COURSE OUTCOME STATEMENT

Course Outcomes: Course Outcomes are narrower statements that describe what students are expected to know, and be able to do at the end of each course. These relate to the skills, knowledge, and behaviour that students acquire in their enrolment through the course.

M.PHARM (REGULATORY AFFAIRS)	
Course Outcome Code	**Course Outcome Statements**
MRA101T.1	To recall the concepts of current Good Manufacturing Practices (cGMP) and Global Harmonization Task Force (GHTF) official guidelines for medical devices.
MRA101T.2	To Illustrate the concepts of Good Laboratory Practices and its regulations including ISO and QCI standards.
MRA101T.3	To make use of the Good Automated Laboratory Practices and its requirements as per US FDA and other regulatory guidelines like ISO and QCI.
MRA101T.4	To explain the Good Distribution Practices which involves personnel, self-inspection, document handling and following its relevant guidelines as per WHO, ISO and CDSCO.
MRA102T.1	To recall the documentation in pharmaceutical industries and its plan to product development and to learn preparing documents like SMF and DMF.
MRA102T.2	To outline the process and preparation of regulatory dossier and its online submission by following ICH e-CTD guidelines and other guidelines like ACTD etc.
MRA102T.3	To utilize the concepts of audits and its different types, preparing the reports and maintaining the audit timelines as well as referring the ISO and GHTF guidance documents.
MRA102T.4	To evaluate the reports of Regulatory Inspections and understanding the concepts of Root cause analysis and CAPA.
MRA103T.1	To define the concepts of clinical drug development process and to plan the clinical investigation and its evaluation process for Medical devices.
MRA103T.2	To outline the concepts related to Ethics in clinical research and understand the role of Sponsors and Investigators including functions of CROs.
MRA103T.3	To apply the regulations governing the clinical trials in INDIA, US and EU by following its official research guidelines towards clinical trials and its registration process.
MRA103T.4	To compare the different clinical research related guidelines by following ICH GCP, ICMR and GHTF guidance documents.

MRA104T.1	To recall the acts and rules related to drugs, biologicals, herbals and nutraceuticals.
MRA104T.2	To explain the guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals
MRA104T.3	To compare the Indian Pharmacopoeial, BIS, ISO and other relevant standards
MRA104T.4	To interpret the Bioavailability & Bioequivalence data, Guidelines for Drug testing in animals, humans and ICMR-DBT Guidelines for Stem Cell Research
MRA105PA.1	To select the case studies of Good Manufacturing Practices and documentation for in-process finished products and their QC tests.
MRA105PA.2	To outline the SOP's, documentation record, protocols and analytical reports for BMR, MFR and DR for stability and validation process.
MRA105PA.3	To identify the regulatory requirements, registration process and submission guidelines for different pharmaceutical products.
MRA105PA.4	To compare the regulatory requirement checklists and documents for registration and submission to different regulatory bodies.
MRA105PB.1	To elaborate regulatory requirements checklists for conducting clinical trials in different countries.
MRA105PB.2	To prepare and compare clinical trial application requirements of US, EU and japan.
MRA105PB.3	To Case studies on USFDA warning letter
MRA105PB.4	Preparation and submission of checklist list of IMPD for EU submission
MRA106S.1	To recall the fundamentals of proposed topic and carry out literature review.
MRA106S.2	To organize the collected data in chronological order and develop writing skills.
MRA106S.3	To recall the fundamentals of proposed topic and carry out literature review.
MRA106S.4	To propose, design research in given concept and improve presentation skills.
MRA201T.1	To recall the regulatory drug approval process and marketing in US and CANADA by following its official guidelines provided by regulatory bodies like USFDA and Health Canada
MRA201T.2	To show the regulatory drug approval process and marketing in EU and AUSTRALIA by following its official guidelines provided by regulatory bodies like EMA and TGA.
MRA201T.3	To plan the regulatory drug approval process and marketing in JAPAN by following its official guidelines provided by regulatory bodies like PMDA.
MRA201T.4	To compare the regulatory drug approval process and marketing in Emerging Markets like ASEAN, APEC, EAC, GCC, PANDRH and SADC etc.
MRA202T.1	To recall the knowledge of regulations, guidelines, market authorization and post market data of similar biologics in India.
MRA202T.2	To compare the generic drug & biosimilars and to study the laws, regulations, guidance and packaging of biologics as per USA.

MRA202T.3	To make use of the scientific guidelines, development pre-clinical and clinical development considerations; stability, safety, advertising, labeling, packing and regulatory approval of biologics in European Union (EU).
MRA202T.4	To take part in the marketing authorisation, clinical evaluation, licensing, quality assessment and pharmacovigilance of vaccines in India
MRA203T.1	To relate the Medical Devices and its risk-based classification along with history of MD and guidance documents of IMDRF like STED and GMDN.
MRA203T.2	To recall the ethics in clinical investigations of medical Devices and its quality related guidelines by ISO.
MRA203T.3	To identify the regulatory approval process and marketing of medical devices in US by following US FDA official guidance documents.
MRA203T.4	To discuss the regulatory approval process and marketing of medical devices in EU by following EMA official guidance documents.
MRA204T.1	To define the concepts related to Nutraceuticals and its opportunities in Nutraceutical market.
MRA204T.2	To illustrate the global aspects of Nutraceuticals and its guidelines provided by WHO and NSF Internationals.
MRA204T.3	To identify the regulatory approval process of Nutraceuticals and its market regulations in INDIA with reference to RDA
MRA204T.4	To explain the regulatory approval process of Nutraceuticals and its market regulations in USA with reference to RDA.
MRA205PA.1	To find case studies of change controls, deviations and CAPA in pharmaceutical industries.
MRA205PA.2	To Illustrate the preparation of submission through eCTD software for FDA, EMA and MHRA.
MRA205PA.3	To compare the drug registration requirements procedures for different regulatory and emerging market countries for marketing authorization.
MRA205PA.4	To assess the checklist for different pharmaceutical products for regulatory submissions.
MRA205PB.1	To design applications and clinical investigation plans for Medical devices and its facilities.
MRA205PB.2	To illustrate the registration requirement comparison study in emerging markets
MRA205PB.3	To describe the STED applications for class III devices.
MRA205PB.4	To study the clinical investigation plan for medical devices
MRA206S.1	To organize the collected data in chronological order and develop writing skills.
MRA206S.2	To evaluate and conclude the given topic.
MRA206S.3	To analyze the data and interpret the relationships.
MRA206S.4	To organize the collected data in chronological order and develop writing skills.
MRM301T.1	To recall the concepts of research methodology which includes study design, type of studies, stratifies and different design techniques.
MRM301T.2	To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests as well as recognize the importance of samples size and its significances.

MRM301T.3	To learn the history of medical research for understanding the values of clinical ethics as well as its importance in communication and sociological relationships.
MRM301T.4	To explain the CPCSEA guidelines for laboratory animal facilities which include handling, maintenance, record keeping and transportation of lab animals.
MRM302S.1	To select the scientific concept based on literature and define the objectives of research.
MRM302S.2	To outline the hypothesis and summarize the concept for presentation.
MRM302S.3	To plan for a meeting, discuss SOWT analysis, the design and methods used in concept.
MRM302S.4	To analyze the variables and their inter relationships.
MRM303S.1	To recall the fundamentals, carry out literature review on proposed research topic and identify research problem.
MRM303S.2	To outline the requirements toperform the proposed research.
MRM303S.3	To construct the research hypothesis.
MRM303S.4	To take part in research experiments meticulously and documentation as per format.
MRM401P.1	Understanding and debating current topics of active interest in their field
MRM401P.2	Apply skills to use search engines for selection of scientific articles of their interest
MRM401P.3	To conclude the results and to discuss its significance.
MRM401P.4	To appraise the concept for societal needs, acknowledge and improve presentation skills.
MRM402P.1	Identify relevant information, defining and explaining topics under discussion
MRM402P.2	Evaluate information and use and apply relevant theories
MRM402P.3	To evaluate and conclude the results using statistical analysis.
MRM402P.4	To appraise societal application and appreciation.