Q-Pharm Pty Limited

- Private company established July 2002 as a spin-out from The University of Queensland
- Specializing in Early Phase trials (I/II) and pharmacokinetic and bioequivalence studies
- Located on campus of the Royal Brisbane & Women’s Hospital within Queensland Institute of Medical Research
- Excellent inpatient & outpatient clinic facilities
- Staff highly experienced in early phase clinical research
- FDA Inspected in 2007 (successful, data accepted, no 483s)
Q-Pharm Location 1

Brisbane:
- Population - 1.6 million
- 3rd largest Australian city
- Voted a “World’s Most Livable city”
Q-Pharm Location 2

Location: Brisbane, Queensland, Australia
• Royal Brisbane & Women’s Hospital Complex
• Co-located within QIMR
Q-Pharm - Services

- Phase 1 trials, broadly defined, including first-in-humans, early stage pharmacokinetic, vaccines
- Bioavailability and bioequivalence studies
- Pharmacokinetic drug-drug interaction studies
- Out-patient or in-patient trials
- Strategic Alliance with TetraQ for sub-contracted bioanalytical services
# Q-Pharm Management Personnel

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
<tr>
<td>Chief Executive Officer</td>
<td>Terry Hurst</td>
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<tr>
<td>Operations Manager</td>
<td>Suzanne Elliott</td>
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<tr>
<td>Medical Services</td>
<td>Joanne Marjason</td>
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<tr>
<td>Clinical Services</td>
<td>Laurie Kear</td>
</tr>
<tr>
<td>Data Management</td>
<td>Carolyn Madigan</td>
</tr>
<tr>
<td>Business and Corporate Development</td>
<td>Nathan Martinez</td>
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<tr>
<td>Business Services</td>
<td>Rob Box</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Andrew King</td>
</tr>
<tr>
<td>Consultant (Immediate Past Managing Director)</td>
<td>Professor Wayne Hooper</td>
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</tbody>
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Copyright: Q-Pharm Pty Limited
Q-Pharm Clinic Personnel

**Medical**
- Four staff doctors
- CT Pharmacist

**Clinic** - Clinic Manager
- Project Managers
- Nurse Supervisor
  - Clinic Resources & Training
  - Appointed nurses/clinic staff
  - Casual nurses and clinic assistants
- Clinic Laboratory Coordinator

**Data Management Unit**
- Unit Supervisor
- Data Manager
- Clinical Trial Assistants (CTA)
Clinic Facilities (Levels 3 & 6 - Block 9)

Features
- Recruitment & Outpatient Facilities
- 36 bed ward with subject amenities and recreation areas
- Synchronized clocks
- Processing laboratory
- Emergency trolleys & Immediate access to emergency response team
- Access to dietary services
Phase 1 Clinic (D Floor-CBCRC)

Features

- In & out patient beds with full electrophysiological monitoring and telemetry
  - 12 bed highly specialised facility for early phase trials & patient based trials
- Secured pharmacy
- Minor procedures room
- On-site Laboratory processing (PC2)
- Subject recreation areas
- Emergency trolleys & Immediate access to emergency response team
Q-Pharm Clients

- Australian & International
  - Pharma
  - Biotech
  - CRO
  - Nutraceutical

Projects Cover
- Small molecule drugs
- Biotech products (therapeutic & diagnostic)
- Vaccines
Q-Pharm Experience

Completed

- “first-in-humans” trials – biologic (MAb + others), NCE
- Genetically modified vaccine trials
- Vaccine and drug interaction studies
- Healthy Volunteers & Patient Groups
- Major routes of drug delivery
  (oral, S/C, IV, inhaled, implant, transdermal)
Q-Pharm Experience

.Completed 150 trials to January 2008

. Healthy Volunteers
  - BA/BE/PK studies
  - Proof of Concept studies
  - SAD/MAD/Food effect studies
  - Japanese Bridging studies
  - Radioimmunoscintigraphy
  - Gastric pH monitoring
  - Anaesthetic agents
  - Medical Devices
  - Long term confinements

. Patient Groups
  - Glucose Clamp
  - Cytotoxic agents
  - Anti viral dose escalation study
  - Inhaled deliveries/Devices
Therapeutic areas of experience

- Cardiovascular: CHF, COPD
- Endocrinology: Diabetes
- Dermatology: Anti-infectives, Common skin cancer
- Gastroenterology: Crohn’s Disease, Reflux
- Infectious Diseases: Hepatitis C, JE vaccine, Influenza vaccine, Malaria vaccines
- Respiratory: Asthma, Cystic Fibrosis, Antibiotic
- Rheumatology: Rheumatoid Arthritis
- Oncology: Advanced cancer
- CNS/Neurology: Epilepsy, Alzheimer's, Pain
- Psychiatry: Drug addiction
- Gynaecology: HPV vaccine, Contraceptives
- Anaesthesia: Healthy Volunteer study
- Medical Imaging: Radiolabelled MAb
- Orthopaedics: Tibial fractures, Osteoporosis
- Haematology: Erythropoeisis
Q-Pharm Memberships and Collaborations

❖ **Memberships**
  ❖ AusBiotech
  ❖ Queensland Clinical Trials Network
  ❖ Association of Regulatory & Clinical Scientists

❖ **Strategic Alliance**
  ❖ TetraQ
    ❖ Bioanalytical services in support of PK studies

❖ **Collaborations**
  ❖ Microdosing units
    ❖ Specialist overseas companies
  ❖ Brain Gut Research group
    ❖ Bern, Switzerland
    ❖ Highly experienced niche provider in Pain and GE
Successful Inspections/Audits

**Inspections by Regulatory authorities**
- **FDA** 2007
- **ANVISA (Brazil)** 2006, 2003

**Inspections by Australian Regulators**
- **TGA** does not conduct routine inspections (has the authority to do so)
- **Queensland Health** 2004 (dispensary recognition)
- Other Regulators, OGTR

**Audits by Sponsors**
- International and Local ~5 per year
- Monitoring required by GCP
Q-Pharm – Special Services

Gamma camera radioscintigraphy

- Excellent collaboration with RBWH Nuclear medicine
- Able to label doses with technetium
- Have conducted imaging studies with technetium labelled monoclonal antibodies
Q-Pharm has conducted two bridging studies in healthy subjects involving Japanese and Caucasian participants.

- Established subject database
- Employing support staff
  - Japanese & Japanese-speaking nurses
  - Japanese Project Support Office
Q-Pharm – Special Services

Phase Zero (microdosing) studies

- Collaboration with specialist overseas companies
- Q-Pharm conducts clinical studies to GCP*
- Samples sent to specialist overseas companies
- Accelerator Mass Spectrometry used for sample analysis.

* Requires availability of trace quantities of $^{14}$C-labelled active ingredient for dosing
In June 2008 TetraQ, the integrated preclinical contract research organisation based at The University of Queensland (UQ), and Q-Pharm, a leading early phase clinical trial facility in Australasia, announced a strategic alliance to enhance the delivery of bioanalytical services to clients in the biotechnology and pharmaceutical industries.

- The alignment of the two organizations at the interface of the preclinical and early phase clinical stages of the drug development pathway presents significant opportunities for capturing operational economies, co-marketing of services, cross-referral of potential clients and providing a more complete and streamlined service.
- Since its announcement in June, this alliance has been positive and has already resulted in 6 projects of significant size being undertaken at Q-Pharm/TetraQ with many more in the pipeline.
Quality
In
Contract Clinical Research

www.qpharm.com.au