

RACI PHARMACEUTICAL SCIENCE GROUP (NSW)

RELEASE OF THERAPEUTIC GOODS (HUMAN AND VET) FOR SUPPLY IN AUSTRALIA

Thursday 26 May, 2011
Auditorium
Ryde-Eastwood Leagues Club
117 Ryedale Road
WEST RYDE NSW 2114
Note venue address

This seminar is to be addressed by both TGA and APVMA managers, responsible for the auditing of company "Release for Supply" procedures and implementation. This vitally important aspect of GMP becomes more complex with the advent of manufacture and testing in multi-sites, both in Australia and overseas. Areas to be addressed include:

- *Product and documentation criteria*
- *Procedures for Australian and non-Australian manufacture and testing*
- *Distinction of partially finished and fully finished product for release*

This seminar should be attended by personnel signing off therapeutic goods for supply, whether for sale, use for clinical trials, samples etc, together with those responsible for providing the requisite information and documentation and all relevant technical and regulatory managers.

There are no industry speakers in order to allow maximum time for TGA and APVMA presentations and subsequent questions and discussion.

Questions are requested in advance, specifically addressed to TGA and APVMA where appropriate. Where possible, please send questions in advance to davidedmonds@yahoo.com.au by **4 May**.

Programme

1.45 – 2.25	Registration
2.25 – 2.30	Chairman's introduction
2.30 – 3.00	Release for Supply Mr Doug Fenwick <i>Medicines Audit Manager (Sydney), Office of Manufacturing Quality, TGA</i>
3.00 – 3.30	Questions to TGA
3.30 – 4.00	Afternoon Tea
4.00 – 4.30	Release for Supply Ms Kathryn Winterton <i>Senior Reviewer, Manufacturing Quality & Licensing Section, APVMA</i>
4.30 – 5.00	Questions to APVMA
5.00 – 5.30	General Questions
5.30 –	Drinks and buffet dinner

Please circulate this registration form to all relevant personnel.

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Enquiries for Payment/Registrations contact Edwina Hine at RACI (NSW) office: 02 9663 4960
Fax: 02 9385 6141 or raci-nsw@raci.org.au

For further information regarding the seminar, please contact
David Edmonds davidaedmonds@yahoo.com.au,

GST Inclusive RACI Members **\$70.00 earlybird**, then **\$90**
GST Inclusive Non RACI Members **\$100.00 earlybird**, then **\$130**
Cost includes both Seminar and Dinner

Payment Options – Cheques are preferred,

Earlybird registrations *with payment* close 18th May, 2011.

TAX Invoice/Receipt ABN: 69 030 287 244
Date of issue: 26 May 2011

Title	First Name	Surname	RACI member No	Print Organisation ----- Print E-mail Address & Phone Number

Total Amount Payable: \$ _____

Cheque MasterCard Visa Amex

Please forward your cheque in Australian Dollars payable to **RACI**, along with this completed form to **RACI (NSW), School of Chemistry UNSW Sydney 2052**.

or

Cardholder Name: _____

Card Number: _____

Expiry Date: ____/____

Signature of cardholder: _____

EFT payment; please contact the RACI (NSW) Office

Number of vegetarian meals required: _____

It is recommended that transport is by train to West Ryde station as parking in the Ryde-Eastwood club is sometimes limited. Alight east side of station to Ryedale Road and walk 100 m north to the venue.

Group website: <http://www.raci.org.au/branches/nsw-branch/pharmaceutical-science-group>