QPS

helps you navigate

QPS IS YOUR GLOBAL LINK FROM CANDIDATE SELECTION TO PHASE II PROOF OF CONCEPT

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QPS is a highly competent, high-quality, yet cost effective and accessible CRO that goes above-and-beyond to build a trusting relationship with you.
Please allow us to help save you valuable time and decrease the cost of drug development by linking with QPS for the following suite of global drug discovery and development services:

YOUR GLOBAL LINK TO DMPK & TOXICOLOGY SERVICES

- Preclinical Services at our USA and Taiwan Facilities
- High quality DMPK & Toxicology capabilities (full AAALAC Accreditation since 2000)
- Supported over 1000 GLP toxicology studies since 1997

YOUR GLOBAL LINK TO BIOANALYTICAL SERVICES

- GLP Bioanalytical Facilities in the USA, Europe, India and Taiwan
- One of the largest CROs in bioanalysis for small molecules and biologics
- Extensive list of validated assays; > 800 and growing
- Chromatography & Mass Spectrometry (LC-MS/MS)
- Biochemistry & Immunology (ELISA, hybridization-ELISA)
- Elemental Spectrometry (ICP-MS)

YOUR GLOBAL LINK TO TRANSLATIONAL MEDICINE SERVICES

- Specialized biomarker assay capabilities in various niche areas
- Assistance with selection and evaluation of the right biomarkers during early drug development
- Molecular biology/genomic services including RNA/DNA isolation; SNP genotyping and genetic mutation analysis; quantitative RT-PCR; RNA expression analysis; and microarray gene expression profiling

YOUR GLOBAL LINK TO EARLY STAGE CLINICAL RESEARCH SERVICES

- Over 400 phase I beds in the USA, Europe, India, and Taiwan; one of the best and largest phase I site offerings in the world catering both to the needs of the innovative and the generic pharmaceutical industries
- Highly experienced, flexible and customer-focus phase I units leading to better efficiency and quality during the conduct of your early stage clinical trials

YOUR GLOBAL LINK TO LATE STAGE CLINICAL RESEARCH SERVICES

- Worldwide contract clinical staffing and pharmacometrics capabilities (incl. data management, biostatistics, PK/PD evaluation and medical writing capabilities) that will expedite your next development milestone ahead of schedule

QPS will help you navigate effectively through the discovery processes of lead optimization and candidate selection to accelerate your compounds into development!

A well-conceived and executed IND-enabling preclinical program and completion of early clinical trials will provide you with a detailed assessment of your drug candidate including the most cost-effective and timely pathway to filing an IND and completion of the phase II proof-of-concept studies. Before we begin executing your IND-enabling preclinical program at QPS, you will receive strategic review and advice on the design of your ADME and pharmacology-toxicology studies together with an in-depth analysis of deficiencies and potential roadblocks whereby non-clinical development objectives will be confirmed. Furthermore timelines for your overall program and individual studies will be mapped out and crucial milestones established. In addition, you will receive consultation by experienced clinical pharmacologists and project managers on developing the clinical development plan beginning with the first-in-human study to completion of the phase II proof-of-concept studies. The latter consultation will involve the identification of appropriate biomarkers for early indications of biological activity by highly trained translational medicine scientists as well.

During execution of your IND-enabling program you will benefit from QPS' operational strengths, strong scientific/regulatory pre-IND/IND support and drug development experience:

OPERATIONAL STRENGTHS

- ADME scientists and toxicologists with extensive industry and CRO experience allow for optimal planning, and execution of ADME and pharmacology-toxicology studies
- State-of-the-art ADME, toxicology, and bioanalytical facilities
- Rapid execution and completion of all non-clinical studies required for IND submissions
- All studies will be carefully monitored and every phase of the studies critically assess for scientific rigor and quality by a dedicated program manager with pharma or biotech background
- Fast turnaround on high quality non-clinical study reports
- Extensive experience in the preparation of ADME and pharmacology-toxicology sections of IND submissions
- Rapid initiation of study and enrollment of human subjects in phase I studies
- Seamless coordination between the clinical research unit and the bioanalytical facility to rapidly generate data from single and multiple dose escalation studies
- Data management, statistical analysis and preparation of high quality clinical study reports

SCIENTIFIC REGULATORY PRE-IND/IND/EARLY CLINICAL RESEARCH SUPPORT

- Review and gap analysis of available data, non-clinical and clinical development plans
- Advice on the design and timing of ADME, safety pharmacology, toxicology, clinical pharmacology and phase II proof-of-concept studies
- Provide expert advice on ADME and pharmacology toxicology issues associated with a broad range of therapeutic areas
- Rapid completion of the ADME and pharmacology toxicology sections of the IND to enable client to file the IND in a timely manner
- Participate in pre-IND meeting with regulatory agencies
- Rapid completion of phase I and phase II proof-of-concept studies and advance drug candidate to phase IIb

Should you want to discuss your questions in more detail with one of our experts, please contact us directly at: **info@qps.com**

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