# A FLEXIBLE APPROACH TO TOXICOLOGY

## AT QPS, OUR COMMITMENT IS TO PROVIDE EACH ONE OF OUR VALUED CUSTOMERS

with a fast and reliable route to clinical Phase I/II studies. We offer a wide range of toxicity and DMPK studies as well as other preclinical safety tests that are essential for your preclinical drug development programs.



#### **QPS TOXICOLOGY OVERVIEW**

QPS' globally recognized toxicology scientists offer a wide range of toxicity studies and preclinical safety tests that are essential for preclinical drug development programs. We have a long and successful track record of designing specialized *in vivo* studies.











General Genetic Toxicity Toxicity

Reproductive Toxicity

Biocompatibility Testing

Clinical Pathology

#### **TOXICOLOGY SERVICES**

Quality, expertise, and flexibility are key factors in our services. At QPS, we work closely with our clients to ensure that all of the regulatory studies required for your IND filing are included in the plans we develop. We will design and execute the most appropriate development strategies for your drug candidates.

QPS Taiwan is a GLP compliant (US FDA, TFDA, TAF OECD), AAALAC accredited facility and is a member of the Taiwanese Medical Products Agency GLP inspection program. Our GLP-compliant, quality assurance-audited studies are specifically designed to meet the compliance requirements of the OECD GLP and US FDA GLP while fulfilling the exploratory or validation needs of our clients.

Excellence in animal care and use are achieved following the AAALAC accreditation program. All studies are approved by a local Animal Ethics Committee. The barrier-designed facility provides housing capacity for major test systems of rodent and non-rodent species including mice, rats, hamsters, guinea pigs, rabbits, dogs, and mini pigs.





#### **BIOCOMPATIBILITY TESTING**

- Mutagenicity Test (ISO 10993-3)
- in vitro Hemolysis (ISO 10993-4)
- Cytotoxicity (ISO 10993-5)
- ▶ Implantation (ISO 10993-6)
- ▶ Irritation / Sensitization Test (ISO 10993-10)
- System Toxicity Test (ISO 10993-11)

#### **GENERAL & REPRODUCTIVE TOXICITY**

- Single Dose Toxicity Studies
- Repeated Dose Toxicity Studies
- Systemic Safety and Risk Assessment
- ▶ Fertility and Early Embryonic Development
- ► Embryo-fetal Development

#### **GENETIC TOXICITY**

#### **Gene Mutation Assays**

- Ames Test
- in vitro Mouse Lymphoma Assay

#### **Chromosome Aberration Assay**

- ▶ CHO Cells
- Human Lympocytes

#### Micronucleus Assays

- ▶ in vitro in CHO Cells
- in vivo in Mice and Rats

#### HISTOPATHOLOGY

- Slide Preparation
- ▶ Tissue Image
- ▶ Pathology Consultation and Evaluation
- ▶ Board Certified Veterinary Pathologists

#### **CLINICAL PATHOLOGY**

- ► Hematology (including coagulation)
- Serum Chemistry
- Urine Analyses



#### SCIENTIFIC LEADERSHIP AND PROVEN RESULTS



Our dedicated, experienced team ensures that toxicology studies done at QPS meet all timelines and regulatory requirements. QPS provides high quality data, direct access to our technical staff, regularly scheduled updates in a format that works for you, and prompt and courteous answers to your inquiries.







#### QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD



### BENEFIT FROM THE WORLDWIDE RESOURCES THAT A GLOBAL CONTRACT RESEARCH ORGANIZATION BRINGS

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of bioanalytical services to support drug development needs from discovery, through clinical development and regulatory filing.





TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!