Pharmaceutical Sciences/ Pharmaceutics (M.S.)

About The Program:

The School of Pharmacy offers a graduate program leading to the M.S., with a choice of Thesis or Non-Thesis Option, and the Ph.D. in Pharmaceutical Sciences with a concentration in Pharmaceutics. The program is designed to prepare students for positions in the pharmaceutical industry, government agencies, and faculty positions in schools of pharmacy.

Career Options: Graduates generally find employment in the pharmaceutical industry, government agencies, or academia.

Prerequisites for Admission: A baccalaureate degree in Pharmacy, Biology, Biochemistry, Chemistry, Engineering, or a related discipline is required.

Areas of Specialization: Faculty members specialize and offer graduate coursework in controlled release dosage forms, drug metabolism, encapsulation, mechanisms of drug action, pharmaceutical analysis, pharmacokinetics, and solid dosage forms.

Requirements of Programs:

- **Total Credit Hours**: 30

Core Courses (Thesis Option)

Topics in Pharmaceutical Sciences - Topics vary; specific topic(s) announced prior to the start of the semester.

Pharmaceutical Analysis - Application of chemical analysis as it relates to pharmaceuticals and pharmaceutical manufacturing. Classical separation methods including GC, HPLC, and NMR as well as, hyphenated techniques (GC-MS & HPLC-MC) will be explored. The student will also be introduced to immunologic antibody based procedures and emerging technologies.

Seminar in Pharm Science

Department of Pharmaceutical Sciences Seminar Series - The goal of the course is to expose graduate students in the Department of Pharmaceutical Sciences to the faculty research in our department. Students will be presented with a number of research topics, including pharmaceutics, pharmacokinetics, medicinal chemistry, biotransformation, pharmacology, and physiology. In addition to the presentations by faculty members, several guest speakers will present their research topics and discuss their opinions on science careers outside of academia (i.e., industry, medical writing, medical science liaison, etc.). Through exposure to these diverse research topics, students will become more well-rounded scientists and become more aware of career opportunities that are available to them.

Pharmacokinetics - The objective of this course is to present the fundamental principles of pharmacokinetics (PK). The topics will include PK data analysis, dosage regimen design, and the

determinants of drug absorption, distribution, metabolism, and excretion. Pharmacodynamics, the study of drug concentration - response relationships, will also be presented.

Principles in Drug Discovery - In this course, students will receive an introduction to the fundamental principles of drug discovery and development, beginning with an historical overview of drug discovery.

Bioethics in Research

Advanced Pharmacogenomics - The course is a one semester course focused on inherited factors that modulate drug response. Special problems of genetic variability in humans, detection and prediction of pharmacologically relevant genetic polymorphisms will be discussed. The course will integrate current mechanistic knowledge of drugs, human genetics, data mining, and analytical tools to tailor drug administration for a specific genetic background.

Statistical Quality Control - An introduction to statistical concepts, this course reviews control charts for variables, probability theory, control charts for attributes, and acceptance sampling systems. Class discussions include application to quality control of pharmaceutical manufacturing.

Concentration-Specific Courses

Pharmaceutical Manufacturing I: Preformulation/Formulation - Presents techniques relevant to all aspects of preformulation and formulation phases, as well as principles and mechanisms of incompatibility and stability testing.

Pharmaceutical Manufacturing II – Presents processing and principles that apply to solid dosage form design and product development.

Electives (3 credits)

Non-Didactic Course

Master's Research - Master's Research course appropriate for students finished with coursework and working with a faculty member on the thesis.

Core Courses (Non-Thesis Option)

Pharmaceutical Analysis - Application of chemical analysis as it relates to pharmaceuticals and pharmaceutical manufacturing. Classical separation methods including GC, HPLC, and NMR as well as, hyphenated techniques (GC-MS & HPLC-MC) will be explored. The student will also be introduced to immunologic antibody based procedures and emerging technologies.

Pharmaceutical Manufacturing I: Preformulation/Formulation - Presents techniques relevant to all aspects of preformulation and formulation phases, as well as principles and mechanisms of incompatibility and stability testing.

Pharmaceutical Manufacturing II – Presents processing and principles that apply to solid dosage form design and product development.

Pharmaceutical Biotechnology – This course will introduce students to pharmaceutical biotechnology, biophysical and chemical aspects of biotech products, and their pharmaceutical formulations and clinical applications. Amino acids, proteins, peptides, and nucleotides are of particular interest. The principles of pharmaceutical formulations and physicochemical evaluation of formulations will be discussed. Pharmacokinetics of biologics and current analytical methods used in pharmaceutical biotechnology are included. In addition, the course provides an introduction to biopharmaceuticals that encompass a variety of technologies ranging from products derived from natural sources, peptides, therapeutic proteins/monoclonal antibodies, oligonucleotide therapeutics (e.g. antisense, ribozymes, apatmers, siRNA), gene therapy and special issues in drug delivery. The course will begin with a review of the molecular, biochemical, pharmaceutical underpinnings that support each of the technologies and will move into a more detailed discussion of each therapeutic technology. Preclinical and clinical development, safety, efficacy and manufacturing issues will be discussed.

Physical Pharmacy I – The emphasis of this course is to form bridge between the concepts of physical pharmacy and the application of pharmaceutical sciences. Students will understand basic aspects of intermolecular forces, physical properties of solutions, ionic equilibria, buffers and isotonic solutions, solubility and partition phenomena, complexation and protein binding, reaction kinetics, mass transport, dissolution phenomena, interfacial phenomena, and rheology. Pharmaceutical applications based on the basic principles will be discussed as well. Students will be expected to be able to apply the basic concepts from this course to typical formulation and stability issues of pharmaceutical dosage forms. A previous course is physical chemistry.

Applied Biopharmaceutics – Presents the interrelationships of the physicochemical properties of the drug and the dosage form, to the route of administration and to the rate and extent of systemic absorption. Drug absorption mechanisms, physiological and GIT constraints on dosage form transit and bioavailability, effect of formulation parameters, dissolution methodologies, in-vitro/in-vivo correlation of drug product performance as well as SUPAC, ICH and FDA guidelines on development and approval process will be covered. Formulation strategies for optimum therapeutic outcome via application of pharmaceutical sciences to the design of drug delivery systems is provided.

Electives

Select six of the following approved courses:

Statistical Quality Control – An introduction to statistical concepts, this course reviews control charts for variables, probability theory, control charts for attributes, and acceptance sampling systems. Class discussions include application to quality control of pharmaceutical manufacturing. Note: Not open to students who have taken the former PHARMACEUTICS 451.

Production of Sterile Products – This course reviews the theory and practice involved in the preparation of sterile, injectable products, covering formulation, manufacturing, facility requirements, validation and regulatory issues. Upon completion of the course, students will develop an understanding of the routes of administration of injectable drugs and the types of injections, current formulation methods, aseptic manufacturing processes, requirements for sterile manufacturing facilities, and validation, compliance and regulatory issues. Note: Not open to students who have taken the former PHARMACEUTICS 492. Also note that prior to fall 2016, the title of PS 5492 was "Production of Sterile Parenterals."

Sterilization Processes – This course surveys sterilization processes used in the pharmaceutical, medical device, in-vitro diagnostic, and biotech industries. Current methods of sterilization are discussed, including thermal, gaseous, radiation, filtration, and aseptic processing. Students learn basic aspects of sterilization science as well as design, review, and audit sterilization validations and processes according to industry practices. Note: Not open to students who have taken the former PHARMACEUTICS 493.

Pharmaceutical Drug Dosage Forms – Through an overview of drug dosage form design and manufacturing technology, principles of pharmaceutical processing and pharmaceutical dosage form design (including preformulation and biopharmaceutics) are discussed, including dosage forms such as tablets, capsules, modified dosage forms, semi-solid products, and transdermal delivery systems.

Development of Sterile Products – A study of the theory and practice in the development of parenteral products; dosage form design, formulation, solubility/physical pharmacy, excipients, assays, stability, physiochemical properties of biomolecules, delivery systems for controlled/sustained release and manufacturing methods. Note: Not open to students who have taken the former PHARMACEUTICS 501. Also note that prior to fall 2016, the title of PS 5501 was Development - Parenterals."

Advanced Principles of Pharmacokinetics – An advanced course in the theory and application of pharmacokinetics and pharmacodynamics.

Introduction to Toxicology – Toxicology is a multi-disciplinary science focused on the adverse effects of chemicals, drugs and environmental agents. In the first part of this course the basic principles of toxicology will be covered, including dose response relationships, mechanisms of toxicity and exposure. In the second part, target organs of toxicity will be presented with an overview of anatomy and physiology of different target organs (e.g. liver, kidney), as well as organ-specific response to toxic insult. In the final segment of the course, students will be exposed to a variety of areas of applied toxicology, including risk assessment, clinical & forensic toxicology, chemical carcinogenesis, reproductive toxicology and the role of toxicology in drug development.

Modified Release Dosage Forms – The fundamentals involved in various extended release dosage forms and their modification for use in particular dosage formulations. Biopharmaceutical and pharmacokinetic aspects of extended-release dosage forms are discussed as well. Overview of polymeric excipients used in the formulation of extended-release dosage forms. Current commercial products under development will be discussed.

Physical Pharmacy II – The rheological behavior of polymer systems will be discussed. The physical chemical properties of proteins and peptides will be presented with formulation applications. This is an advanced course. Physical Pharmacy I is a prerequisite.

Pharmaceutical Laboratory Quality Systems and Operations – The laboratory plays a key role in the manufacture and release of pharmaceuticals. An effective QC lab assures the integrity of the data generated to enable the release of raw materials, in-process, and finished products and also meets production schedules. In addition, production-related responsibilities must meet with compliance standards. This course covers these responsibilities in detail while providing insight on how to meet internal and regulatory requirements for lab operations. Why labs fail and what actions must be taken to prevent failure are covered in depth.

Good Manufacturing Practices – This course provides an introduction to cGMP (current good manufacturing practices). Regulations for drugs under the Food, Drug and Cosmetic Act (21 CFR 210 and 211) and their implication for personnel, buildings, equipment, and records will be thoroughly reviewed and studied. It includes a study of pertinent legal decisions and regulatory actions based on non-compliance. Note: This course fulfills the GxP requirement for RA and QA MS students and for the Drug Development Certificate. Students with extensive manufacturing experience in GMPs may petition the School to allow them to replace the basic GMP class with Advanced GMPs. To do so, students must have at least five years of GMP experience and submit a resume to the RA and QA Office for final approval.

High Purity Water Systems – This course examines high purity water systems from the Quality Function perspective, covering basic aspects of system design and operation. Special attention is paid to unit operations, sanitization procedures, and routine monitoring programs. Students learn to plan validations and establish routine monitoring programs to assess ongoing quality. Domestic (NFDWR/NSDWR) requirements and international standards and regulatory expectations are discussed.

Microbiological Concepts in Pharmaceutical Manufacturing – This course addresses essential microbiology concepts of manufacturing and quality control that form the basis of Good Manufacturing Practices for both sterile and non-sterile pharmaceuticals. Emphasis is placed on a review of the following from a microbiological perspective: manufacturing technologies and techniques, building quality into processes, influence of raw material quality on finished product, the meaning of the qualification and validation studies conducted by drug firms, and key microbiological tests performed at in-process and finished product stages. The course stresses practical matters and includes case studies to prepare students for daily issues arising in industry.

Regulatory Sciences: Managing the Guidelines to Quality – The International Conference on Harmonization (ICH) has revolutionized the format and content of global regulatory filings with the Common Technical Document (CTD). Recent FDA draft guidelines have incorporated and expanded upon concepts described by the ICH. As the term "guideline" implies, such documents should not be generally viewed as regulations, but as "recommendations" to consider when developing the body of scientific information. Proper interpretation of the guidelines based on sound scientific principles is essential to optimize both the quality and quantity of information submitted to global regulatory agencies. Consequently, review of various ICH and FDA Quality guidelines will be supplemented by a discussion of the basic scientific principles that may influence implementation. After completing this course, students should understand the basic expectations set forth in various ICH and FDA Quality Guidelines. They should also realize that the guidelines are subject to interpretation and not definitive regulations.

Analytical Chemistry in Pharmaceutical Laboratories – This course provides an overview of laboratory operations and the critical role of an analytical scientist. It reviews regulatory requirements for pharmaceutical lab operations and provides a framework for quality in a drug development laboratory. Although the course is designed for pharmaceutical scientists, many of the operations discussed are applicable to the chemical and environmental industries.

Courses:

Click HERE for more information on the courses below.

- Statistical Quality Control
- Biotechnology: Bioprocess Basic
- Good Manufacturing Practices
- High Purity Water System
- Production of Sterile Products
- Sterilization Processes
- Pharmaceutical Drug Dosage Forms
- Development of Sterile Products
- Regulatory Sciences
- Topics in Pharmaceutical Sciences
- Principles of Drug Action/ Pharmacokinetics
- Pharmaceutical Analysis
- Pharmaceutical Manufacturing I: Preformulation/ Formulation
- Pharmaceutical Manufacturing II
- Pharmaceutical Biotechnology
- Physical Pharmacy I
- Applied Biopharmaceutics
- Advanced Principles of Pharmacokinetics
- Advanced Medicinal Chemistry I
- Advanced Medicinal Chemistry II
- Radioisotope Methodology
- Seminar in Pharm Science
- Introduction to Toxicology
- Department of Pharmaceutical Sciences Seminar Series
- Writing and Publishing a Review Article
- Bioinformatic Genes Drug
- Journ Club/ Pharmacodynam
- Laboratory Experience in Pharmaceutical Sciences
- Pharmacokinetics
- Principles in Drug Discovery
- Bioethics in Research
- Principles of Biochemistry
- Topics in Pharmaceutical Biotechnology
- Introduction to Translational Molecular Technology
- Neuroscience of Pain
- Pharmacodynamics
- Advanced Pharmacogenomics
- Pharmaceutical Sciences Literature Review
- Abuses of Drugs and Chemicals
- Modified Release Dosage Forms
- Advanced Pharmacokinetic Modeling I
- Physical Pharmacy II
- Chemical Surfaces & Interfaces
- Advanced Drug and Gene Delivery Systems
- Food and Drug Law
- Dermatopharmaceutics
- Teaching in Higher Educ
- Preliminary Examination Preparation
- Master's Research