

# QPS BIOSIMILAR EXPERIENCE

## FULL SERVICE CRO SUPPORT

QPS is a leading full-service global CRO with extensive experience conducting research, offering comprehensive services to ensure successful drug development. Our experienced and dedicated global team provides unmatched support, from preclinical studies to bioanalysis and all phases of clinical trials.

### WHY CHOOSE QPS FOR BIOSIMILAR STUDIES?

#### 1. Expert Global Team

- ▶ **Specialized Expertise:** Our team includes board-certified physicians, experienced clinical research coordinators, project managers, and skilled data analysts specializing in biosimilars.
- ▶ **Patient-Centric Approach:** We prioritize patient comfort and compliance, ensuring high retention rates and reliable data collection.

#### 2. Understanding the RA pathways and guidelines:

- ▶ FDA 351(k) pathways
- ▶ EMA biosimilar guidelines (CHMP)
- ▶ MHRA, PMDA
- ▶ NMPA nuances
- ▶ Interchangeability study requirements (US)
- ▶ Comparative PK/PD study design standards
- ▶ Immunogenicity expertise (ADA, NAb testing)

#### 3. Biologic and Biosimilar Experience

- ▶ Comparative PK/PD studies
- ▶ Comparative clinical efficacy studies
- ▶ Access to patient population and site networks
- ▶ Comparator sourcing and management

#### 4. Bioanalytical Capabilities

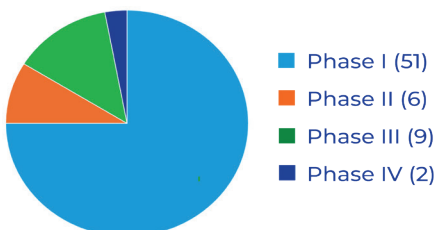
- ▶ PK Assay development
- ▶ Statistical modeling
- ▶ Immunogenicity data analysis
- ▶ Central Safety Labs

#### 5. Proven Track Record

- ▶ **Global Reach:** Access to a diverse patient population through our extensive network of clinical sites.
- ▶ **Successful Trials:** QPS has successfully conducted a wide variety of Phase I - IV biosimilar studies around the world.

### QPS CLINICAL EXPERIENCE IN BIOSIMILIARS

QPS Biosimilars & Biologics by Phase (N=68)



QPS Biosimilars & Biologics by Indication (N=68)



## A GLOBAL SERVICE CRO

### Drug Development Services

- ▶ Pharmacology
- ▶ Toxicology
- ▶ DMPK
- ▶ Bioanalysis
- ▶ Translational Medicine
- ▶ Clinical Trial Units
- ▶ Clinical Research Services
- ▶ Clinical Trial Kits
- ▶ Central Lab Services
- ▶ PBMC and DEXA Scanning Services

### Clinical Research Services

- ▶ Project Management
- ▶ Clinical Program Management
- ▶ Clinical & Medical Monitoring
- ▶ Data Management & Biostatistics
- ▶ Medical Writing
- ▶ Quality Assurance
- ▶ Regulatory & Medical Affairs
- ▶ Safety & Pharmacovigilance
- ▶ Site Selection & Monitoring



Pharmacology



Toxicology



DMPK



Bioanalysis



Translational  
Medicine



Phase I Clinics

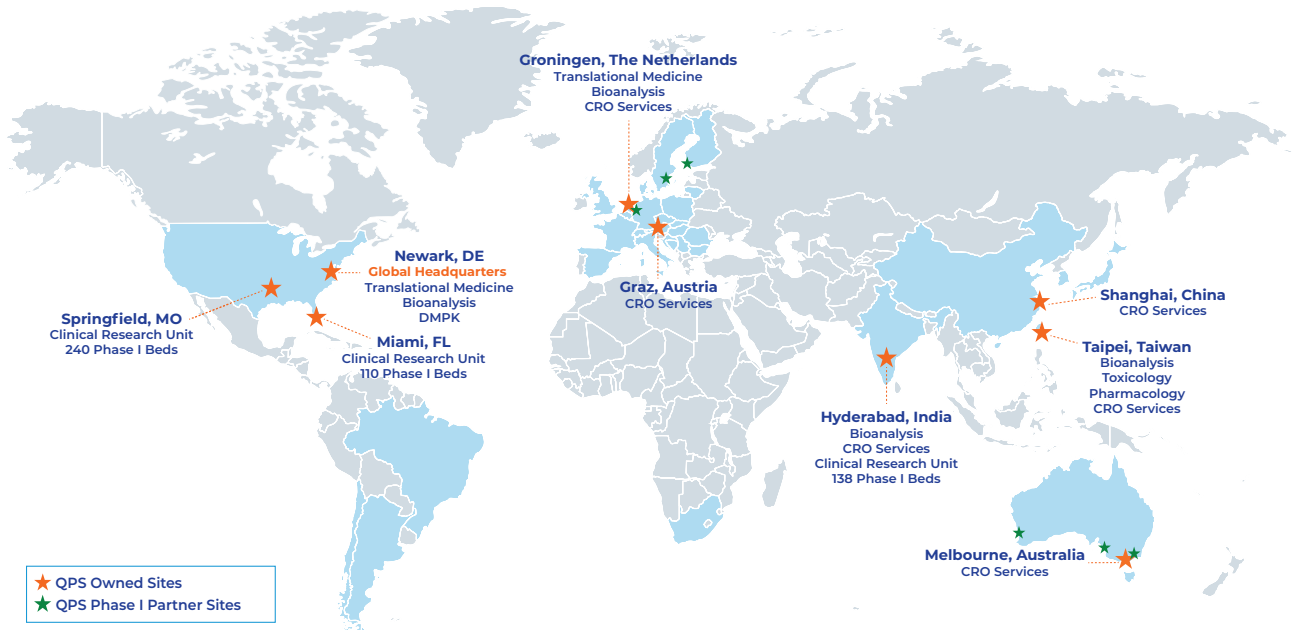


Regulatory &  
Medical



Central Lab  
Services

## QPS CLINICAL TRIAL SITES AND NETWORK LOCATIONS



**NETWORK LOCATIONS** USA / Austria / Australia / Argentina / Belgium / Bosnia / Brazil / Bulgaria / Chile / China / Croatia / Czech Republic / Denmark / France / Finland / Germany / Hungary / India / Italy / Lithuania / Netherlands / Poland / Romania / Serbia / Slovakia / South Africa / South Korea / Spain / Sweden / Taiwan / United Kingdom

Discover how QPS can accelerate your clinical research.

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