cooperate with local partners in preclinical studies of generics and have sound comprehension of Russian regulatory strategies.

- Full clinical management, monitoring, quality assurance
- Pharmacokinetics and statistical expertise (350+ data sets & molecules)
- Cost effective solutions (CRO tendering and qualification)
- Own BA/BE clinical site with 44 beds
- Regulatory strategy consultancy
- Russian LEC approval



QUINTA ANALYTICA

# ...and much more

We've got you covered.

## Pharmacovigilance

+ Agency inspected
+ EU QPPV / Deputy and medical support
+ Literatura screening
+ Signal management
+ Quality systems audits / inspections

## Readability testing

+ Readability testing
+ Focus testing
+ Bridging statement & Bridging report

## Regulatory Affairs & Compliance

+ Local M1 preparation
+ Submission management
+ Scientific Advise Meeting
+ MA holding
+ Life Cycle Management

## Translation

+ Translation & Localisation (100+ languages)
+ Harmonisations
+ Proofreading

## Dossier Development & Publishing

+ Due diligence & Gap analysis
+ Global CTD / eCTD publishing
+ Dossier writing & compilation (M1-M5)
+ ASMF & CEP compilation
+ Structured Product Labeling (SPL) Publishing

## Medical devices

+ Clinical evaluation report
+ Coordination of application submission
+ Categorization and company registration
+ Complete service in MD notification in EU

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# GET IN TOUCH


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