

# BioSkills @

# Box Hill Institute



The Specialist Centre for Biotechnology Training

## *TGA Medicine / Biologicals*

**Dates:** 27<sup>th</sup> March 2009  
21<sup>st</sup> August 2009

### **Course Description**

#### **Course Objective**

The Federal Government requirements for the registration of Prescription Medicines / Biologicals for the Australian marketplace are complex. This one day introductory program exposes participants to theoretical and practical elements of the role of a Regulatory Affairs Officer as it relates to the registration of Prescription Medicines/Biologicals. A workshop approach will be taken to give participants hands-on experience in the navigational tools required to prepare- submit and monitor a product submission to the TGA.

#### **Course Outline**

- Introduction to Regulatory Affairs
- Applications for New Prescription Products
- Post approval requirements and changes
- Case Studies: Preparing a TGA submission; Labelling, GMP clearance and post approval changes; Bioequivalence and Shelf Life determination

#### **Certificate of Participation**

- Awarded to participants who have achieved 75% attendance for the course.

#### **For Whom**

- Those responsible for complying with TGA requirements
- Researchers looking to commercialise products
- Those looking to manufacture products for clinical trials and/or commercial sale
- Staff seeking to update their skills
- Post-graduate students

#### **Outcomes**

- Provide the historical background to regulatory control in Australia
- Describe the legislative basis to marketing Medicines and Biologicals
- Define the role of the sponsor, manufacturer and Regulatory Affairs Officer
- Outline the submission requirements for OTC and complementary medicines
- Understand the continuing requirements for and how to make changes to approved products

#### **Course information**

Course code:	BIO 18
Course fee (incl GST):	\$660.00
Maximum class size:	20 participants
Time:	8.30am – 5.00pm
Total course duration:	8.5 hours (inc. lunch)

#### **Venue:**

Building 8, Level 3, Room to be advised  
Box Hill Institute,  
465 Elgar Road, Box Hill