

Faculty	Natural Sciences			
Home Department	School of Pharmacy			
Module Topic	Pharmacovigilance			
Generic Module Name	Pharmacovigilance			
Alpha-numeric Code	PAR816			
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"> • Appreciate the effect on patient safety and a product's licence by the different types of adverse events/reactions. • Identify the key safety reporting requirements, according to the type of adverse event/reaction (in clinical research or in commercial products). • Construct and evaluate benefit/risk assessments throughout the lifecycle of a medicine, with reference where applicable to issues around pre- and post-market authorization. 			
Main Content	<ul style="list-style-type: none"> • Pharmacovigilance deals with drugs and their safety. The topics include the prediction and analysis of the actions of drugs upon the body. Students will be taught to report signals, the different types of adverse drug events and lastly they are taught how to construct and evaluate benefit/risk assessments. • This module will give participants a working knowledge of all aspects of drug safety monitoring and risk management and will enable them to predict and analyse drug interactions, and recognise the implications for prescribing and product licence. The participant will also be familiarized with pharmacovigilance best practice which includes monitoring strategies and action plans and be fully cognisant of regulatory reporting requirements. 			
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)			

