

Q - Pharm



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Development of New Pharmaceuticals: Opportunities and Challenges for Quality Assurance

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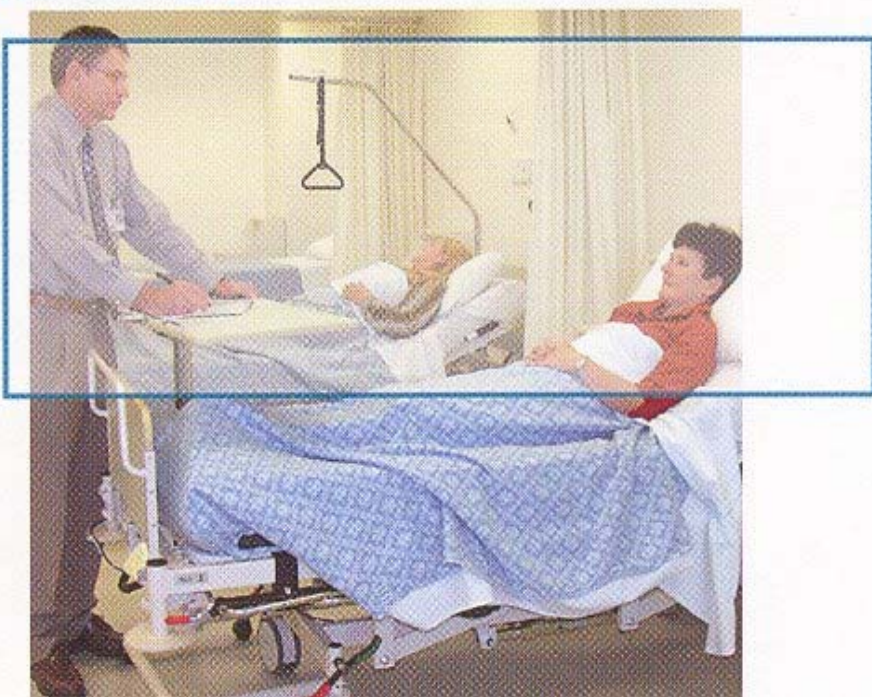
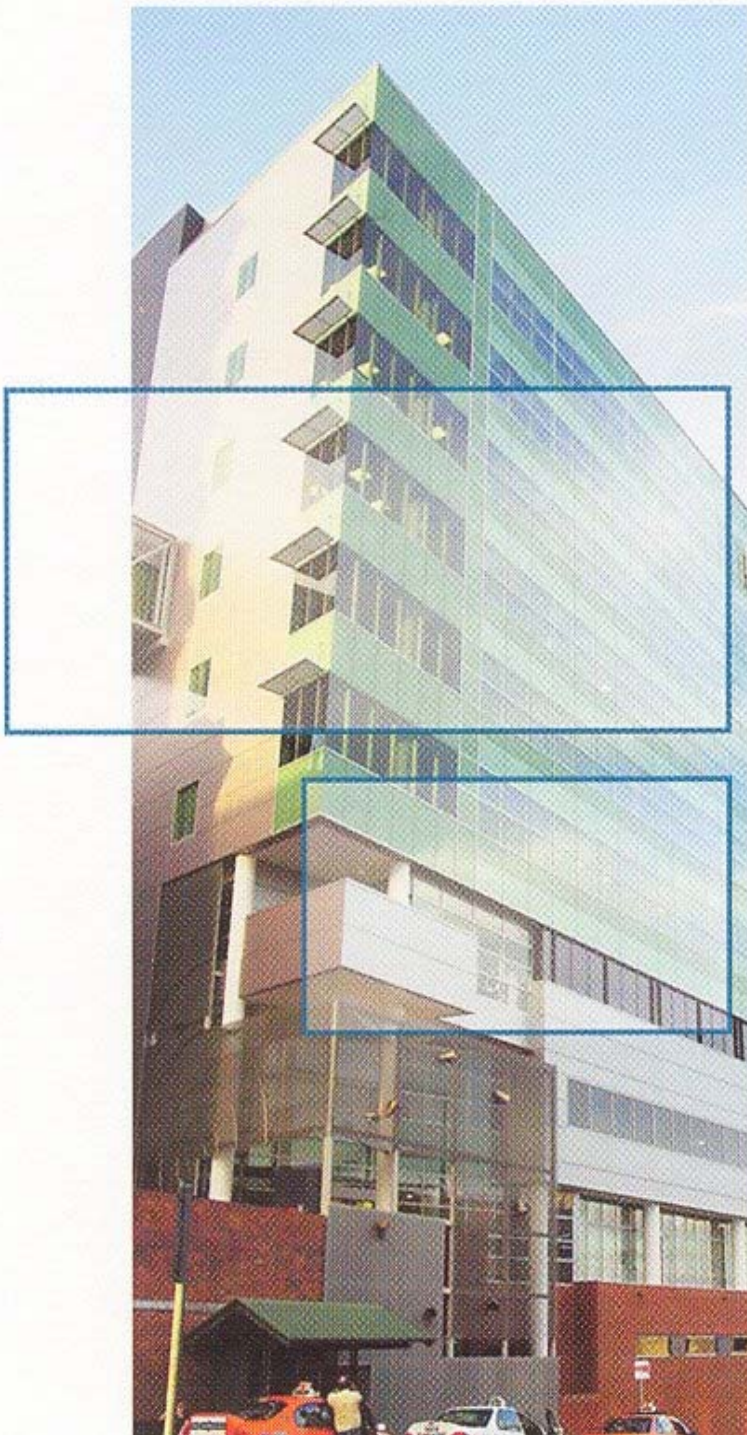
Q-Pharm Pty Limited

Introduction

Development of New Pharmaceuticals: Opportunities and Challenges for QA

- ◆ Pharmaceutical Regulatory Requirements
- ◆ Quality Assurance Responsibilities
- ◆ Opportunities for Quality Assurance

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Background

Location: Brisbane, Queensland

- **Royal Brisbane Hospital Complex**
- **Co-located within QIMR**



Mervyn Eadie Clinic (Level E)

Q-Pharm Clinic Facilities

Q - Pharm



Features

- In & out patient beds with full electrophysiological monitoring
- Secured pharmacy
- Minor procedures rooms
- Laboratory for on-site processing



Q-Pharm Laboratory Facilities

- ◆ Trials in accordance with NATA accreditation
- ◆ Operating in compliance with ISO/IEC standard 17025-1999



Equipment:

- ◆ 6 HPLC + all detector options
- ◆ 1 GC/MS
- ◆ 2 API 2000 LC/MS-MS



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Driving the economic development of Queensland



Queensland Pharmaceuticals Action Plan

Queensland's pharmaceutical industry is an important contributor to sustainable economic growth, being highly innovative, globally competitive, attractive to investment and export focused.

The objectives of the Queensland Pharmaceuticals Action Plan are as follows:

- Jobs** Increased employment in the sector – R&D, manufacturing
- Industry Size** Increased establishment of organisations listed or registered with the TGA
- Exports** Increase in quantum of exports and number of export markets

8.26 x 11.69 in 1 of 2 Internet

An Industry in Growth

Industry	Projected 5 Year Revenue Average Compound Growth Rate
Scientific research	3.0%
Medicinal and pharmaceutical product manufacturing	4.9%
Medical and surgical equipment manufacturing	3.4%
Cosmetic and toiletry preparation manufacturing	4.3%
Pharmaceutical and toiletry wholesaling	4.6%
Pharmaceutical, cosmetic and toiletry retailing	5.8%

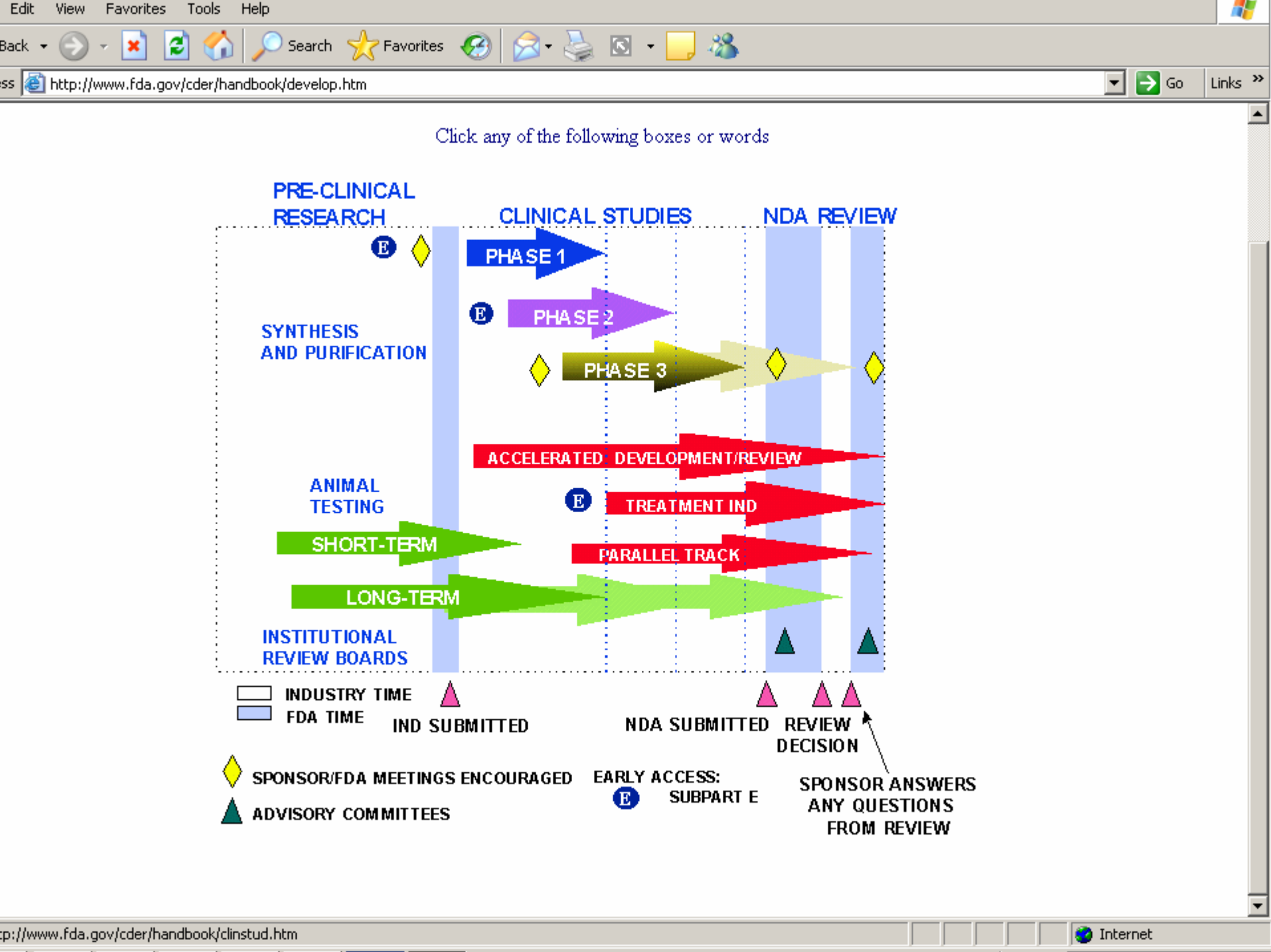
Source: www.sdi.qld.gov.au

REGULATORY REQUIREMENTS

DEVELOPMENT OF PHARMACEUTICALS

- ◆ **Pharmaceutical Development Process**
- ◆ **Codes and Standards**
- ◆ **Expectations of Clients and Regulators**





Regulatory Compliance

CODES AND STANDARDS (GxPs)

- ◆ **GLP – Good Laboratory Practice**
OECD v. US FDA
- ◆ **GCP – Good Clinical (Research) Practice**
ICH
- ◆ **GMP – Good Manufacturing Practice**
Also for GCP

International trends to harmonize

Regulatory Compliance

EXPECTATIONS

◆ Documentation

Authorised description of how the process or task is conducted and recorded. I.e., “policies”

◆ Records

Evidence (legally acceptable) of what was done.

◆ Responsibility

System for staff responsibility for actions.

Regulators: TGA (NATA – GLP), FDA, EMEA

Regulatory Compliance

◆ Computerised Systems

- ◆ Both strengths and weaknesses are recognised

◆ *A single task may involve compliance with a number of legally binding requirements, e.g.:*

- *Regulatory acceptance of study (Australian or OS)*
- *Regulation of clinical studies (Fed & State)*
- *Staff safety (State)*
- *Hygiene, waste etc. (Local & State)*

Admissibility of evidence of compliance may depend on application of a published standard or code (Australian and ISO standards are widely accepted.)

Regulatory Compliance

Requirements for Regulatory Acceptability

(Protocol, Records, Calibrations, Staff Training etc.)

Genetically Modified
Organisms

STUDY

ACTIVITY

OGTR

Pharmacy Regulations &
Holding of restricted items

Lab Data: - NATA
& lab compliance

Importation – license

HREC

GCP
**Requirements for
Clinical Trials**

**OH&S
FIRE**

AQIS

**Waste Treatment
biological / chemical**

EMS

Regulators: Local - State - Federal - International



Data - ALCOA

- ◆ **Attributable**
 - ◆ **Legible**
 - ◆ **Contemporaneous**
 - ◆ **Original**
 - ◆ **Accurate**
- ◆ Reference: US FDA.

QUALITY ASSURANCE

RESPONSIBILITIES IN DRUG DEVELOPMENT

- ◆ **Current Situation**
- ◆ **Example – Good Laboratory Practice**
- ◆ **Future for QA**

QA Responsibilities

CURRENT SITUATION

◆ Traditional Nature

Compliance focussed – little TQM, variable with code, often confused with Quality Control

◆ GLP – QA role defined by GLP

◆ GCP – rules if conducted; industry expectation equates to a requirement

◆ GMP – defined by regulators (“Qualified Person” – Fit and Proper)

QA Responsibilities

GLP (summarised from OECD GLP)

- ◆ maintain copies of approved study plans and Standard Operating Procedures
- ◆ verify that the study plan contains the information required for compliance
- ◆ conduct inspections to assess GLP compliance
- ◆ inspect the final reports to confirm both compliance and data accuracy
- ◆ promptly report any inspection results
- ◆ prepare and sign a statement, for the final report, (inspections and their dates, the reporting dates, confirm report accurately reflects raw data)

QA Responsibilities

FUTURE

- ◆ **Emerging: standards for R&D conduct**
 - Efforts in Australia (NATA, Federal Government review of research) and Overseas (UK – DEFRA)*
- ◆ **Drivers**
 - ◆ Outsourcing of Research and Development
 - ◆ Demonstration of diligence
 - ◆ Community expectations
 - ◆ Return on Investment
- ◆ **Regulatory QA Profession at Crossroads**
 - ◆ No national research QA organisation (cf BARQA)

QUALITY ASSURANCE

OPPORTUNITIES AND CHALLENGES

- ◆ **Assessment of Opportunities**
- ◆ **Challenges facing the Sector**
- ◆ **Challenges facing QA Professionals**

"Obstacles are those frightful things you see when you take your eyes off your goal." - Henry Ford (1863-1947)

Opportunities

PHARMACEUTICAL AND QUALITY SECTORS

◆ Growth of industries in Australia

Pharma, Biotech AND their support industries all need QA/Regulatory expertise

◆ Expansion in QA roles

Emerging debate – the need for Pharma to embrace what mainstream Quality has to offer

◆ The government IS here to help

Federal – AusIndustry, Qld – State Development & Innovation

(Notable local successes)

Challenges

INDUSTRY

◆ **Convince industry to embrace TQM**

This debate will be driven globally by competition

◆ **Develop the pool of regulatory professionals**

Several arenas – QA, regulatory affairs, corporate compliance, research writers

Knowledge needed beyond regulatory professionals

◆ **Responsibility**

Who should drive this? Industry will benefit from growth of expertise

Challenges

QA PROFESSIONALS

◆ Where to start?

Not a clear profession path (usually from another profession – this may be good)

◆ Collegiate opportunities

Associations limited – ARCS, BARQA

◆ Convincing management re holistic QA

Who should drive this?

"All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident." - Arthur Schopenhauer (1788-1860)

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