



FACULTY OF  
SCIENCE AND  
HEALTH SCIENCE



2024 - 25

## PG Diploma in Regulatory Affairs

Programme Structure

<b>Division</b>	Faculty of Science & Health Science
<b>School Name</b>	School of Health Sciences & Technology
<b>Department Name</b>	Department of Pharmaceutical Science
<b>Programme Name</b>	PG Diploma in Regulatory Affairs

## Course Basket

Course Type	Description
Programme Core	Courses dealing with foundations, depth and breadth of the major in which student is admitted at MIT-WPU
Programme Electives	Open electives under the programme allow students to specialise in a particular area connected to their major.
University Core	Courses that reflect the core MIT-WPU values and the mission of Life Transformation of students.
University Electives	Multidisciplinary courses across the faculties at MIT-WPU and outside the programme core.

Semester	Course	Credits
I	Global Regulatory Affairs 30 Hrs	2
I	Regulatory Requirements Compilation and Submissions 30 Hrs	2
I	Discovery Development and Technology 30 Hrs	2
I	Regulatory Aspects of Drugs and Cosmetics 30 Hrs	2
I	Regulatory Affairs Practical I 60 Hrs	2
I	World Famous Philosophers, Sages/Saints and Great Kings 30 Hrs.	2
I	Seminar	2
I	Capstone Project	6
Total		20

Semester	Course	Credits
II	Clinical Research Regulations 30 H	2
II	Medical Devices and IVD Regulations and Submissions 30 H	2
II	Regulatory Aspects of Herbal and Biologicals 30 H	2
II	Regulatory Aspects of Food and Nutraceuticals 30H	2
II	Regulatory Affairs Practical II 60 H	2
II	eCTD Hands on Training and Evaluation	2
II	Capstone Project	6
II	Seminar	2
Total		20

\*Modifications to the programmes and courses are contingent upon adherence to university guidelines and procedures. Any proposed changes must undergo a thorough review process, including consultation with relevant academic departments, approval from the appropriate administrative bodies, and compliance with accreditation standards.

Additionally, consideration will be given to feedback from students, faculty, and other stakeholders to ensure that modifications align with the overall educational objectives and mission of the university. The implementation of any approved changes will be communicated transparently to the university community, and appropriate measures will be taken to facilitate a smooth transition for all affected parties.