



Preclinical outsourcing Korea, Taiwan and Singapore: Contrast capabilities with US and China

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Director & Co-founder

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Hong Kong, SAR



Tiawan and Singapore

- Maccine Singapore
- QPS Taiwan (Formerly CTPS)
- KIT South Korea



QPS Taiwan

- QPS Taiwan acquired the Center of Toxicology and Preclinical Sciences (CTPS) from Taiwan's Development Center for Biotechnology (DCB) in 2011.
- CTPS was set up by the DCB in the late 90's to provide preclinical testing services for government, academic and industrial groups working in the country's drug sector and is one of the oldest and most experienced GLP laboratories in Asia.



QPS CTPS Taiwan

- QPS CTPS Taiwan is a ISO/IEC 17025 certified, GLP compliant (Taiwan DOH, OECD) and AAALAC accredited facility specializing in general nonclinical toxicity and safety testing, genetic toxicology, reproductive toxicology, immunotoxicity testing, biocompatibility testing, and DMPK studies. The center for toxicology and preclinical services covers 5600 square meters (60,000 square feet) and includes: seven laboratories, three culture rooms, a quality assurance unit, archives, and two floors of animal housing.
- In the past 12 years, CTPS has conducted over 900 studies for local and international clients, including 17 projects for US IND submissions, 18 projects for Taiwan IND submissions or clinical trials, and two products seeking Taiwan NDA approval.



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QPS-CTPS

- **Walter Bee, Ph.D.**
Vice President and Global Head of Safety Assessment and Regulatory Affairs
- Dr. Walter Bee brings over 20 years of CRO and Pharma/Biotech experience in Preclinical Development to QPS. Prior to joining QPS in 2010, Dr. Bee was Vice President, Preclinical Development, at Halozyme, a biotechnology company in San Diego. Before, he held positions as Director of Toxicology, Pathology and Laboratory Animal Medicine at Johnson & Johnson on the West Coast and as Director of Toxicology at Scios Inc. At J&J/Scios,
- **Charlene Chen, Ph.D.**
Senior Director of Toxicology
- Dr. Charlene Chen joined QPS in 2011; she is currently responsible for operation of the Center of Toxicology and Preclinical Sciences. Before joining QPS, Dr. Chen served as the Director of Toxicology facility in Development Center of Biotechnology (DCB), the first and largest preclinical CRO in Taiwan with over 20 years of history in preclinical testing. During her tenure as Managing Director in DCB, Dr. Chen was instrumental in obtaining the Department of Health (DOH) GLP compliance inspection approval and the certification of OECD GLP national compliance monitoring system. The team has complied 17 dossiers for US FDA submission since 2000.
- **Andrew Nen**
Vice President of Operations
- Mr. Andrew Nen joined QPS Taiwan in 2003 as Vice President of Operations. Prior to joining QPS Taiwan, he served as a Vice General Manager at Li Chang Investing Co., Ltd. and at Sagittarius Life Science Co., Ltd. where he was involved in IND filing and regulatory meetings with the DOH, as well as grant application with MOEA. Mr. Nen received his B.S degree and M.S. in pharmaceuticals from National Taiwan University.



Macinne

- *Species*
 - *Rodent*
 - *Non-Human Primate*
- *Protocols*
 - *Dose Range Finding*
 - *Maximum Tolerated Dosing*
 - *Acute, Sub-Chronic and Chronic Toxicity*
 - *Immunotoxicity Evaluation*
- *Administration Routes*
 - *Standard Extra-vascular Routes (Oral Gavage, Dermal, etc.)*
 - *Infusion - Intermittent or Continuous*
 - *Intracranial Infusion and Injection*
 - *Other Routes Upon Request*
- *Support Services*
 - *Dose Formulation Analysis*
 - *Clinical Pathology (Haematology, Serum Chemistry, Coagulation)*
 - *Flow Cytometry*
 - *ELISA*
 - *Histology*
 - *Imaging*
 - *Specialist Consulting*



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Molecular Imaging

- **Combined High Resolution PET & 64-Slice CT**
 - Receptor occupancy studies
 - Biodistribution
 - Novel target evaluations
 - NHP efficacy pharmacology model characterization
- **MRI (3T)**
 - Body composition quantification
 - Characterization of brain activity
 - Muscle density
 - In-vivo drug quantification measurement
 - NHP efficacy pharmacology model characterization
- **DEXA**
 - Bone mineral density
 - Body composition quantification
- **X-Ray**
- **Ultrasound**



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Korea Institute of Toxicology

Korea Institute of Toxicology

Year Established

1980

No. of Employees

186

Website

<http://www.kitox.re.kr/eng/>

Headquarters

Daejeon, South Korea

Laboratories

Daejeon, South Korea

Service Areas

Pharmacology, Toxicology



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Korea Institute of Toxicology

Korea



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Korea Institute of Toxicology

May 2010

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