M.Pharm Pharmaceutical Regulatory Affairs Programoutcome(MRA)

M.PharmPharmaceutical Regulatory AffairsProgramoutcome(MRA)	
PO1(MRA)	Understandkey regulatory, registration and compliance elements with respect to documentation, clinical trials, drugs & cosmetics, biologicals and intellectual property rights.
PO2(MRA)	Understand the regulatory aspects of drugs & cosmetics, herbal & biologicals, medical devices, food and nutraceuticals.
PO3(MRA)	Gain knowledge in research & review article writing, research methodologies and biostatistics tools.
PO4(MRA)	Able to file documents for registration and marketing of drugs, cosmetics, medical devices, biologicals, herbals for different regulatory bodies.

M.Pharm Pharmaceutical Regulatory Affairs Courseoutcome

M.PharmPharmaceutical Regulatory Affairs Courseoutcome	
ID	**OUTCOME**
CO1(MRA)	Tounderstandkey regulatory, compliance elements with respect to GMP, GLP,GALP, GDP, implement check lists and SOPs for audits and good regulatory practices.
CO2(MRA)	To gain fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

CO3(MRA)	Abletoknow history, origin, ethics of clinical & biomedical research, phases of clinical trials, medical device development, regulatory requirements and guidance for conduct of clinical trials and research.
CO4(MRA)	Gain knowledge on different acts & guidelines, approval process & regulatory requirements for drugs & cosmetics, Medical Devices, Biologicals & Herbals, Food & Nutraceuticals.
CO5(MRA)	To be able to prepare protocols for documentation, registration and submission to various agencies and to be able to make regulatory dossier and checklists for submission.
CO6(MRA)	Able to know regulatory approval process and registration procedures for API, drug products, cosmectics in US, EU, Australia, Canada, Japan and semi regulated countries.
CO7(MRA)	Able to know regulatory requirements, preclinical studies, clinical trial application for Biologics, Vaccines, Blood, blood components, biosimilars in India, USA, Europe Union. Regulations for herbal products.
CO8(MRA)	Able to know basics, ethical & quality considerations, regulatory approval process, marketing, clinical evaluation & investigation of Medical devices and IVDs in India, US, Canada, EU, Japan, ASEAN.
CO9(MRA)	To impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe and to learn about Regulatory Aspects for nutraceuticals and food supplements.
CO10(MRA)	Gain knowledge on Documentation, check lists for Audits, CE marking, submission by eCTD software and registration requirements for WHO, BRICS, ASEAN, GCC, China and South Korea.
CO11(MRA)	Abilitytogetideaaboutresearchmethodologies,biostatisticaltoolsthatcanbeemployedinresearch,variousmedicalcareprotocols,CPCSEAguidelinesforlaboratoryanimals. Abilitytounderstandthedetailsofajournalanditsimportancealongwithprotocolsofwritingajournal.Abilitytoexpresstheirideasandthoughtsoftheirperspectiveinchoosingaprojectoftheirowninterestunderthesupervisionofrespectiveguides.
CO12(MRA)	Able to file documents for registration and marketing of drugs, cosmetics, medical devices, biologicals, herbals for different regulatory bodies.Able to publish papers, present in conferences, present research work for thesis.

M.Pharm Pharmaceutical Regulatory Affairs –Program outcome and course outcome Map

	PO1	PO2	PO3	PO4
CO1(MRA)	X			
CO2(MRA)	X			
CO3(MRA)	X			
CO4(MRA)	X			
CO5(MRA)	X			
CO6(MRA)		x		
CO7(MRA)		x		
CO8(MRA)		x		
CO9(MRA)		x		
CO10(MRA)		x		
CO11(MRA)			x	
CO12(MRA)				x

SPECIFICLEARNINGOUTCOMES(SLO)

M.Pharm Pharmaceutical Regulatory Affairs I Semester

Code: MRA 101T-GOOD REGULATORY PRACTICES(GRP)		
ID	**Unit/Topic**	**Outcomestatement**
SLO1(GRP)	UnitI	To know various cGMP guidance docs (US, EC, WHO) pertaining to pharmaceutical industry and medical device and IVDs Global Harmonization Task Force Guidance docs.
SLO2(GRP)	UnitII	To understand about USFDA GLP Regulations, GLP inspection process and relevant ISO and Quality Council of India (QCI) Standards
SLO3(GRP)	UnitIII	To know about the requirements, SOPs of GALP, Software Evaluation checklist, relevant ISO and QCI Standards.
SLO4(GRP)	UnitIV	To know about worldwide Legal GDP requirements, Deliveries to Customers, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards.
SLO5(GRP)	UnitV	To know about Total Quality Management, Validation, ICH guidelines, ISO 13485, Schedule MIII and other relevant CDSCO regulatory guidance documents.
Code: MRA 102T-DOCUMENTATION AND REGULATORY WRITING(DRW)		
SLO6(DRW)	UnitI	To know various documents pertaining to drugs in pharmaceutical industry.
SLO7(DRW)	Unit II	To understand about requirements for dossier preparation and submission.
SLO8(DRW)	UnitIII	To know about types, strategies, planning and conduction of audits.
SLO9(DRW)	UnitIV	To know about inspection procedure, report, root cause analysis and corrective and preventive action.
SLO10(DRW)	UnitV	To know about post approval document requirements and regulatory procedures.
Code: MRA 103T-CLINICAL RESEARCH REGULATIONS(CR)		

SLO11(CR)	UnitI	Gain knowledge on different phases of clinical trials, clinical investigation & evaluation of medical devices & IVDs.
SLO12(CR)	Unit II	Gain knowledge on ethics in clinical research, ICH GCP, responsibilities and documentation.
SLO13(CR)	UnitIII	Gain knowledge on regulations governing clinical trials in India, USA & Europe.
SLO14(CR)	UnitIV	Gain knowledge on clinical research related guidelines with reg to ICH, ICMR, CDSCO & GHTF.
SLO15(CR)	UnitV	Able to understand USA & EU guidance documents related to clinical trials.
Code: MRA 104T-Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights (R&L)		
SLO16(R&L)	UnitI	Gain knowledge on acts and rules for drugs, cosmetics, biologicals & herbals, food & nutraceuticals.
SLO17(R&L)	Unit II	Gain knowledge on regulatory requirements and approval procedures for drugs, cosmetics, biologicals & herbals, food & nutraceuticals.
SLO18(R&L)	UnitIII	Gain knowledge on Indian Pharmacopoeialstandards, BIS standards, ISO and relevant standards.
SLO19(R&L)	UnitIV	Gain knowledge on BA & BE data, BCS classification, ICH, WHO, CPCSEA, ethical guidelines, ICMR-DBT guidelines.
SLO20(R&L)	UnitV	Gain knowledge on IPR.
Code: MRA 105P-Regulatory Affairs Practical- I(RAPI)		
SLO21(RAPI)		Able to prepare protocols for documentation of various types of records, understand case studies on Good Pharmaceutical Practices and on response with scientific rationale to USFDA Warning Letter.
SLO22(RAPI)		Able to prepare Clinical Trial Application and checklist for conducting clinical trials in India, Europe and USA, regulatory dossier and its submission to SUGAM.
SLO23(RAPI)		Able to prepare protocol of registering for different Intellectual Property Rights in India
SLO24(RAPI)		Able to prepare protocol of registration for conducting Clinical trials, BA/ BE studies in India, US, EU and Japan, checklist for registration of IND, NDA and ANDA as per CTD format. Able to compare DMF system in US, EU and Japan.

SPECIFICLEARNINGOUTCOMES(SLO)

M.Pharm Pharmaceutical Regulatory Affairs II Semester

Code: MRA 201T-Regulatory Aspects of Drugs and cosmetics(RADC)		
ID	**Unit/Topic**	**Outcomestatement**
SLO25(RADC)	UnitI	Gain knowledge on regulatory approval process & registration procedure for new drug, generic drug, combination product, cosmetic in USA & Canada.
SLO26(RADC)	UnitII	Gain knowledge on regulatory approval process, marketing authorization, import &manufacturing of cosmetics in Europe Union & Australia.
SLO27(RADC)	UnitIII	Gain knowledge on regulatory approval process, regulatory considerations for pharmaceuticals, legislations & regulations for Cosmetics in Japan.
SLO28(RADC)	UnitIV	Gain knowledge on emerging markets, WHO GMP & regulatory requirements for registration of drugs in WHO countries through prequalification programme.
SLO29(RADC)	UnitV	Gain knowledge on regulatory requirements for registration of drugs & post approval requirements in China, South Korea, Brazil, ASEAN, CIS and GCC countries.
Code: MRA 202T-Regulatory Aspects of Herbal and Biologicals(RAHB)		
SLO30(RAHB)	UnitI	Gain knowledge on regulations and guidelines for biologics.
SLO31(RAHB)	Unit II	Gain knowledge on regulations and guidance for biologics and biosimilars in USA.
SLO32(RAHB)	UnitIII	Gain knowledge on regulations and guidance for biologics and biosimilars in Europe Union.
SLO33(RAHB)	UnitIV	Gain knowledge on Vaccine regulations in India, USA & Europe Union.

SLO34(RAHB)	UnitV	Gain knowledge on Quality, Safety & legislation for herbal products in India, USA and Europe Union.
Code: MRA 203T-Regulatory Aspects of Medical Devices(RAMD)		
SLO35(RAMD)	UnitI	Able to know the basics of medical devices and IVDs, process of development.
SLO36(RAMD)	Unit II	Able to know about ethical and quality considerations, Validation and Verification of Medical devices.
SLO37(RAMD)	UnitIII	Able to understand the Regulatory approval process for Medical Devices and Post marketing surveillance of Medical Devices in USA.
SLO38(RAMD)	UnitIV	Able to understand the Regulatory approval process for Medical Devices and IVDs in European Union.
SLO39(RAMD)	UnitV	Able to understand the Regulatory approval process for Medical Devices and IVDs and able to know about IMDRF study groups and guidance documents.
Code: MRA 204T-Regulatory Aspects of Food and Nutraceuticals(RAFN)		
SLO40(RAFN)	UnitI	To know about basics of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods and to understand regulatory requirements for Food and Nutraceuticals.
SLO41(RAFN)	Unit II	To know about WHO guidelines on nutrition, NSF International and GMP for Nutraceuticals.
SLO42(RAFN)	UnitIII	To understand organization and functions of FSSAI and to know about the regulation for registration and labeling of nutraceuticals and food supplements in India
SLO43(RAFN)	UnitIV	To understandFSMA and know about the regulation for registration and labeling of nutraceuticals and food supplements in USA
SLO44(RAFN)	UnitV	To understand organization and functions of EFSA and know about the regulation for registration and labeling of nutraceuticals and food supplements in EU
Code: MRA 205P-Regulatory Affairs Practical- II(RAPII)		
SLO45(RAPII)		Able to understand case studies on change management, change control, CAPA, documentation of raw materials as per official monographs.
SLO46(RAPII)		Able to prepare audit checklist, BLA, documents for FDA, EMA & MHRA using eCTD software.
SLO47(RAPII)		Able to prepare documents for marketing authorization for WHO, BRICS, China, South Korea, ASEAN, GCC.

SLO48(RAPII)		Able to prepare checklist for 510K, PMA, CE marking, STED, Medical device facility, clinical investigation plan for medical devices.

SPECIFICLEARNINGOUTCOMES(SLO)

M.Pharm Pharmaceutical Regulatory Affairs III & IV Semester

Code: MRM 301T- RESEARCHMETHODOLOGYANDBIOSTATISTICS(RMB)		
Id	**Unit/Topic**	**Outcomestatement**
SLO49(RMB)	UnitI	UnderstandingofGeneralresearchmethodology
SLO50(RMB)	UnitII	IntroductiontoBiostatistics
SLO51(RMB)	UnitIII	Detailedstudyonprotocolsofmedicalresearch
SLO52(RMB)	UnitIV	ClearperspectiveofCPCSEAguidelinesforlaboratoryanimalfacilities
SLO53(RMB)	UnitV	ImportanceofdeclarationofHelsinkirule,additionalprinciplescombinedwithmedicalcare
RESEARCH WORK		
SLO54(RW)		Abilityto file documents for regulatory agencies,publishpapersinvariousnationalandinternationaljournalsapprovedbyUGC,competewithothersbypresentinginvariousnationalandinternationalseminars/conferenceswithinnovativeresearchideas. Abilitytoexplaintheirresearchprojectsthroughseminars,alongwiththeirthesis,inpartialfulfillmentfortheawardoftheir post-graduationdegree.

M.Pharm Pharmaceutical Regulatory Affairs Course outcome and Specific Learning Outcome Map

	CO1 **(MRA)**	CO2 **(MRA)**	CO3 **(MRA)**	CO4 **(MRA)**	CO5 **(MRA)**	CO6 **(MRA)**	CO7 **(MRA)**	CO8 **(MRA)**	CO9 **(MRA)**	CO10 **(MRA)**	CO11 **(MRA)**	CO12 **(MRA)**
SLO1(GRP)	**X**											
SLO2(GRP)	**X**											
SLO3(GRP)	**X**											
SLO4(GRP)	**X**											
SLO5(GRP)	**X**											
SLO6(DRW)		**X**										
SLO7(DRW)		**X**										
SLO8(DRW)		**X**										
SLO9(DRW)		**X**										
SLO10(DRW)		**X**										
SLO11(CR)			**X**									
SLO12(CR)			**X**									
SLO13(CR)			**X**									
SLO14(CR)			**X**									

SLO15(CR)			X									
SLO16(R&L)				X								
SLO17(R&L)				X								
SLO18(R&L)				X								
SLO19(R&L)				X								
SLO20(R&L)				X								
SLO21(RAPI)					X							
SLO22(RAPI)					X							
SLO23(RAPI)					X							
SLO24(RAPI)					X							
SLO25(RADC)						X						
SLO26(RADC)						X						
SLO27(RADC)						X						
SLO28(RADC)						X						
SLO29(RADC)						X						
SLO30(RAHB)							X					
SLO31(RAHB)							X					

SLO32(RAHB)							**X**					
SLO33(RAHB)							**X**					
SLO34(RAHB)							**X**					
SLO35(RAMD)								**X**				
SLO36(RAMD)								**X**				
SLO37(RAMD)								**X**				
SLO38(RAMD)								**X**				
SLO39(RAMD)								**X**				
SLO40(RAFN)									**X**			
SLO41(RAFN)									**X**			
SLO42(RAFN)									**X**			
SLO43(RAFN)									**X**			
SLO44(RAFN)									**X**			
SLO45(RAPII)										**X**		
SLO46(RAPII)										**X**		
SLO47(RAPII)										**X**		
SLO48(RAPII)										**X**		

SLO49(RMB)											**X**	
SLO50(RMB)											**X**	
SLO51(RMB)											**X**	
SLO52(RMB)											**X**	
SLO53(RMB)											**X**	
SLO54(RW)												**X**

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