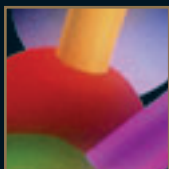


Module 9



Aim:

The purpose of this module is to provide students with an understanding of the different philosophy for development of biological/ biotechnology products and how this impacts registration.

Registration of Biological and Biotechnology Products

Learning outcomes

- Students will be able to describe the difference between a biological and a chemical entity and will be familiar with the phrase "case-by-case".
- Students will have an understanding of the quality issues specific to biologicals, for example potential virus contamination, assay by bioassay.
- Students will be aware of the implications of change in production process on product and the concept of comparability.
- Students will be introduced to different classes of biological products such as vaccines, monoclonal antibodies and gene therapy and the data requirements specific to these products.
- Students will be aware of the regulatory procedures for approval in the major territories.

The module will cover the following topics

- What is a biological? How are they regulated?
- Financing biotech product development, investment and risks
- Quality issues arising from the method of manufacture
- Implications for change in process on product development
- Preclinical requirements
- Clinical development of biotech products
- New technologies, for example gene therapy, and how they are regulated
- Regulatory procedures in the major territories

Links with other modules

- Module 1 covers global regulatory strategy.
- Module 2 covers preclinical aspects of the regulatory strategy for a new active substance.



Validated
by the
University of Wales