

The Specialist Centre for Biotechnology Training

TGA Devices

Dates: 27th March 2009
21st August 2009

Course Description

Course Objective

Manufacture and marketing of medical devices in Australia is governed by federal legislation. Medical devices have to be approved by the Therapeutic Goods Administration (TGA) before they can be sold, and companies have substantial responsibility for monitoring products in the marketplace. This one day introductory program exposes participants to both theoretical and practical elements of the role of a Regulatory Affairs Officer as it relates to the registration and marketing of Medical Devices. A workshop approach will be taken to give the participants hands-on experience in the navigational tools required to prepare, submit and monitor a product submission to the TGA.

Course Outline

- Introduction to Australian Regulatory System
- Introduction to inclusion of Medical Devices on the ARTG
- Case Studies: Submitting an application; Designing a Label; Approval of promotional materials; Reviewing risk assessment and clinical part of a dossier

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 commercial release and sale
- Those wanting to comply with October 2007 regulation changes
- People looking for a change in career
- Staff seeking to update their skills
- Post-graduate students

Outcomes

- Describe the historical background to regulatory control in Australia
- Define the role of the sponsor, manufacturer and Regulatory Affairs Officer
- Outline the submission requirements for different classes of Medical Devices
- Prepare an online submission to TGA
- Understand the requirements for a post market surveillance system

Course information

Course code:	BIO 17
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