

RACI PHARMACEUTICAL SCIENCE GROUP (NSW)

Thursday 11 July, 2013
Ryde-Eastwood Leagues Club
117 Ryedale Road
WEST RYDE NSW 2114

RELEASE FOR SUPPLY/GMP DEFICIENCIES & UPDATE (TGA & NZ Medsafe update)

In consultation with industry associations, TGA Office of Manufacturing Quality is preparing a guidance document for those companies and personnel, particularly the Authorised Person, involved in product Release for Supply process (including Investigational Products) to the Australian market from both local and overseas manufacturers. A draft guidance paper has been posted by TGA for comment by 6 September, outlining proposed procedures and requirements. <http://www.tga.gov.au/newsroom/consult-manuf-rfs-medicines-130603.htm>.

These criteria are to be introduced and explained by Anton Norder of the OMQ at this seminar as part of the consultation process. NZ Medsafe will also present regarding its current approach to Release for Supply for the NZ market, for both local and overseas (especially Australian) manufacture.

Product may be manufactured by a single manufacturer or through a more complex multi-sited (local and overseas) manufacturing chain, the latter involving step-wise release. As well as GMP and Marketing Authorisation (MA) conformance, Release for Supply involves data and conclusions ascertained from product stability studies and Product Quality Review(s).

Anton Norder will also update TGA's noted deficiencies in the inspection of manufacturers' premises and documentation. Industry presenters will describe two areas of continuing concern, PQR and Risk Management. Eugene Salole will describe how vital knowledge of the product in development is to eventual Release for Sale under MA and GMP requirements.

This seminar is essential for all personnel involved in GMP and related TGA/Medsafe policies.

PROGRAM

1.00 – 1.25	Registrations
1.25 – 1.30	Chairman's introduction <i>Dr Michael Kimber</i> , Principal Consultant, HS Business School
1.30 – 2.15	Release for Supply update <i>Mr Anton Norder</i> , Quality & Technical Manager, Office of Manufacturing Quality, TGA
2.15 – 3.00	Release for supply for New Zealand Medsafe GMP update Communicating quality issues <i>Mr Derek Fitzgerald</i> , Manager, Compliance Management, NZ Medsafe
3.00 – 3.15	Questions
3.15 – 3.45	Afternoon Tea
3.45 – 4.30	GMP deficiencies update and future GMP revisions <i>Mr Anton Norder</i> , Quality & Technical Manager, Office of Manufacturing Quality, TGA
4.30 - 5.15	Medicine design: relevance of raw material specifications and robust preformulation evaluation to Marketing Authorisation and GMP. <i>Dr Eugene Salole</i> , Principal, Value-Based Access Pty Ltd
5.15 – 5.30	Questions
5.30 -	Drinks and dinner

REGISTRATION FORM
RELEASE FOR SUPPLY/GMP DEFICIENCIES & UPDATE

Event 247
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Enquiries for Payment/Registrations contact Lindy Chew at RACI NSW Branch office, (02) 9663 4960 or fax (02) 9385 6141 or email raci-nsw@raci.org.au

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

**Earlybird registrations *with payment* close 4 July, 2013;
final registration 9 July, 2013.**

No refunds will be given on cancellations after this date; change of registrant personnel is allowed at any time.

GST Inclusive Earlybird RACI/ARCS Members \$115

GST Inclusive Earlybird Non Members \$150

Later payment GST Inclusive RACI/ARCS Members \$135

Later payment GST Inclusive Non Members \$180

Cost includes both Seminar and Dinner

TAX Invoice/Receipt ABN: 69 030 287 244

Date of issue: 11 July 2013

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

Total Amount Payable: \$ _____

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

or

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Signature of cardholder: _____

EFT payment; please contact the RACI (NSW) Office

Pharma Group website:

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

Note: for attendees planning to attend the evening CAPSIG seminar, please contact David Edmonds at davidaedmonds@yahoo.com.au before registering for this RACI seminar.