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| Faculty | Natural Sciences | | | |
| Home Department | School of Pharmacy | | | |
| Module Topic | Regulatory Sciences and Medical Devices | | | |
| Generic Module Name | Regulatory Sciences and Medical Devices 815 | | | |
| Alpha-numeric Code | PAR815 | | | |
| 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"> • Understand and contextualize major issues affecting the development of medical devices. • The regulatory control of medical devices, with special reference to the EMA CE-Mark and other key international legislation. • Review the key standards, conformity assessments, clinical issues, safety and risk assessment as well as medical devices containing drugs and the latest developments in diagnostics. | | | |
| Main Content | <ul style="list-style-type: none"> • Major issues impacting medical devices and their regulatory control both national and internationally with special attention given to those medical devices containing drugs e.g. drug-eluting stents | | | |
| 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 |
| <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) | | | |