Program's Study Plan

- **First Level**:

#	Course Code	Name	**No. of Study Units** Lecture + Practical
1	EDRA 511	Drug Regulatory Systems Overview	2 (2+0)
2	EDRA 512	Quality in Pharmaceutical Industry	2 (2+0)
3	EDRA 513	Pharmaceutical Research Methods	2 (1+2)
4	EDRA 514	Pharmacoeconomics & Health Policy	2 (2+0)
5	EDRA 515	Drug Discovery & Preclinical Development	2 (2+0)
Total			**(10) Study Units**

- **Second Level**:

#	Course Code	Name	**No. of Study Units** Lecture + Practical
1	EDRA 521	Regulation of Clinical Trials	2 (2+0)
2	EDRA 522	Chemistry, Manufacturing, & Controls	2 (1+2)
3	EDRA 523	Drug Regulatory Compliance & Enforcement	2 (2+0)
4	EDRA 524	Pharmacovigilance & Drug Safety	2 (2+0)
5	EDRA 525	Product Registration in Kingdom of Saudi Arabia	2 (1+2)
6	EDRA ….	Elective Course (1)	2 (2+0)
Total			**(12) Study Units**

- **Third Level**:

#	Course Code	Name	**No. of Study Units** Lecture + Practical
1	EDRA 531	Regulation of Herbal Products & Health Supplements	2 (2+0)
2	EDRA 532	Regulation of Biologics & Biosimilars	2 (2+0)
3	EDRA 533	Regulation of Veterinary Products	1 (1+0)
4	EDRA 534	Regulation of pharmaceutical Products	2 (2+0)
5	EDRA 335	Regulation of Cosmetic Products	1 (1+0)
6	EDRA ….	Elective Course (2)	2 (2+0)
Total			**(10) Study Units**

- **Fourth Level & following levels**:

#	Course Code	Name	**No. of Study Units** Lecture + Practical
1	EDRA 599	Graduation Project	4 (0+8)
Total			**(36) Study Units**

- **List of elective courses: student must select (2) courses from the following**

#	Course Code	Name	No. of Study Units
1	EDRA 541	Drug Supply Chain Management	2 (2+0)
2	EDRA 542	Principles of Drug Marketing & Advertising	2 (2+0)
3	EDRA 543	Drug Benefit-Risk Assessment	2 (2+0)
4	EDRA 544	Analytical & Biological Testing	2 (2+0)
5	EDRA 545	Pharmacoepidemiology Principles	2 (2+0)

Program Courses Description:

EDRA 511	**Drug Regulatory Systems Overview**	**2 (2+0)**
Introductory overview of Regulatory authorities' rules and responsibilities in ensuring the safety, quality and efficacy of pharmaceutical products. Students will understand the concept of the regulatory system and its relationship to- and impact on healthcare and the pharmaceutical industry. The course provides an insight into harmonization initiatives. It explores the rules and functions of some international regulatory bodies such as: US-FDA, EMA, and WHO.		
EDRA 512	**Quality in Pharmaceutical Industry**	**2 (2+0)**
This course introduces the role and major elements of pharmaceutical quality, the impact of management practices, and quality management throughout the product life cycle. It will include the basic principles and practices of Quality Management (QM), Quality Assurance (QA), Quality Control (QC), and the use of robust Quality Systems in the pharmaceutical industry. Students will also be familiarized with the use of techniques such as Risk Management, Quality-by-Design (QbD) and the Pharmaceutical Quality System (PQS) approach.		
EDRA 513	**Pharmaceutical Research Methods**	**2 (1+2)**
Introduces biostatistics concepts and research methodology necessary for the interpretation, evaluation, and communication of biomedical research. Students will be provided with sessions on statistical packages such as SPSS.		

EDRA 514	Pharmacoeconomics & Health Policy	2 (2+0)
In this course, students will learn how to analyze the health policy in terms of financing the health care services, demand of health care services, policies, ethics, laws and quality of the services, and explore the relationship between the regulatory system and health policy. This course also introduces students to the basic principle and concepts of pharmacoeconomics. It will also provide an overview of the pharmaceutical pricing strategies and policies.		
EDRA 515	**Drug Discovery & Preclinical Development**	**2 (2+0)**
This course provides an in-depth study of the discovery of an active molecule throughout all stages of preclinical development including pharmacological and toxicological assessment. Students will be exposed to evaluation examples of potential drug targets, discovery, optimization and preclinical development of IND.		
EDRA 521	**Regulation of Clinical Trials**	**2 (2+0)**
The students will learn how to prepare, implement, monitor and manage a clinical trial according to the regulation and guidelines. The course will cover topics such as Good Clinical Practices (GCP), auditing a clinical trials and roles and responsibilities of each professional member involved in the clinical trial. It also discusses institutional review boards (IRBs) and informed consents .		
EDRA 522	**Chemistry, Manufacturing, & Controls**	**2 (1+2)**
This course covers requirements for regulatory submissions, as well as, how to adhere to Good Manufacturing Practices (GMP) throughout the product life cycle. It offers a broad understanding of CMC topics and includes other specialized areas such as formal experimental design and process analytical technology (PAT). This course covers CMC information for both chemical drugs and biologics.		
EDRA 523	**Drug Regulatory Compliance & Enforcement**	**2 (2+0)**
This course is designed to provide students with an understanding of the parameters for regulatory compliance, successful approaches to compliance, and meeting the concerns of regulators. Students will obtain a comprehensive set of tools for preparing regulatory initiatives, coping with challenges, and managing compliance. It will also deal with ethical issues, which regulatory professionals may encounter including a general introduction to complex concepts such as bioethics and legal principles. It also identifies and explains the core values related to local and international codes of ethics.		
EDRA 524	**Pharmacovigilance & Drug Safety**	**2 (2+0)**
This course covers the fundamentals of regulatory requirements relevant to drug safety and pharmacovigilance including adverse event reporting, signaling, and risk management. The course addresses the regulatory issues that improve safety, but slow down the product approval process. This course will provide students with regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet regulatory safety		

reporting standards.		
EDRA 525	**Product Registration in Kingdom of Saudi Arabia**	**2 (1+2)**
Students will learn the SFDA requirements to submit a product for registration. The course will include practical exercises on preparing file submissions to the SFDA. The course will also cover variations submission for registered products and how to respond to inquiries from the SFDA. The course will also touch upon GCC submission and registration requirements.		
EDRA 531	**Regulation of Herbal Products & Health Supplements**	**2 (2+0)**
This course will cover the definition of herbal products, their forms/formulations, evidence-based risk, safety measures, and evidence-based uses. The course will also provide a brief overview on the regulation elements in the main regulatory bodies. The regulation of herbal products in Saudi Arabia via SFDA will be also covered in details in this course. This course will also explore local and international practices for supplement regulation.		

EDRA 532	**Regulation of Biologics & Biosimilars**	**2 (2+0)**
This course covers the major steps of the upstream and downstream manufacturing process of biologics. Consideration is also given to their regulatory and control aspects including the existing regulatory guidelines of the US-FDA, EMA, WHO, and compare them to the SFDA guidance.		
EDRA 533	**Regulation of Veterinary Products**	**1 (1+0)**
This course will explain the local and international practice for veterinary products regulation. Students will know the common deficiencies in veterinary products submissions. The course will also explore the potential hazard of veterinary products remnants on human.		
EDRA 534	**Regulation of pharmaceutical Products**	**2 (2+0)**
This course discusses the registration requirements of generic products. Students will know the most common challenges and deficiencies in generic products submissions. At the end of this course, students will be provided with fundamental pharmacokinetic concepts and be able to use them to understand the proper design of bioequivalence studies and their importance in regulation of generic products.		
EDRA 335	**Regulation of Cosmetic Products**	**1 (1+0)**
This course will explain the local and international practices for cosmetic regulations and guidelines. Students will know the common deficiencies in cosmetic products submissions including safety and toxicological assessment.		
EDRA 599	**Graduation Project**	**4 (0+8)**
The project can be field study and practical training in regulatory or industrial sites.		

EDRA 541	Drug Supply Chain Management	2 (2+0)
This course aims to provide students with a complete overview of professional supply chain management processes and spotlights the issues and challenges that exist specifically within pharmaceuticals and biologics.		
EDRA 542	**Principles of Drug Marketing & Advertising**	**2 (2+0)**
Students will learn how to get their product to the market successfully through analyzing the market and applying marketing principles. They will also understand the local code of ethics in pharmaceutical marketing and advertising.		
EDRA 543	**Drug Benefit-Risk Assessment**	**2 (2+0)**
The objective of the course is to gain insight in the role of benefit-risk assessment in the process of decision making on medicines by different stakeholders. At the end of this course, students will be able to: understand the rationale of benefit-risk assessment and evaluate the methodology and results of benefit-risk process, and finally translate the results into the process of decision-making.		
EDRA 544	**Analytical & Biological Testing**	**2 (2+0)**
The course will provide students with essential tools for identification and quantification associated with pharmaceuticals and biologics. The course will enable them to distinguish compendial and non-compendial testing methods and compare different pharmacopeial techniques.		
EDRA 545	**Pharmacoepidemiology Principles**	**2 (2+0)**
In this course, students will learn and apply basic concepts of epidemiology to multiple domains of pharmaceutical research, with an emphasis on critical thinking, analytic skills, and application to clinical practice and research. The course introduces study designs applied to human populations. In addition, the course will provide a basic understanding of causation, measures of disease occurrence and causal effect, types of epidemiology studies, biases in study design, data analysis (including methods to control confounding) and use of epidemiology in clinical settings. Principles and methods will be illustrated through in-class discussion of examples from the literature.		