

Faculty	Natural Sciences			
Home Department	School of Pharmacy			
Module Topic	Regulatory Affairs			
Generic Module Name	Regulatory Affairs			
Alpha-numeric Code	PAR817			
NQF Level	9			
NQF Credit Value	10			
Duration	Semester			
Proposed semester to be offered.	First Semester			
Programmes in which the module will be offered	MSc (Pharmacy Administration and Policy Regulation) (3859)			
Year level	8			
Main Outcomes	<p>On completion of this module students should be able to:</p> <ul style="list-style-type: none"> • Evaluate the regulatory issues affecting the pharmaceutical industry. • Compare the regulation of medicines in different global markets. • Develop and critically appraise product-related information to ensure adherence to ethical and legal provisions. • Compare and evaluate the different roles of Regulatory and Medical Affairs departments in order to propose consistent strategies involving the marketing of pharmaceuticals, medical information, the role of a pharmaceutical company's country medical department and licensing agreements. 			
Main Content	<ul style="list-style-type: none"> • Regulatory Affairs covers the key regulatory and medical affairs issues including Good Manufacturing Practice (cGMP) affecting the national and international Industry today, from an overview of the major drug regulators and the requirements during finished medicinal product development to medical information and regulations including prescribing issues to life cycle management issues. 			
Pre-requisite modules	None			
Co-requisite modules	None			
Prohibited module Combination	None			
Breakdown of Learning Time	Hours	Timetable Requirement per week		Other teaching modes that does not require time-table Online Course. No Timetable Requirements.
<i>Contact with lecturer / tutor:</i>	20	<i>Lectures p.w.</i>	0	
<i>Assignments & tasks:</i>	35	<i>Practicals p.w.</i>	0	
<i>Practicals:</i>	0	<i>Tutorials p.w.</i>	0	
<i>Tutorials:</i>	10			
<i>Tests & Examinations:</i>	0			
<i>Selfstudy:</i>	0			
<i>Other:</i>	35			
Total Learning Time	100			
Methods of Student Assessment	Continuous Assessment (CA): 50% Final Assessment (FA): 50%			
Assessment Module type	Continuous and Final Assessment (CFA)			