

A flexible approach to

Toxicology and Preclinical Services

**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.

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

CALL +1 512 350 2827 **EMAIL** infobd@qps.com



Toxicology Services Overview

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. As a direct result, we will design and execute the most appropriate development strategies for your drug candidates.

QPS Taiwan is an ISO/IEC 17025 certified and GLP compliant (US FDA, TFDA, TAF OECD), AAALAC accredited facility and is part of the Taiwanese Medical Products Agency GLP inspection program. Studies can be performed in compliance with OECD GLP guidelines and complete quality assurance conducted for those studies aimed for regulatory purposes.

The animal facility is a barrier-designed facility, which houses various species including mice, rats, hamsters, guinea pigs, rabbits and dogs. Excellence in animal care and use are achieved following the AAALAC accreditation program. All studies are approved by a local Animal Ethics Committee.

General Toxicity

- ▶ Single Dose Toxicity Studies
- ▶ Repeated Dose Toxicity Studies
- ▶ Systemic Safety and Risk Assessment
- ▶ Serum Chemistry

Reproductive Toxicity

- ▶ Fertility and Early Embryonic Development Studies
- ▶ Teratology Studies (Embryo-fetal Development Studies)

Genetic Toxicology

- ▶ Gene Mutation Assays
 - Ames Test
 - *In vitro* mouse lymphoma assay
- ▶ Chromosome Aberration Assay
 - In CHO cells
 - In human lymphocytes
- ▶ Micronucleus Assays
 - *In vitro* in CHO cells
 - *In vivo* in mouse peripheral blood

Biocompatibility Testing

- ▶ Mutagenicity Test (ISO 10993-3)
- ▶ *In vitro* hemolysis (ISO 10993-4)
- ▶ Cytotoxicity (ISO 10993-5)
- ▶ Implantation (ISO 10993-6)
- ▶ Skin Irritation / Sensitization Test (ISO 10993-10)
- ▶ System Toxicity Test (ISO 10993-11)

Clinical Pathology

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

Histopathology

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

QPS is a Global CRO with locations around the world

