



QUALITY • PERFORMANCE • SERVICE



»» QPS Early Stage Clinical Overview



# Talk to QPS

QPS is Your Global Link to all Your  
Early Stage Clinical Sourcing Needs



### Introduction to QPS' Early Stage Clinical Research Services:

With four highly experienced Phase I sites established around the globe, QPS has positioned itself as a true global leader in early stage clinical research services. QPS Clinical Pharmacology Teams routinely conduct over 100 Phase I/IIa studies annually. QPS provides you with one of the world's largest Phase 1 site offerings with 400 Phase I beds on three continents:

- »» 24 in the Netherlands
- »» 92 in India
- »» 40 in Taiwan
- »» 240 in the USA

### Why should QPS be your first and only choice to conduct your Phase I studies?

#### Professional and Experienced Staff

With QPS you get immediate access to its Clinical Pharmacology Teams, including internationally established clinical pharmacologists that have superior scientific expertise in the appropriate – and innovative - design of all types of Phase I studies, as well as the interpretation of the study data. Each Phase I study will have a client dedicated team, headed by an experienced Project Leader, who has the overall responsibility for the conduct of your study and is your single point of contact throughout your Phase I study.

As a full service unit, QPS can assist you with the entire early stage drug development process:

- »» Review of Preclinical Data
- »» Study Design and Medical Writing
- »» Clinical Conduct
- »» Bioanalysis/Biomarker Assays
- »» Data Management
- »» PK/PD Analysis
- »» Biostatistics
- »» Provision of Fully Integrated Clinical Study Reports

#### Global Flexibility and Capacity

At QPS, we realize that in today's drug development space you face many challenges:

- »» Strict timelines
- »» Demanding clinical data collection and reporting requirements
- »» Insufficient Phase I/IIa trial populations
- »» Budgetary constraints

With our four state-of-the-art and strategically located global Phase I facilities, QPS is in an excellent position to cater to all of the above needs. QPS provides high quality data, industry best timelines and a very competitive price. We also have access to a large number of volunteers for all types of clinical studies.

#### Customer Focus

QPS focuses on the needs of each client and works to make sure that those needs are met. We strive to make certain all studies are recruited full and completed on time. We also strive to ensure optimal communications so you have always complete visibility into your project's status and can rest assured that your deadlines will be met and your budgets will not be exceeded. At QPS, we measure our success by your success.

### Specialty/Patient Studies

For Proof of Concept (POC) studies in patient populations, QPS works together with local university and general hospitals. QPS can measure a wide range of pharmacodynamic endpoints and laboratory biomarker assays that are critical to your early stage studies for the evaluation of compounds targeted for a wide variety of therapeutic indications including but not limited to:

- »» Adrenal/Pituitary Disorders
- »» Allergy
- »» Alzheimer's Disease/CNS Disorders
- »» Anemia
- »» Asthma/COPD
- »» Bone Disease/Metabolism
- »» Cardiac Markers
- »» Cell Response
- »» Diabetes/Obesity/Lipid Metabolism/Carbohydrate Metabolism
- »» Gastrointestinal
- »» Hemostasis/Angiogenesis
- »» Immunology/Autoimmune Disease/Rheumatoid Arthritis
- »» Infectious Disease
- »» Inflammation/Immune Status/Cell Response
- »» Phenotypic Markers of Drug Metabolism
- »» Renal Function
- »» Female Health Care/Gynecological Endocrinology/Reproductive Endocrinology
- »» Thyroid Function
- »» Tumor/Neoplasia Markers

### Preferred Provider Relationship: Improved Efficiency and Lower Costs

Each of our four global Phase I sites has unique and complimentary core capabilities and expertise and remains focused on those types of studies in order to gain maximal efficiency. This translates to improved overall quality and project and time management which in turn translates to cost effectiveness, enhanced resource utilization and fewer delays. Improve the efficiency and effectiveness of your drug development efforts and qualify for volume discounts by embracing QPS as your preferred provider for all your Phase I studies. This way you will be assigned a dedicated program manager to handle all your Phase I needs and enjoy maximum benefit of our leveraged strengths of doing different types of Phase I studies at distinct global Phase I sites in order to keep your overall early stage clinical development costs as low as possible.

The QPS Clinical Pharmacology Teams in Groningen - the Netherlands, Taipei - Taiwan, Hyderabad - India and Springfield, MO - USA will work to ensure your study is completed to global standards and procedures. All QPS sites are connected through a global data network to simplify study management for sponsors, providing integrated information and perspective during the entire course of the drug development process.

QPS offers a full range of Phase I services including but not limited to:

- »» First-in-Man Programs (SAD + MAD + FE + CYP450 Interaction) – the Netherlands
- »» Clinical PK/PD studies - the Netherlands, Taiwan, India and USA
- »» Bioavailability studies - Taiwan, India and USA
- »» Bioequivalence studies - Taiwan, India and USA
- »» Drug-Drug Interaction studies - the Netherlands, Taiwan, India and USA
- »» Human Mass Balance studies - the Netherlands
- »» Microdosing studies - the Netherlands
- »» Imaging (PET, fMRI) studies - the Netherlands
- »» Vaccine studies - Taiwan, India and USA
- »» Thorough QT/QTc studies - USA



From left to Right: Level 1: Jerry Gromelski, Irma Scheepstra, Level 2: Jeff Moran, Edwin van Vulpen, Livia Legg, Andrew Nehls, Lily Rosa, Jelle Hempenius, Marina Abanto, Mary Ann Gagnon, Brendon Bourg, Level 3: Jim Cunningham, Wendy Nelson

**QPS-Biokinetic USA** >

Contact: Mark Slama  
 Vice President and General Manager  
 ☎ +1 417 831 0456  
 ✉ mark.slama@bkcaus.com

**QPS-Bioserve India** >

Contact: Suneil Reddy  
 Managing Director  
 ☎ +91 40 2377 0873  
 ✉ suneil@bioserve.co.in

**QPS Netherlands** >

Contact: Wim Tamminga, Division  
 Director Clinical Pharmacology  
 ☎ +31 50 304 8000  
 ✉ wim.tamminga@qps.com

**QPS Taiwan** >

Contact: Vincent Yen  
 President & CEO  
 ☎ +886 2 2655 7555  
 ✉ vincent.yen@qps-taiwan.com.tw

Europe >	
<b>Bioanalysis, DMPK &amp; Toxicology</b>	<b>Early Stage Clinical</b>
Contact: Jelle Hempenius ☎ +31 50 304 8000 ✉ jelle.hempenius@qps.com	Contact: Edwin van Vulpen ☎ +31 50 304 8000 ✉ edwin.van.vulpen@qps.com
<b>Late Stage Clinical</b>	
Contact: Irma Scheepstra ☎ +31 50 304 8000 ✉ irma.scheepstra@qps.com	

**HQ BD Office** >

**USA**

Contact: Lily Rosa  
 ☎ +1 512 350 2827  
 ✉ lily.rosa@qps-usa.com

North America >	
<b>Bioanalysis, DMPK &amp; Toxicology</b>	<b>Early &amp; Late Stage Clinical</b>
Northeast: Wendy Nelson ☎ +1 508 543 0228 ✉ wendy.nelson@qps-usa.com	East Coast: Andrew Nehls ☎ +1 402 895 2022 ✉ andrew.nehls@qps-usa.com
Mid Atlantic: Jerry Gromelski ☎ +1 570 451 3015 ✉ jerry.gromelski@qps-usa.com	Central: Jim Cunningham ☎ +1 402 541 6041 ✉ jim.cunningham@qps-usa.com
Southeast: Marina Abanto ☎ +1 513 232 4772 ✉ marina.abanto@qps-usa.com	West Coast: Jeff Moran ☎ +1 302 690 2163 ✉ jeff.moran@qps-usa.com
Central: Jim Cunningham ☎ +1 402 541 6041 ✉ jim.cunningham@qps-usa.com	
West Coast: Jeff Moran ☎ +1 302 690 2163 ✉ jeff.moran@qps-usa.com	

**Asia** >

**Taiwan**

Contact: Alex Chang  
 ☎ +886 2 2655 7555  
 ✉ alex.chang@qps-taiwan.com.tw

**India**

Contact: Manish Kalwani  
 ☎ +91 40 2377 0873 74  
 ✉ manish@bioserve.co.in

**Japan**

Contact: Alex Chang  
 ☎ +886 2 2655 7555  
 ✉ alex.chang@qps-taiwan.com.tw

**Other Asian Countries**

Contact: Alex Chang  
 ☎ +886 2 2655 7555  
 ✉ alex.chang@qps-taiwan.com.tw

Delaware Technology Park  
 3 Innovation Way, Suite 240  
 Newark, DE 19711



WEB www.qps.com  
 TEL (302) 369-5601  
 FAX (302) 369-5602