



European Biotechnology Regulations

ERA Consulting and SeerPharma (Program attached)

Date: 15th November 2004
Registrations due 8th November 2004

Venue: Northern Sydney Education Centre
 Wicks Road (in the grounds of Macquarie Hospital)
 North Ryde NSW

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 1st November 2004

Fax this completed form to ARCS Secretariat on 02 9904 7599 by 8/11/2004

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 8th 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 1st 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" [SW]
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

SW: Dr. Steve Williams, Director, SeerPharma Pty Ltd