



# European Biotechnology Regulations

## ERA Consulting and SeerPharma (Program attached)

**Date:** 16<sup>th</sup> November 2004  
Registrations due 9<sup>th</sup> November 2004

**Venue:** Rydges Riverwalk  
649 Bridge Road  
Richmond VIC 3121

**Time:** 1:00 pm to 5:00 pm. Drinks and nibbles to follow

**Cost:**  ARCS and  AusBiotech Members: **\$77.00 incl. GST**  
Student and Retired Members: **\$55.00 incl. GST**  
Non- Members: **\$99.00 incl. GST**

**EARLY BIRD DISCOUNT**  
**A \$10.00 discount applies to each registration if payment is received prior to the 2<sup>nd</sup> November 2004**

Fax this completed form to ARCS Secretariat on 02 9904 7599 by 9/11/2004

Name: \_\_\_\_\_ Phone No: \_\_\_\_\_





Company: \_\_\_\_\_ Fax No: \_\_\_\_\_

Email Address for invoicing \_\_\_\_\_

**Cheques will only be accepted as payment if prior arrangements have been made with ARCS  
NO REGISTRATIONS OR REFUNDS AFTER 9<sup>th</sup> November 2004**

**TAX INVOICES WILL BE SENT ON RECEIPT OF THE REGISTRATION FORM**  
**Note: Cancellations must be in writing – substitutions allowed**

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## The current status of European regulations and directives relating to biotech/biologics

Many fundamental rules and procedures relating to the regulation of biological medicinal products in the European Union have recently been revised or overhauled, coinciding with the accession of ten new Member States on 1<sup>st</sup> May. Not the least of these new measures is the introduction of the new EU Clinical Trials Directive and the proposed EU GCP Directive. Furthermore, a number of new guidelines have been introduced that are of immediate relevance to the development of biotech products and other biologics. The aim of this seminar is to provide participants with a thorough update on the current status of European regulations and directives, providing insight into the consequences and practical application of these rules in the development of biotech/biologics, including advanced therapy medicinal products and tissue-engineered products.

13:00	–	13:45	Introduction [DJM] Regulation of biologics in the European Union: historical background and overview [DJM]
13:45	–	14:30	Revisions to EU regulations, directives and guidelines of relevance to biological medicinal products [AMW]
14:30	–	15:00	Afternoon tea
15:00	–	15:45	“Quality Systems and Risk Management Strategies for Biologics cGMP Compliance” [CC]
15:45	–	16:30	The new EU Clinical Trials Directive and GCP developments: practical guidance for non-European companies [DJM]
16:30	–	17:00	Panel discussion: Case Studies/Questions and Answers

### Panel of Speakers:

DJM: Dr. Dianne Jackson–Matthews, Director of Regulatory Affairs, ERA Consulting (Australia) Pty Ltd

AMW: Dr. Allison Wyndham, Senior Consultant, ERA Consulting (UK) Ltd

CC: Ms Cathy Cropp, Senior Consultant, SeerPharma Pty Ltd