

### Who should attend?

- Regulatory affairs professionals
- Project managers
- Development team members
- Business development managers

- Intensive course, providing a comprehensive update on the regulation of medicinal products in the EU
- Special emphasis on aspects pertaining to early stage development of medicinal products
- New aspects relating to biotech and advanced therapy medicinal products

# EU Regulatory Update

The same event in three locations, saving you travel and hotel costs - and time

### SPEAKERS:

Dr Chris Holloway  
Dr Dianne Jackson-Matthews

### Melbourne:

Monday, 14<sup>th</sup> November 2005  
9:15 a.m. – 3:30 p.m.

### Sydney:

Tuesday, 15<sup>th</sup> November 2005  
9:15 a.m. – 3:30 p.m.

### Brisbane:

Wednesday, 16<sup>th</sup> November 2005  
9:15 a.m. – 3:30 p.m.



On 1st May 2004 the European Union was extended to a total population of 460 million by the accession of 10 new Member States to the existing 15 countries. During the past one to two years, much EU legislation has been amended to take account of the expansion of the Union. Furthermore, new procedures and guidelines have been developed for special classes of medicinal product, notably 'advanced therapy medicinal products' and 'similar biological medicinal products' (follow-on biologics). Many other important changes to EU regulatory procedures and a plethora of new guidelines make the timing of our events particularly appropriate for those requiring a concise status report or an update.

# WORKSHOP AGENDA



09:15 – 09:45	<b>Registration</b>
09:45 – 10:00	Introduction to the workshop
10:00 – 11:15	<b>SESSION 1: Procedures</b>
	1.1 The Pharmaceutical Review Package
	1.2 Centralised <i>versus</i> decentralised
	1.3 Special marketing authorisation procedures
	Discussion
11:15 – 11:45	<b>Coffee break</b>
11:45 – 13:00	<b>SESSION 2: Products</b>
	2.1 Advanced therapy medicinal products
	2.2 Vaccines and blood products
	2.3 Products for special target populations
	Discussion
13:00 – 14:00	<b>Lunch break</b>
14:00 – 15:15	<b>SESSION 3: Practices</b>
	3.1 Scientific advice
	3.2 Clinical trial applications, GCP and GMP
	3.3 Adding value during early development
	Discussion
15:15 – 15:30	Concluding remarks

## EVENT LOCATIONS

**14<sup>th</sup> November**  
State Library  
of Victoria  
328 Swanston St  
Melbourne  
Victoria 3000

**15<sup>th</sup> November**  
Northern Sydney  
Education Centre  
Wicks Rd  
North Ryde  
NSW 2113

**16<sup>th</sup> November**  
Tattersall's  
Club  
215 Queen St  
Brisbane  
Queensland 4000

This seminar will suit the needs of those requiring a basic understanding of European regulatory affairs, for example in the context of manufacturing requirements, clinical trial applications or future Marketing Authorisation Applications. For those who already have an understanding of this subject matter, the seminar will provide an update of the very latest developments in European regulation of medicinal products. Biotech products and important features of development strategy will be one of the key aspects addressed in the seminar.

Cost structure	Before Nov. 1, 2005	After Nov. 1, 2005
1 delegate	AU\$ 250.00 + GST	AU\$ 325.00 + GST
2 delegates (from the same company)	AU\$ 200.00 + GST per delegate	AU\$ 275.00 + GST per delegate
3 or more delegates (from the same company)	AU\$ 150.00 + GST per delegate	AU\$ 225.00 + GST per delegate

All prices are subject to 10% GST

# REGISTRATION FORM



## DELEGATE INFORMATION

Name	
Title	
Company	
Address	
Post/Zip	
Tel	
Fax	
Email	
Website	

## Please select your LOCATION

**14th November 2005; State Library of Victoria, 328 Swanston Street, Melbourne, Victoria 3000.**

**15th November 2005; Northern Sydney Education Centre, Wicks Road, North Ryde, New South Wales 2113.**

**16th November 2005; Tattersall's Club, 215 Queen Street, Brisbane, Queensland 4000**

### Terms and Conditions

**PAYMENT:** Upon receipt of the registration form, delegates will be sent an invoice. Registration will be possible on the day of the event 'at the door' subject to availability of places, which cannot be guaranteed except for advanced registrations. For those registering at the event, payment will be required on the day by cash or cheque (we regret that credit cards are not accepted).

**FEE:** This includes all technical sessions, lunch, refreshments and documentation. 10% GST are applicable to all fees.

**CANCELLATIONS:** Refunds for cancellations received in writing before 1st November 2005 will be subject to a service charge of 50% of the registration fee. We regret that no refunds can be made for cancellations received after 1st November 2005. A registration may be transferred to a delegate from the same company or organisation at anytime.

In the unlikely event that this conference has to be cancelled for any reasons, intERActions and the ERA Consulting Group are not liable for any costs incurred by delegates in connection with their attendance. However, in this eventuality the registration fee paid will be refunded in full.

**DATA PROTECTION:** The personal information shown, or provided by you, will be held on a database and may be shared with companies in the ERA Consulting Group. They may be used to keep you up-to-date with developments in your industry. If you do not wish your details to be used for this purpose, please email [info@eraconsulting.com](mailto:info@eraconsulting.com).

**FAX BACK TO +61-(0)7-3878-1071**