

QCTN News

From the CEO's desk...



Mario Pennisi

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Good Clinical Practice

Despite the necessity to conduct all research to GCP standards there are a limited number of people in the industry who have significant, formal training in the requirements of GCP.

There are a number of pressures on Australian researchers to formalise their knowledge of GCP in order to maintain international competitiveness and to reduce their development costs. Increasingly, Australia's competitors are now focusing on GCP training as a measure of quality. Most clinical researchers in Australia have short, usually one hour, training in GCP as part

of a formal 'initiation meeting' for a commercially sponsored clinical trial. Many investigator sponsored trials do not have a formal initiation meeting and do not maintain records of training in GCP. This shortage of formal, documented training in GCP may soon come to haunt Australian researchers.

For this reason it is pertinent for all applicable QCTN members to ensure their staff members have the appropriate up-to-date training in their required fields to maintain a competitive advantage (or at least not fall behind). QCTN provides support for members undertaking GCP training - please see our website for these training events.

AusBiotech wrap-up

As you would all be aware QCTN and several members attended the recent AusBiotech Conference held at the Brisbane Convention & Exhibition Centre on 21-24 October. This event proved successful for all members who attended and for the industry here in Queensland. A highlight of the event was a Memorandum of Understanding (MoU) signing between QCTN and the Korean Agency - KHIDI. Details of the MoU can be found on our website in the Latest News Section under News & Materials.

TrialChecker - ensuring safety in clinical trials

All members should now have heard about *TrialChecker* which will allow authorised staff in Clinical Trial Centres (CTCs):

- to verify whether a patient or healthy volunteer has previously been in a clinical trial; and
- to assess the impact of this subject's clinical trial history on the decision whether or not to enrol the subject in the new clinical trial.

CTCs must be members of QCTN to use TrialChecker and nominated staff members must be registered with QCTN for authorised and secure access. *For more information, please contact QCTN.*



BIO Korea -
September 2007



BIO Japan -
September 2007

WIT Awards Gala Dinner



WIT Awards Gala Dinner - September 2007

On Saturday 15 September 2007, QCTN was the proud sponsor of WIT's Biotech Rising Star Award. Through sponsorship of the Award, QCTN encourages the advancement of women in the biotechnology and technological industries.

The QCTN Biotech Rising Star Award is intended to celebrate, recognise and reward a candidate regarded as having the potential to make significant contributions to the future of the biotechnology industry or research sector – Queensland's Rising Star.

The finalists were Dr Paige Maguire, Dr Willa Huston and Dr Amanda Mabbett - all of whom were worthy candidates. On behalf of QCTN, Otto Damsma presented the award to this year's winner - Dr Paige Maguire.

Dr Maguire not only congratulated the other finalists and thanked the organisers but also stated that QCTN did a great job in promoting the Queensland based life sciences and biotechnology industry.

Please refer below for detailed information about Dr Maguire and the QUT commercialisation company bluebox where she works.



Dr Paige Maguire General Manager Life Sciences

Paige has an extensive background in basic medical research and the biotech sector spanning 15 years. After completing her PhD she held a joint fellowship at Harvard University and Massachusetts General Hospital in Boston. From there she was asked to join CIPHERGEN Biosystems, a proteomics company based in Silicon Valley where she was responsible for scientific applications and development throughout Australasia and SE

Asia. In 2002 she joined UniQuest where her responsibilities included the assessment and valuation of new technologies in the life sciences, devising IP protection strategies, managing out-licensing/partnering activities, managing a proof-of-concept fund, developing commercialisation strategies and raising equity funding.

At bluebox, Paige is responsible for managing the life sciences commercialisation team, which provides commercialisation support for technologies developed in the life sciences. bluebox was founded in late 2006 to consolidate and develop commercial interactions with external communities of interest, including industry, government and the investment community. bluebox has taken over responsibility for commercialisation from the University's Office of Commercial Services, and is now the single point of contact for all enquiries relating to technology transfer and commercialisation of QUT's intellectual property.



QCTN AGM & Networking Event at McCullough Robertson - November 2007



MoU Signing - AusBiotech - October 2007



QCTN Seminar - Japan - September 2007

Member Comment

Lawyers

**McCullough
Robertson**

*James Cameron
Senior Associate*

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McCullough Robertson - Life Sciences Group

The McCullough Robertson Life Sciences Group has a very active life sciences practice and is one of the largest groups of specialist life sciences lawyers of any legal firm, with significant depth of experience. Seven lawyers have science qualifications, all practising in the area of intellectual property and life sciences.

The lawyers act for ASX-listed life sciences companies, together with a wide range of life sciences start up and spinout companies, universities and life sciences research institutes. The group advises on all aspects of bio-business, including intellectual property protection and commercialisation, venture capital, capital raising and clinical and regulatory issues.

The McCullough Robertson Life Sciences Group has a broad range of intellectual property and corporate experience in and provide the following legal services to the life sciences industry:

1. advice on and documentation of start up and spin off companies, sponsored and collaborative research and development arrangements and advice and negotiation of grant and funding agreements
2. advice on the protection, management and commercialisation of intellectual property, including technology management and transfer, employment and intellectual property policy issues
3. preparation of materials transfer, licensing, clinical trial, manufacturing, supply and distribution agreements
4. advice on making companies 'investor ready', initial structuring requirements, venture capital negotiations and fund-raising issues under the Corporations Act
5. preparation of information memoranda, prospectuses, offer information statements, short form prospectuses and profile statements
6. due diligence and verification for mergers and acquisitions, and capital raisings
7. project management of entire capital raisings from exempt offers to IPOs, Australian and overseas stock exchange listing applications and ongoing ASX Listing Rules compliance.

Visit the new QCTN website pages:

QCTN has updated the 'Public Information' section of the website - from the main menu on the home page, click on 'Public Information' to view the updated pages. Contact Clare if you would like to have your corporate brochure uploaded under the 'Useful Documents' section. Resumes and Job advertisements can also be placed on the QCTN website, contact Clare.

Please also visit our TrialChecker website at www.trialchecker.com.au

welcome to new members

Ordinary members



Affiliate members



Find all members at www.qctn.com.au/members

NOTICE TO MEMBERS

Effective from 1 January 2008, membership fees will increase.

Current prices will apply to renewals/applications undertaken prior to 31 December 2007.

Visit our website for the new price list.

ADVERTISING

*Want more exposure for less?
Then why not consider QCTN's advertising opportunities?*

QCTN offers several advertising options for members including the website and QCTNews at competitive rates.

Contact Clare on marketing@qctn.com.au

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www.qctn.com.au

Events

For further information on these events and more, visit the Events Section on our website, or contact Clare Schodel at marketing@qctn.com.au

Date	Event	Location
3 December	IBC Meeting	QCTN Offices
17 January	IBC Application Submission Deadline for 04.02.08 Meeting	
End January	Seminar in Japan	Osaka
4 February	IBC Meeting	QCTN Offices
Mid February	Deadline for Membership for the 2008 Directory	
20 March	IBC Application Submission Deadline for 07.04.08 Meeting	
31 Mar - 7 Apr	NZ BIO 2008	Auckland
7 April	IBC Meeting	QCTN Offices
15 May	IBC Application Submission Deadline for 02.06.08 Meeting	
2 June	IBC Meeting	QCTN Offices
17-20 June	BIO 2008	San Diego
22-26 June	DIA 2008	Boston

REMINDER: If you would like your business cards and promotional marketing collateral displayed at the events, please send them into Clare Schodel at the QCTN office.



Visiting a potential client's worldwide R&D Headquarters - Japan - September 2007

contact us...

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