

Q - Pharm



Q - Pharm

# 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**



**Mervyn Eadie Clinic (Level 6), Outpatients Clinic (Level 3)**

Copyright: Q-Pharm Pty Limited



# Royal Brisbane & Women's Hospital Campus



BUTTERFIELD STREET



GARRICK TERRACE

Ronald McDonald House



Main Entrance

Walkway

**Adult Emergency**

Herston Medical Research Facility

H.A.D.S. Building

Joyce Tweddell Building

Oncology (Cancer Services)  
(Infectious Diseases (Wittle Ina))

Royal Brisbane and Women's Hospital  
Ned Hanlon Building  
Birthing Suite  
General Wards and Services

Dr James Mayne Building  
Intensive Care  
Coronary Care  
Burns Unit  
Specialist Services

Child & Family Therapy Unit (CFTU)

Joyce Tweddell Building Entrance

Block 50 Engineering

Education Centre

St. Alberts Research Laboratory

Central Energy Plant

Block 15 Safety & Security

Block 20

Leonard Lodge

Kidsafe House

Lady Ramsey Childcare Centre

Childrens Nutrition Research

Edith Cowell Building

Fye House

Clinical Sciences

Block 19

Education Centre

Lady Norman Wing

Lady Larlington Building

Mental Health Centre

Block 6  
Queensland Health State Development Centre  
Hanlon Medical Library

BRAMSTON TERRACE



Royal Children's Hospital  
**Children's Emergency**

level 3 lift

level 4 lift

Block 7  
QHPS Information Services

Woolworths Building

Centre block

Surgical Building

Hydrotherapy Pool

QIMR Bancroft Centre

Block 9

Clive Berghofer Cancer Research Centre

HERSTON ROAD

**Q-Pharm facilities**



BOWEN BRIDGE ROAD



# 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

Q - Pharm

<b>Chief Executive Officer</b>	<b>Terry Hurst</b>
<b>Operations Manager</b>	<b>Suzanne Elliott</b>
<b>Medical Services</b>	<b>Joanne Marjason</b>
<b>Clinical Services</b>	<b>Laurie Kear</b>
<b>Data Management</b>	<b>Carolyn Madigan</b>
<b>Business and Corporate Development</b>	<b>Nathan Martinez</b>
<b>Business Services</b>	<b>Rob Box</b>
<b>Quality Assurance</b>	<b>Andrew King</b>
<b>Consultant</b> (Immediate Past Managing Director)	<b>Professor Wayne Hooper</b>

# 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)

Q - Pharm



## 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



Copyright: Q-Pharm Pty Limited



# 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
- ◆ Radioimmunosciintigraphy
- ◆ 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** Erythropoiesis

# 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)
  - ◆ **NATA** 2007, 2004, 2001  
(National Association of Testing Authorities)
  - ◆ **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 radiosciintigraphy

- ◆ **Excellent collaboration with RBWH Nuclear medicine**
- ◆ **Able to label doses with technetium**
- ◆ **Have conducted imaging studies with technetium labelled monoclonal antibodies**



# Q-Pharm Special Services

## Bridging Studies

- ◆ **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  $^{14}\text{C}$ -labelled active ingredient for dosing





# Q-Pharm – TetraQ Strategic Alliance



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](http://www.qpharm.com.au)**