



RACI PHARMACEUTICAL SCIENCE GROUP (NSW)

Update to Manufacturing Principles for Medicinal Products - Code of GMP

Monday 9 November, 2009
Ryde-Eastwood Leagues Club
117 Ryedale Road
WEST RYDE NSW 2114

As announced on the TGA website 31 July 2009 and subsequently edited here, *"the TGA National Manager determined new principles to be observed for manufacturers of medicinal products"*. <http://www.tga.gov.au/manuf/mpupdate.htm>. In practice this means that TGA will adopt the Guide to Good Manufacturing Practice for Medicinal Products as issued by PIC/S in January 2009. (The PIC/S Guide also incorporates the Guideline Good Manufacturing Practice for Active Pharmaceutical Ingredients and the TGA intends that the Manufacturing Principles will be updated over time in line with changes to the PIC/S Guide.)

"The Determination provides for a transitional period for manufacturers to make any changes to their manufacturing procedures that may be needed to comply with the updated Good Manufacturing Practice (GMP) requirements, which will become mandatory on 1 July 2010."

In conjunction with various professional therapeutic goods organisations, TGA is presenting a seminar in the major capital cities in November with the RACI Pharmaceutical Science Group (NSW) organising the Sydney meeting, details as below. The seminar is to outline the changes of the Code from the current 2002 version and to explain the implementation timelines and implications.

This is a must attend seminar for senior management, QA, production, laboratory, computer and regulatory personnel and associated consultants in the therapeutic goods industry.

Programme

3.00 - 3.30	Registration
3.30 - 3.45	Chairman's Introduction
3.45 - 5.15	Update of Code of GMP and its Implementation Mr Michel Lok Head of Office, Office of Manufacturing Quality, TGA Mr Doug Fenwick Manager - Medicines Audit Team, Office of Manufacturing Quality, TGA
5.15 - 5.45	Questions
5.45 -	Drinks and dinner
Notes:	This seminar is to be presented in Melbourne and Brisbane, see TGA website for details.

As this seminar is not in the customary RACI Pharmaceutical group format; attendance at the seminar and the following drinks and dinner are costed separately.

RACI Pharmaceutical Science Group – NSW

**Update to Manufacturing Principles for Medicinal Products - Code of GMP
Monday 9 November, 2009
Ryde-Eastwood Leagues Club
117 Ryedale Road
WEST RYDE NSW 2114**

Note venue address

**Enquiries for Payment/Registrations; contact Edwina Hine: 02 9663 4960
Fax: 02 9385 614 or racinsw@chem.unsw.edu.au**

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

RACI/PDA/ISPE Members Seminar only **\$50.00** Seminar + drinks and dinner (total) **\$95**
Non Members Seminar only **\$70.00** Seminar + drinks and dinner (total) **\$115**
Cost includes GST

Registrations close 2 November 2009.

Payment Options – Cheques are preferred

Update to Code of GMP – Event 058

**TAX Invoice/Receipt ABN: 69 030 287 244
Date of issue: 6 October 2009**

Title	Print First Name	Print Surname	RACI/PDA /ISPE Member No.	Print Organisation ----- Drink & Dinner (Y/N)	Print E-mail Address & Phone Number

Total Amount Payable: \$ _____

Cheque MasterCard Visa

Cardholder Name: _____

Card Number: _____

Expiry Date: _____/_____

Signature of cardholder: _____

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