M.PHARMACY PROGRAMME

PHARMACEUTICAL REGULATORY AFFAIRS

PHARMACEUTICAL REGULATORY AFFAIRS	
PROGRAMME OUTCOMES (PO's)	
PO1	**Regulatory Knowledge:** Possess knowledge, comprehension of the core and basic knowledge associated with the profession of Pharmaceutical Regulatory Sciences, including drug development process, dossier preparation, good manufacturing practices, clinical trials and human research.
PO2	**Planning Abilities:** Demonstrate effective planning abilities and elements that are necessary to accumulate the regulatory submissions including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
PO3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions while reviewing and submission of dossiers to regulatory markets.
PO4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources and modern regulatory-related computing tools with an understanding of their limitations.
PO5	**Collaboration and Team Work:** Understand and consider the human reaction to change, motivation, issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities which also includes interpersonal skills, knowledge sharing and strategy in between members of a virtual team.
PO6	**Ethics:** Use ethical frameworks, apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions in clinical research and clinical investigations.
PO7	**Regulatory Professional:** Understand, analyze and communicate the value of their professional roles in society and business development and be reliable with critical thinking and regulatory writing skills.

PO8	**Cross Cultural Communication:** Appreciation of and ability to learn from and work with people from diverse linguistic and cultural backgrounds. It should emphasize how regulatory strategy increases a products chance of entering a market and staying there. Once cross-functional teams understand regulatory strategy and its importance in product development and inter-team communication.
PO9	**Initiative and Entrepreneurialism:** Individual's ability to turn ideas into practice. Like finding new opportunities to share information and concepts. Generating options and solutions to cope with changes. It involves imagination, novelty and risk-taking, as well as the ability to plan and manage projects in order to achieve objectives.
PO10	**Creativity and Innovation:** Function of knowledge, curiosity, imagination, and evaluation. The greater individual knowledge base and level of curiosity, the more ideas, patterns, and combinations will achieve, which then correlates to creating new and innovative products and services.
PO11	**Lifelong Learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self- access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

PHARMACEUTICAL REGULATORY AFFAIRS	
PROGRAMME EDUCATIONAL OBJECTIVES (PEO's)	
PEO1	**Cognition:** Program encompasses the students with profound functional knowledge in core subjects of pharmaceutical regulatory sciences. This enables students to understand the basics of regulatory compilation, create and assemble the regulation submission as per the requirements of regulatory agencies and be competent enough and apply these tools in pharmaceutical and health care industries, research, clinical laboratories, hospitals and community pharmacies for overall maintenance of public health.
PEO2	**Core competence:** To provide students with a strong foundation of regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices as well as prepare for the readiness and conduct of audits and inspections.
PEO3	**Amplitude:** To train students for understanding different acts and guidelines that regulate Drugs & Cosmetics, Medical devices, Biologicals, Herbals and Food & Nutraceuticals industries as well as comprehend the approval process and regulatory requirements for pharmaceutical products in different regulatory markets.
PEO4	**Technicality:** Implementation of innovative teaching learning methodologies with visual aids/ computer aided tools to empower the students in understanding the concepts with clarity and transparency. Students are trained in handling regulatory software's like e-CTD and in their troubleshooting procedures, problem-based learning which makes them to apply the learned theoretical concepts to real time applications and meet the current pharmaceutical industrial demand in regulatory market.
PEO5	**Adroitness:** To inculcate in students professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach and an ability to relate Pharmaceutical, Health care issues to broader social context.

PHARMACEUTICAL REGULATORY AFFAIRS

PROGRAM SPECIFIC OUTCOMES (PSO's)	
PSO1	Gain the respective background information, regulatory framework and necessary resources to understand how pharmaceutical products are regulated in different countries and how regulatory affairs professionals can help organizations navigate through regulatory obstacles.
PSO2	Apply the relevant regulations, policies, guidance documents as well as important initiatives with respect to pharmaceuticals, biologicals, natural health products and various other therapeutic products.
PSO3	The course also helps students to discuss on how regulatory affairs professionals add value to various organizations and opportunities available within the industry.
PSO4	Students able to develop and enhance communication skills, including verbal, nonverbal and written which is essential in professional environments of regulatory affairs. Students learn proper writing, editing and comprehension strategies.
PSO5	Students gain knowledge of project management processes and their application to regulatory submissions. This course equips students with skills necessary for global regulatory submissions, from selection of submission type to planning and preparing such submissions for review by respective regulatory agencies.
PSO6	Students become familiar with the legislative framework and regulations that guide the selection and designation of medical products globally. Case studies are used to provide practical experience in applying international regulations and legislations, including EU and US. Students are also introduced to softwares commonly used in the regulatory affairs field.

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Good Regulatory Practices

Course code : 21S11101 T (Theory)

C101.1	To recall the concepts of current Good Manufacturing Practices (cGMP) and Global Harmonization Task Force (GHTF) official guidelines for medical devices.
C101.2	To Illustrate the concepts of Good Laboratory Practices and its regulations including ISO and QCI standards.
C101.3	To make use of the Good Automated Laboratory Practices and its requirements as per US FDA and other regulatory guidelines like ISO and QCI.
C101.4	To explain the Good Distribution Practices which involves personnel, self-inspection, document handling and following its relevant guidelines as per WHO, ISO and CDSCO.
C101.5	To summarize the concepts and process of Quality Management System and its guidelines provided by ICH, ISO and CDSCO.

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Drug Regulatory Affairs

Course code : 21S11102 T (Theory)

C102.1	To recall the documentation in pharmaceutical industries and its plan to product development and to learn preparing documents like SMF and DMF.
C102.2	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.
C102.3	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.
C102.4	To evaluate the reports of Regulatory Inspections and understanding the concepts of Root cause analysis and CAPA.
C102.5	To adapt the product life cycle management and other concepts like PAS, SUPAC, CBE-30 and EIR including ISO risk management standards.

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Total Quality Management

Course code : 21S11103 T (Theory)

C103.1	To understand the importance of quality
C103.2	To understand ISO management systems
C103.3	To understand Tools for quality improvement
C103.4	To know Analysis of issues in quality
C103.5	To explain Quality evaluation of pharmaceuticals, Stability testing of drug and drug substances and statistical approaches for quality

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Documentation and Regulatory writing

Course code : **21S11104** T (Theory)

C104.1	To recall the documentation in pharmaceutical industries and its plan to product development and to learn preparing documents like SMF and DMF.
C104.2	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.
C104.3	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.
C104.4	To evaluate the reports of Regulatory Inspections and understanding the concepts of Root cause analysis and CAPA.
C104.5	To adapt the product life cycle management and other concepts like PAS, SUPAC, CBE-30 and EIR including ISO risk management standards.

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Good Regulatory Practices Lab

Course code : 21S11105 L (Practical)

C105.1	To recall the concepts of current Good Manufacturing Practices (cGMP) and Global Harmonization Task Force (GHTF) official guidelines for medical devices.
C105.2	To Illustrate the concepts of Good Laboratory Practices and its regulations including ISO and QCI standards.
C105.3	To make use of the Good Automated Laboratory Practices and its requirements as per US FDA and other regulatory guidelines like ISO and QCI.
C105.4	To explain the Good Distribution Practices which involves personnel, self-inspection, document handling and following its relevant guidelines as per WHO, ISO and CDSCO.
C105.5	To summarize the concepts and process of Quality Management System and its guidelines provided by ICH, ISO and CDSCO.

Programme : I/II M.Pharmacy

Semester/Year of Study : 1st Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Drug Regulatory Affairs Lab

Course code : 21S11106 L (Practical)

C106.1	To recall the documentation in pharmaceutical industries and its plan to product development and to learn preparing documents like SMF and DMF.
C106.2	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.
C106.3	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.
C106.4	To evaluate the reports of Regulatory Inspections and understanding the concepts of Root cause analysis and CAPA.
C106.5	To adapt the product life cycle management and other concepts like PAS, SUPAC, CBE-30 and EIR including ISO risk management standards.

Programme : M.Pharmacy

Semester/Year of Study : Ist Semester

Branch : **Pharmaceutical Regulatory Affairs**

Subject Name : Disaster Management

Subject code : 21DAC101b T (Theory)

C101b.1	Analyze the vulnerability of an area to natural and man-made disasters/hazards as per the guidelines to solve complex problems using appropriate techniques ensuring safety, environment and sustainability.
C101b.2	Propose appropriate mitigation strategies for earthquake and tsunami impacts as per code of practice using suitable techniques ensuring safety, environment and sustainability beside communicatingeffectively in graphical form.
C101b.3	Analyze the causes and impacts of floods,cyclones and droughts using appropriate tools and techniques and suggest mitigation measures ensuring safety, environment and sustainability besides communicatingeffectively in graphical form.
C101b.4	Analyze the causes and impacts of landslides using appropriate tools and techniques and suggest mitigation measures ensuring safety, environment and sustainability.
C101b.5	Design disaster management strategies to solve pre, during and post disaster problems using appropriate tools and techniques following the

Programme : I/II M.Pharmacy

Semester/Year of Study : 2nd Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Regulatory aspects of Drugs & Cosmetics

Course code : T (Theory)

C104.1	To recall the acts and rules related to drugs, biologicals, herbals and nutraceuticals.
C104.2	To explain the guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals
C104.3	To compare the Indian Pharmacopoeial, BIS, ISO and other relevant standards
C104.4	To interpret the Bioavailability & Bioequivalence data, Guidelines for Drug testing in animals, humans and ICMR-DBT Guidelines for Stem Cell Research
C104.5	To discuss the concepts of intellectual property rights and comparing IPR vs Regulatory affairs

Programme : I/II M.Pharmacy

Semester/Year of Study : 2nd Semester

Branch : **Pharmaceutical Regulatory Affairs**

Course Name : Regulatory aspects of Herbals and Biologicals

Course code : 21S11202 T (Theory)

C202.1	Recognize the regulation for newly developed biologics and biosimilars.
C202.2	Explain the pre-clinical and clinical development considerations of biologics.
C202.3	Discuss the regulatory requirements of blood and/or its components including blood products and label requirements.
C202.4	Set up the quality and safety of herbal products.
C202.5	Describe the regulatory requirements for biologics and vaccines.
C202.6	Describe the regulatory requirements for the herbal products.

Programme	**:**	I/II M.Pharmacy
Semester/Year of Study	**:**	2nd Semester
Branch	**:**	**Pharmaceutical Regulatory Affairs**
Course Name	**:**	Regulatory Aspects of Medical devices
Course code	**:**	21S11203 T (Theory)

C203.1	To relate the Medical Devices and its risk-based classification along with history of MD and guidance documents of IMDRF like STED andGMDN.
C203.2	To recall the ethics in clinical investigations of medical Devices and its quality related guidelines by ISO.
C203.3	To identify the regulatory approval process and marketing of medical devices in US by following US FDA official guidance documents.
C203.4	To discuss the regulatory approval process and marketing of medical devices in EU by following EMA official guidance documents
C203.5	To compare the regulatory approval process and marketing of medicaldevices in ASEAN countries like china & Japan by following their own countries guidance documents.

Programme	**:**	I/II M.Pharmacy
Semester/Year of Study	**:**	2nd Semester
Branch	**:**	**Pharmaceutical Regulatory Affairs**
Course Name	**:**	Regulatory Aspects of Food &Nutraceuticals
Course code	**:**	21S11204 T (Theory)

C204.1	To define the concepts related to Nutraceuticals and its opportunities in Nutraceutical market.
C204.2	To illustrate the global aspects of Nutraceuticals and its guidelines provided by WHO and NSF Internationals.
C204.3	To identify the regulatory approval process of Nutraceuticals and its market regulations in INDIA with reference to RDA.
C204.4	To explain the regulatory approval process of Nutraceuticals and its market regulations in USA with reference to RDA.
C204.5	To acquire the regulatory approval process of Nutraceuticals and its market regulations in EU with reference to RDA.

Programme	**:**	I/II M.Pharmacy
Semester/Year of Study	**:**	2nd Semester
Branch	**:**	**Pharmaceutical Regulatory Affairs**
Course Name	**:**	Regulatory aspects of Drugs & Cosmetics
Course code	**:**	21S11205 P (Practical)

C205.1	To find case studies of change controls, deviations and CAPA in pharmaceutical industries.
C205.2	To Illustrate the preparation of submission through eCTD software for FDA, EMA and MHRA.
C205.3	To compare the drug registration requirements procedures for different regulatory and emerging market countries for marketing authorization.
C205.4	To assess the checklist for different pharmaceutical products for regulatory submissions.
C205.5	To design applications and clinical investigation plans for Medical devices and its facilities.

Programme	**:**	I/II M.Pharmacy
Semester/Year of Study	**:**	2nd Semester
Branch	**:**	**Pharmaceutical Regulatory Affairs**
Course Name	**:**	Regulatory Aspects of Medical devices Lab
Course code	**:**	21S11206 P (Practical)

C206.1	To relate the Medical Devices and its risk-based classification along with history of MD and guidance documents of IMDRF like STED andGMDN.
C206.2	To recall the ethics in clinical investigations of medical Devices and its quality related guidelines by ISO.
C206.3	To identify the regulatory approval process and marketing of medical devices in US by following US FDA official guidance documents.

C206.4	To discuss the regulatory approval process and marketing of medical devices in EU by following EMA official guidance documents.
C206.5	To compare the regulatory approval process and marketing of medicaldevices in ASEAN countries like china & Japan by following their own countries guidance documents.

Programme : M.Pharmacy

Semester/Year of Study : IInd Semester

Branch : **Pharmaceutical Regulatory Affairs**

Subject Name : Pedagogy Studies

Subject code : 21DAC201a T (Theory)

C201a.1	Recognize the theories underlyingmethodology, searching, and learning.
C201a.2	Describe the pedagogical approaches of teachers in formal and informal classrooms in developing countries practice.
C201a.3	Analysis of pedagogical practices effectiveness.
C201a.4	Describe the teacher's classroom professionaldevelopment in detail.
C201a.5	Determine and fill research gaps for futureresearch actions.

Programme : M.Pharmacy

Semester/Year of Study : IIIrd Semester

Branch : **Pharmaceutical Regulatory Affairs**

Subject Name : Research Methodology and Intellectual Property Rights

Subject code : 21DRM101 T (Theory)

CM101.1	Understand Research Problem formulation.
CM101.2	Analyze research Related information.
CM101.3	Follow research ethics.
CM101.4	Understand that today's world is controlled by computer, Information technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CM101.5	Understand that when IPR would take suchimportant place in growth of individuals &nation, it is needless to emphasis the need of information about Intellectual Property Rightto be promoted among students in general &engineering in particular.
CM101.6	Understand that IPR protection provides an incentive to inventors for further research workand investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

Programme	**:**	II/II M.Pharmacy
Semester/Year of Study	**:**	3rd Semester
Branch	**:**	**Pharmaceutical Regulatory Affairs**
Course Name	**:**	Stability of drugs and dosage forms
Course code	**:**	21S0E301f T (Theory)

E301.1	Evaluation of stability of solutions , solids and formulations against adverse conditions
E301.2	Suggest the measures to retain stability ans storage conditions for retaining the efficacy of the products.

Course Name: ASSIGNMENTS Year of Study: 1stM.Pharmacy 1st and 2nd Semester	
C.1	To recall the fundamentals of proposed topic and carry out literature review.
C.2	To classify / compare, interpret the various methods and techniques.
C.3	To organize the collected data in chronological order and develop writing skills.
C.4	To analyze the data and interpret the relationships.
C.5	To evaluate and conclude the given topic.
C.6	To propose, design research in given concept and improve presentation skills.

Course Name: ASSIGNMENTS Year of Study: 1stM.Pharmacy 1st and 2nd Semester	
C.1	To recall the fundamentals of proposed topic and carry out literature review.
C.2	To classify / compare, interpret the various methods and techniques.
C.3	To organize the collected data in chronological order and develop writing skills.
C.4	To analyze the data and interpret the relationships.
C.5	To evaluate and conclude the given topic.
C.6	To propose, design research in given concept and improve presentation skills.

Course Name: SEMINARS Year of Study: 1stM.Pharmacy 1st and 2nd Semester	
C.1	To recall the fundamentals of proposed topic and carry out literature review.
C.2	To classify / compare, interpret the various methods and techniques.
C.3	To organize the collected data in chronological order and develop writing skills.
C.4	To analyze the data and interpret the relationships.
C.5	To evaluate and conclude the given topic.
C.6	To propose, design research in given concept and improve presentation skills.

Course Name: Journal club Year of Study: 2nd M.Pharmacy 3rd Semester	
C.1	To select the scientific concept based on literature and define the objectives of research.
C.2	To outline the hypothesis and summarize the concept for presentation.
C.3	To plan for a meeting, discuss SOWT analysis, the design and methods used in concept.
C.4	To analyze the variables and their inter relationships.
C.5	To conclude the results and to discuss its significance.
C.6	To appraise the concept for societal needs, acknowledge and improve presentation skills.

Course Name: PROJECT WORK Year of Study: 2nd M.Pharmacy 4th Semester	
C.1	To recall the fundamentals, carry out literature review on proposed research topic and identify research problem.
C.2	To outline the requirements toperform the proposed research.
C.3	To construct the research hypothesis.
C.4	To take part in research experiments meticulously and documentation as per format.
C.5	To evaluate and conclude the results using statistical analysis.
C.6	To appraise societal application and appreciation.