

Module Title:	Regulatory Affairs & GMP – Semester 2
Academic year:	2007 – 2008
Credit Value:	5 – Mandatory
Pre- requisites:	None
Assessment:	70% Final Exam, 30% Continuous Assessment (CA)
Module Content	<ul style="list-style-type: none"> • Regulatory Standards and Guidelines • Marketing Authorisations • Regulatory Compliance • Classification of Medicinal Product • Pharmacovigilance • Use of Regulatory Case Studies where Possible • Other Regulations • Good Manufacturing Practices
Intended Learning Outcomes: (September 2007)	<p>On successful completion of this module the student will be expected to be able to:</p> <ol style="list-style-type: none"> 1. Interpret and apply regulatory guidelines to the workplace 2. Identify and locate Modules 1-5 of Common Technical Dossier 3. Explain the procedure for making and maintaining a marketing authorisation 4. Interpret the regulations associated with Clinical Trials 5. Explain the importance of Pharmacovigilance and the role it plays in the drug cycle 6. Describe the classification of medicinal products 7. Identify the requirements of regulatory compliance 8. Interpret and apply regulatory guidelines to the workplace 9. Describe the necessity and function of GMP regulatory control bodies within industry 10. Identify the steps involved in a GMP inspection