# GRADUATE COURSE DESCRIPTIONS

Course schedules are printed every semester. The listings below are tentative. They are based on past history and are subject to change.

# **Doctor of Philosophy Courses**

#### PHS 021 Seminar In Pharmaceutics

(For Ph.D. Students) A presentation and analysis of recent publications and developments in pharmaceutics. The students are expected to make presentations and/or write reports on specific topics. Outstanding scientists may be involved from time to time. This course is open for the Ph.D. level student. M.S. candidates may be allowed with permission of the Program Director. Ph.D. candidates must register for three consecutive semesters and must attend and participate throughout their studies. Pass-Fail only. *Credits: 1*Every Semester

# PHS 880 Thermal Physics and Applications to the Chemistry of Pharmaceutical Systems I

The first in a series of two elective courses intended for Ph.D. students. These courses offer an integrated treatment of the theory of energetic processes and applications that are relevant to pharmaceutical science. The first semester will develop equilibrium macroscopic and statistical thermodynamics, and introduce the concepts on nonequilibrium thermodynamics. The Second semester will more fully develop the basic theory of nonequilibrium thermodynamics and the thermodynamics of processes. Applications will be introduced throughout the course and include colligative properties of solutions, Debye-Huckel theory, phase changes and thermodynamic stability, chemical equilibrium and reactions, surface effects, adsorption, polymer chain statistics, Flory-Huggins theory, and thermal analysis.

The pre-requisites of PHS 701, 702 and 991 are required.

Credits: 3
Every Fall

# PHS 881 Thermal Physics and Applications to the Chemistry of Pharmaceutical Systems II

(The second course in a two-semester sequence.) These are elective courses intended for Ph.D. students. They offer an integrated treatment of the theory of energetic processes and applications that are relevant to pharmaceutical science. The first semester will develop equilibrium macroscopic and statistical thermodynamics, and introduce the concepts on nonequilibrium thermodynamics. The Second semester will more fully develop the basic theory of nonequilibrium thermodynamics and the thermodynamics of processes. Applications will be introduced throughout the course and include

colligative properties of solutions, Debye-Huckel theory, phase changes and thermodynamic stability, chemical equilibrium and reactions, surface effects, adsorption, polymer chain statistics, Flory-Huggins theory, and thermal analysis.

The pre-requisite of PHS 880 and 992 are required. Credits: 3

Every Spring

# PHS 886 Computational Methods of Data Analysis

This is an elective course intended for Ph.D. students. The course offers an integrated treatment. of the methods of analyzing data using the equations derived from physical models. Topics include elementary statistics review, regression methods, analysis of errors, and computational methods. Special consideration will be given to methods of transforming equations and/or data into forms most useful for data analysis, special functions (error function, Bessel functions, etc.), and special problems that can arise with various methodologies. Many of the examples and exercises will be taken from probability theory and statistics, so this course will also serve as a primer in statistics. The pre-requisites of PHS 701 and 993 are required.

Credits: 3
Every Semester

# PHS 887 Pharmacokinetic / Pharmacodynamic Modeling and Simulation

There is a growing need for scientists trained in pharmacokinetic modeling and simulation. This is an elective course for students in the Ph.D. program in Pharmaceutics. The objectives of the course are: To provide an overview of the role of pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation in the drug development process, to give a graduate level introduction to the field of Pharmacometrics and to demonstrate the applications of Population PK/PD modeling and simulation using examples of biomarkers and clinical endpoints in various therapeutic areas such as CNS, cardiovascular, and infectious diseases. The course will balance theory and "hands on" training and will be a combination of didactic lectures, hands on exercises and larger M&S projects conducted by the students.

The pre-requisite of PHS 987 and 990 are required. Credits: 3

On Occasion

# PHS 901 Basic Pharmaceutics

(Open to foreign students and non-pharmacy majors) An introduction to basic pharmaceutical principles associated with pharmaceutical dosage forms. Discussions will focus on factors affecting dosage form design, manufacturing of different dosage forms, biopharmaceutics, pharmacokinetics, drug stability, FDA approvals and recalls, so that the student can obtain the knowledge needed to succeed in the M.S. and Ph.D. curricula. Waiver may be authorized by the division only.

Credits: 3
Every Fall

# PHS 987 Advanced Biopharmaceutics and Pharmacokinetics

Biopharmaceutics is the study of the relationship between the physical and chemical factors of a drug in a dosage form and the resultant impact on the rate and extent of drug absorption and, ultimately, the pharmacological response observed after its administration. Pharmacokinetics concerns the mathematical representation of drug absorption, distribution, metabolism and excretion. In this course, the principles and theories of biopharmaceutics and pharmacokinetics will be discussed, with emphasis on the various analytical tools to characterize drug disposition in vivo. The relationship between pharmacokinetics and pharmacodynamics will also be presented. The material mastered in this course will be used to develop and test mathematical models of drug disposition in PHS 990 (Mathematical Modeling).

On Occasion

#### PHS 989 Special Topics in Pharmaceutics

Special topics in pharmaceutics which are of current interest.

Credits: 3 On Occasion

# PHS 990 Mathematical Modelng

This course involves application of the pharmacokinetic principles presented in PHS 986 (Advanced Biopharmaceutics and Pharmacokinetics) to develop mathematical models which describe drug absorption, distribution, metabolism and excretion, with emphasis upon computer "fitting" of pharmacokinetic and pharmacokinetic-pharmacodynamic models to characterize the disposition of a compound in biological systems.

The pre-requisite of PHS 987 is required. Credits: 3

On Occasion

### PHS 991 Solubility and Complex Equilibria

The application of physicochemical principles to the study of complex equilibria, including the use of thermodynamics and mathematics to delineate the factors involved.

Credits: 3
On Occasion

### PHS 992 Transport Phenomena and Drug Delivery I

The application of the laws and mathematics of diffusion to dissolution, membrane transport and release of drugs from dosage forms.

The pre-requisites of PHS 701 and MTH 611 are required.

Credits: 3

On Occasion

# PHS 993 Kinetics and Mechanisms of Drug Degradation

A study of the kinetics and mechanisms of drug degradation in the solid and liquid state.

The pre-requisite of PHS 701 is required. The corequisite of MTH 610 is required.

Credits: 3
On Occasion

## PHS 994 Drug Stabilization

A study of drug degradation in multiphasic systems of their use in stabilizing labile drugs.

The pre-requisite of PHS 993 is required.

Credits: 3

On Occasion

# PHS 995 Transport Phenomena and Drug Delivery II

This is an upper-level elective course intended for senior Ph.D. students which builds on the required course PHS 992 (Transport Phenomena and Drug Delivery I). The course offers a more advanced treatment of the physical and theoretical foundations of transport theory, and numerous applications in areas of current research, especially as related to pharmaceutical systems. The main emphasis is on mass transport, but heat and momentum transport will also be included. The necessary mathematics will be developed, as needed. Methods of data analysis and computational methods will be included as an integral part of the course.

The pre-requisite of PHS 992 is required. Credits: 3

On Occasion

#### PHS 996 Intrafacial Phenomena

The application of physicochemical principles to the study of interfacial phenomena. The use of thermodynamics, kinetics and mathematics will be emphasized with applications to pharmaceutical systems, when possible.

Credits: 3
On Occasion

#### PHS 998 Ph.D. Research & Thesis

Each Ph.D. candidate will conduct Ph.D. thesis research under the guidance of a committee whose chair will be the candidate"s major professor. The enrollment and fee for this course registration will be repeated for a minimum of four semesters, and until the dissertation is completed.

Credits: 3
Every Semester

## **Master of Science Courses**

# Pharmaceutics, Industrial Pharmacy, and Cosmetic Science

#### PHS 020 Seminar In Pharmaceutics

(For M.S. Students) A presentation and analysis of recent developments in industrial pharmacy and pharmaceutics. Students are expected to present oral and written reports on a particular subject in consultation with the instructor in charge. May be repeated for credit.

Credits: 3
Every Semester

#### PHS 060 Research And Thesis

(For M.S. Students) Individual research in the various areas of specialization. Students doing the thesis option must register at least twice for this course. Pass-Fail only.

Credits: 3
Every Semester

#### PHS 070 Special Problems

Laboratory, fieldwork or library research in the various areas of specialization. Pass-Fail only. Permission of the instructor required.

Credits: 3
Every Semester

#### PHS 701 Physical Chemistry I

The emphasis will be on chemical thermodynamics, from fundamental principles to applications in chemical equilibrium, including the concept of activity in nonideal systems, and electrochemistry of the pH electrode and other ion selective electrodes. Credits: 3

Every Fall

# PHS 702 Physical Chemistry II

The emphasis of this course is on chemical kinetics, from experimental measurement of rate processes to activation theory and enzyme kinetics. Steady state activation theory will be included. *The pre-requisite of PHS 701 is required.* 

Credits: 3

Every Spring

#### PHS 769 Transdermal Drug Delivery

Today's pharmaceutical scientist, regardless of their area of practice (R & D, manufacturing, etc.) must have a basic knowledge of drug delivery from all dosage forms. Therefore, this course is intended to train the pharmaceutical scientist in preparing a transdermal dosage form capable of delivering the active ingredient to the blood circulation through the skin in quantities sufficient to product a therapeutic effect. Two lecture hours and three laboratory hours.

Credits: 3
On Occasion

#### PHS 931 Advanced Physical Pharmacy I

A systematic study of the application of physicochemical principles to the pharmaceutical and cosmetic sciences. Topics include complexation, colloids, interfacial phenomena, dissolution theory, suspensions, micrometrics and rheology.

The pre-requisite of PHS 701 is required.

Credits: 3

# Every Semester

#### PHS 932 Advanced Physical Pharmacy II

A systematic study of the application of physicochemical principles to the pharmaceutical and cosmetic sciences. Topics include complexation, colloids, interfacial phenomena, dissolution theory, suspensions, micrometrics and rheology.

The pre-requisite of PHS 931 is required.

Credits: 3
Every Semester

## PHS 934 Principles of Industrial Pharmacy I

A study of methods used to formulate, manufacture and stability-test various dosage forms including tablets, ointments, creams, capsules, suspensions, sterile products, etc. The different techniques used to formulate dosage forms possessing unique properties such as sustained or delayed release will also be covered.

Credits: 3
Every Fall

# PHS 935 Principles of Industrial Pharmacy II

A laboratory course designed to give students experience in utilizing industrial instrumentation to test basic principles and theories in the design and production of various dosage forms.

The pre-requisite of PHS 934 is required.

Credits: 3
Every Spring

#### PHS 936 Dosage Form Design

Biopharmaceutic and pharmacokinetic principles, coupled with physical pharmacy concepts, are used to discuss methods necessary for optimizing the design of various drug-delivery systems. The course is intended for those having a basic understanding of dosage forms and their design, and is geared to the underlying principles of drug release from dosage forms. While a major portion of the course is devoted to oral solids, liquids, topicals and parenteral design are also covered, together with means of evaluation and testing.

Credits: 3
On Occasion

## PHS 937 Pharmaceutical Engineering

An introduction to basic engineering principles that are involved in the commercial manufacture of pharmaceutical dosage forms. Discussions will focus on how such principles are blending, mixing, heat and mass transfer are utilized to design and specific equipment used in producing powders, tablets, capsules and parenteral products. Basic concepts of cost estimation will also be discussed.

Credits: 3

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On Occasion

# PHS 950 Cosmetic/Dermatological Formulations and Technology I

(The first course in a two-semester sequence.) Designed for in-depth studies of skin, mechanistic analysis of the relevant skin functions, percutaneous absorption, rationale for dermatologic formulations, physicochemical principles used, performance criteria and evaluation of the topical systems. Emphasis is placed on the product development, scale-ups, manufacturing, stability-testing and performance evaluations of modern-day cosmetic, toiletry and pharmaceutical topical products. The courses cover all types of skin care, hair care and treatment systems including creams, lotions, shampoos, gels, fluids, makeups, sunscreens and pharmaceutical dermatologicals. Credits: 3 Every Fall

# PHS 951 Cosmetic/Dermatological Formulations and Technology II

(The second course of a two-semester sequence) Designed for in-depth studies of skin, mechanistic analysis of the relevant skin functions, percutaneous absorption, rationale for dermatologic formulations, physicochemical principles used, performance criteria and evaluation of the topical systems. Emphasis is placed on the product development, scale-ups, manufacturing, stability-testing and performance evaluations of modern-day cosmetic, toiletry and pharmaceutical topical products. The courses cover all types of skin care, hair care and treatment systems including creams, lotions, shampoos, gels, fluids, makeups, sunscreens and pharmaceutical dermatologicals. The pre-requisite of PHS 950 is required. Credits: 3

Every Spring

# PHS 952 Cosmetic/Dermatological Formulations and Technology Laboratory

Designed for in-depth study of product development, scale-up, manufacturing, stabilitytesting and performance evaluations of modern-day cosmetic and toiletry products.

Credits: 3 On Occasion

# PHS 958 Aerosol Science and Technology

An in-depth study of the physicochemical principles of aerosol science and technology. The topics covered include: aerosol propellants, containers, valve and actuator systems, product development, manufacturing, stability testing and performance evaluations of all types of aerosol products. Special emphasis is placed on the homogeneous and heterogeneous systems used in the formulations of topical, nasal and inhalation aerosol drug delivery products.

Credits: 3 On Occasion

# PHS 960 Properties/Applications of Cosmetic and **Pharmaceutical Raw Materials**

Designed to be of special value to individuals involved in formulation and manufacturing work of cosmetic, toiletry and pharmaceutical products. Covers the physicochemical properties of major classes of raw materials. These include tablets, ointments and creams, surfactants, film formers, plasticizers, preservatives, antioxidants, sunscreens, thickeners and dispersants, pharmaceutical solvents, etc. Special emphasis is placed on the creative and innovative application of these raw materials in the development of contemporary cosmetic/toiletry and pharmaceutical dosage forms. Credits: 3

Every Fall

#### PHS 972 Methods of Pharmaceutical Analysis

Theory of chromatographic, spectrophotometric and other methods of analysis as applied to clinical, pharmaceutical and cosmetic problems is discussed. Credits: 3

Every Spring

# PHS 979 Design of Peptide and Protein Drug **Delivery Systems**

The course covers an introduction to the genecloning technology and ex-vivo cell cultures as a new source of protein and peptide drugs. The course will discuss the chemistry, physical chemistry and biochemical properties of polypeptides; physical and chemical degradation pathways characteristic to protein drugs; suggested mechanisms of protein drug absorption; classification and properties of absorption promoters for macromolecules; how to design the appropriate delivery system for a stable, effective protein drug through parenteral or non-parenteral routes. Specific protein products for the diagnosis, treatment and prevention of diseases, which are now commercially available, will be covered. Credits: 3

On Occasion

# PHS 982 Science and Technology of Controlled Release Systems

This course will cover design and fabrication of currently utilized devices for controlling the release of drugs to the human body. A wide variety of drug delivery system designs will be analyzed in this course. Mechanisms and kinetics of drug release from these systems, structure and properties of fabrication materials, principles of molecular diffusion across polymer barriers and transport across biological interfaces will be covered. This course is a senior elective for both M.S. and Ph.D. students

Credits: 3 On Occasion

# Pharmacology, Toxicology and **Medicinal Chemistry**

#### PTM 020 Seminar In Pharmacology/Toxicology

Students, faculty and guests review and discuss original works and recent advances in pharmacology and toxicology. The seminar will include invited lectures on cutting edge research. Mandatory for every student graduating in Pharmacology/Toxicology. May be repeated for credit.

Credits: 3

Every Semester

#### PTM 060 Research And Thesis

Individual research in the various areas of specialization. Students doing the thesis option must register at least twice for this course. Pass-Fail only.

Credits: 3

Every Semester

#### PTM 070 Special Problems

Laboratory, fieldwork or library research in the various areas of specialization. Pass-Fail only. Permission of the instructor required.

Credits: 3

Every Semester

#### PTM 704 Autonomic Pharmacology

A course designed to acquaint the students with the historical development of the concept of neurohumoral transmission, adrenergic and cholinergic receptors, storage and release of neurohormones, blocking agents, and biochemical aspects of adrenergic and cholinergic action. Students will be required to read and discuss selected references

Credits: 3 Every Fall

## PTM 705 Biochemical Pharmacology

This course considers the mechanisms of drug action from the molecular-biochemical viewpoint. Initial discussion of the fundamentals of drug action is followed by extensive coverage of major drug groups such as anticancer, antimicrobials, analgesics and autonomic drugs. Molecular parameters of receptors are emphasized throughout as in enzymology, where applicable. Outside readings will be assigned.

Credits: 3

Every Fall and Spring

# PTM 707 Carcinogens, Mutagens, Teratogens

Basic concepts of biochemical toxogenesis; mechanisms involved in the types of carcinogenesis, mutagenesis and teratogenesis; chemical carcinogens; tests for carcinogenesis and mutagenesis; experimental aspects of teratogenesis; environmental agents, drugs and other agents as causative factors.

Credits: 3

On Occasion

#### PTM 708 Cardiovascular Pharmacology

This course will consider the rational therapy in cardiovascular diseases. Principles of physiology, pathology and pharmacology will be included in the discussion of hypertension, coronary artery disease, angina pectoris, myocardial infarction, congestive heart failure and arrhythmias. New treatment modalities will be considered.

Credits: 3
On Occasion

#### PTM 709 Advanced Pharmacology

This is an advanced course in the basic principles of pharmacology. Discussion will include receptor theory, enzyme activity and inhibition, structure activity relationship, pharmacokinetics, adverse reactions and drug-drug interactions.

Credits: 3
Every Fall

# PTM 711 Current Technologies in Pharmaceutical Research and Development

The healthcare professional of the 21st century must have a basic knowledge of scientific technologies that affect the community and impact the delivery of effective health care. This course will involve a combination of lectures and student presentations to explore the current areas of medical technology that are important to the healthcare professional. Topics to be covered will include the latest developments in the areas of stem cell research, gene therapy, pharmacogenomics, human cloning, therapeutic antibodies, DNA profiling and genetically modified foods. *Credits: 3* 

On Demand

# PTM 802 Experimental Methods in Pharmacology and Toxicology

Modern techniques used in the qualitative and quantitative evaluation of drugs and drug toxicity in animal systems. These include whole animal studies, isolated tissue techniques and analytical instrumentation.

Credits: 3
On Occasion

# PTM 804 Inborn Errors of Metabolism

This course will consider those inherited disorders which are the result of the body"s failure to synthesize specific proteins (enzymes) needed for normal metabolism or the synthesis of abnormal proteins.

Credits: 3
On Occasion

# PTM 905 Principles of Immunotherapy

This course is concerned with the study of antigens and the immune system, the humoral response and the cellular response to antigen. Non-atopic immunological drug reactions and disease states characterized by abnormal immunological responses will be discussed. Research papers dealing with

selected immunological topics will be assigned and discussed.

Credits: 3
On Occasion

#### PTM 907 Psychopharmacology

A comprehensive course covering the clinical considerations and biochemical basis of psychotic and neurotic disorders responding to drug therapy. Emphasis to be placed on the complete animal and human pharmacology of antipsychotic, anti-anxiety, antidepressant and antimanic drugs. Appropriate stimulant and sedative/hypnotic agents and current trends and issues will be discussed. Student participation through research papers and seminars will be implemented.

Credits: 3
On Occasion

### PTM 910 Toxicology of Drugs and Chemicals

General principles of toxicology; current trends and recent developments in the prevention, detection, diagnosis and treatment of acute and chronic toxicities from drugs and chemicals; toxic drug interactions.

Credits: 3
Every Fall

#### PTM 917 Molecular Toxicology

A comprehensive course which will discuss highly focussed toxin-induced intracellular mechanisms and their molecular targets. Drug- and chemical-induced gene expression, modulation of expression of various genes by chemical antidotes. This course will include detailed discussion of toxin-induced perturbations, modes of cell death, and events at subcellular molecular sites inside the cell, e.g. nuclear (including DNA degrading and repair enzymes), electron transport chain dysfunctions, and cytoplasmic compartments (ribosomes, microsomes and other cytosolic components). *Credits: 3* 

On Occasion

# PTM 920 Molecular Pharmacology

An advanced course in pharmacology dealing with the molecular mechanisms of drug action. The discussions will include receptor-drug interactions, importance of chirality, receptor-ligand interactions, interactions of drugs with endogenous polymers, modulators of chemical transmitters and such other topics involving molecular biology.

Credits: 3 On Occasion

## PTM 925 Pharmacogenomics

Pharmacogenomics, the union of pharmacology and genomics, is emerging as a novel medical research field. This course reviews the history and current status of the influence of hereditary factors on drug action and metabolism, as well as predisposition to diseases. It is intended to introduce graduate students to pharmacogenomics and personalized medicine through a series of lectures, case studies and students" presentations of

cutting-edge technologies used in this field.

Credits: 3

On Occasion

#### PTM 938 Stem Cells and Regenerative Medicine

This course is designed to introduce students to the characteristics of the various types of stem cells and their applications in basic research, drug discovery and regenerative medicine. Topics will include the origin of embryonic and adult stem cells and the cutting edge potential and applications of induced pluripotent stem cells (iPS). The course will provide details about the role of stem cells as therapeutic vehicles for treating cancer, cardiovascular diseases, Alzheimer's, arthritis, Parkinson's disease and many inherited disorders such as Huntington's, Muscular Dystrophies, and Sickle Cell disease. Students will also discuss controversial issues that pose a dilemma in the widespread adoption and application of stem cells as potential therapy.

The pre-requisites of PTM 704 and 705 are required.

Credits: 3 On Occasion

# Pharmacy Administration and Drug Regulatory Affairs

#### PHA 010 Biostatistics

(This course is a prerequisite for all Division of Social and Administrative Sciences majors.) An introductory course in statistics with emphasis on applications in the health sciences. Topics include description of data, measures of central tendency and dispersion, inferences from data, significant differences, and measures of similarity and differences among groups of data.

Credits: 3

Every Fall and Spring

#### PHA 050 Research Methodology

A course in the design, implementation and evaluation of research. Topics include problem identification, literature review, research approaches, hypotheses, data-gathering instruments and methods, data analysis and generalization. *Credits: 3* 

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On Occasion

# PHA 060 Research And Thesis

Individual research in the various areas of specialization, Pass-Fail only.

The pre-requisites of PHA 050 and 653 are required.

Credits: 3

Every Semester

#### PHA 070 Special Problems

Laboratory, fieldwork or library research in the various areas of specialization. Pass-Fail only. Permission of the instructor required.

Credits: 3

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On Occasion

#### PHA 601 Marketing Research and Analysis

Insight is provided into research techniques and audits in preparing marketing and media studies and reports. A comprehensive study of marketing research principles, including sampling, questionnaire construction, surveys and panels. Readings and case studies provide practical experience in dealing with marketing research problems.

Credits: 3
On Occasion

#### PHA 603 Drug Regulatory Affairs

(This course is a prerequisite for all DRA courses, except PHA 661 (The Pharmaceutical Industry.) A comprehensive introductory course which provides an overview, understanding of, and appreciation for the numerous statutes and regulations governing drugs, medical devices and cosmetics.

Credits: 3
Every Fall

#### PHA 604 Pharmacoeconomics

This course presents socioeconomic aspects of health care that influence need, demand and provision of health care through the private and public sectors. The course will also develop basic concepts of economic theory as an analytical tool to understand them from provider as well as consumer points of view in an evolving healthcare delivery system.

Credits: 3
Every Fall

# PHA 605 Human Resources Management

The objective of the course is to provide students with an understanding of the importance of using human resources to the optimum level through a review and application of the principles of continuous quality improvement (CQI). The course will examine several decision making techniques, leadership and management skills that are consistent with CQI. Students can expect a better understanding of developing a more organized work setting focusing upon teamwork to meet specified outcomes.

Credits: 3
On Occasion

#### PHA 606 Sales Management

Attention is given to the development of the sales administrator and the salesperson. Among the topics discussed are: the structure of the sales organization, sales policies, selection of salespersons, and methods of compensation and motivation.

Credits: 3
Every Fall

## PHA 607 Behavioral Pharmacy

This course directs students towards an understanding, analysis and application of theories in organizational behavior, psychology, sociology

and education as they apply to a range of problems and issues found within various work environments within the pharmaceutical industry and profession. Through lecture, reading, group work and analysis of case studies, students will be able to identify and apply relevant theory in order to solve problems that occur in organizational settings.

Credits: 3
Every Spring

#### PHA 613 Marketing Management

Designed to develop an understanding of the function and role of product management systems, including, among others, the following topics: product cycle analysis, preparing the annual marketing plan, financial tools for product management, sales coordination and product management, control of the product marketing plan.

Credits: 3
Every Fall

#### PHA 614 Health Literacy

This course offers a problem-based approach to meeting the health information needs of consumers with low health literacy. Issues addressed are difficulties in sending or receiving written or spoken information containing either words, numbers, or graphs; ESL; non-communicative consumers and health practitioners; and cultural disparities which affect communication.

Credits: 3
On Occasion

# PHA 615 Consumer Behavior and Contemporary Healthcare Issues

This class will present contemporary concepts, principles and research related to consumer behavior that could be applied in developing marketing tools and techniques for improving consumer access, participation and utilization of the healthcare system. It introduces students to individual and group level theories that explain and change consumer behavior. The course also presents relevant research tools and methods for conducting investigations in the area of consumer behavior. It requires students to synthesize, integrate and apply related knowledge and skill toward developing, analyzing, and reporting measures specific to consumer behavior related outcomes. Upon completion of this course, students will be able to design, conduct and evaluate projects or initiatives for changing consumer behaviors.

Credits: 3
On Occasion

# PHA 633 Pharmaceutical Advertising and Promotion

Investigates the principles of advertising and sales promotion to the medical community. Course material examines each stage in the development of actual advertising programs and guides the student from the stated objectives in the product market plan through the various levels of creating,

producing and issuing each promotional element (i.e., journals ads, direct to consumer advertising, sales/detail aids, sample packages, etc.) into a coordinated program. The student also studies the structural financial operation and business relationship of the medical advertising agency as an important marketing extension of the pharmaceutical product manager and/or advertising director.

Credits: 3
Every Spring

#### PHA 644 Internship in Marketing Management

This course is designed for those graduate students who have an interest in employment opportunities within the healthcare industry at pharmaceutical companies, medical advertising agencies and other sites. The student works in an on-the-job setting on carefully planned work activities designed to provide a basic understanding of how the healthcare industry operates. A report on these work activities is required at the completion of the course. Pass-Fail only.

Credits: 3
On Occasion

#### PHA 645 Internship in Drug Regulatory Affairs

This course is designed for those graduate students who have an interest in employment opportunities in the pharmaceutical industry or government. The student works in an on-the-job setting on carefully planned work activities designed to provide a basic understanding of the drug regulatory environment, process and outcome. A report of these work activities is required at the completion of the course. Pass-Fail only.

Credits: 3
On Occasion

# PHA 651 Pharmaceutical Labeling, Advertising and Promotion

A comprehensive course which reviews prescription and OTC drug labeling, advertising and promotion regulations. Examines the development and clearance of labeling and advertising pieces (container labels, package inserts, journal ads, direct mail, visual aids, reminder advertising, etc.). Discussion of principles of Fair Balance, Brief Summary and Full Disclosure. Students will be required to prepare advertising and promotional pieces. The role of the regulatory affairs department, product manager, advertising agency, etc., will be discussed. Review of institutional advertising, preapproval advertising, prescription drug advertising to the consumer (PDAC), comparative advertising.

The pre-requisite of PHA 603 is required. Credits: 3

On Occasion

# PHA 653 Seminar in Social and Administrative Sciences

Students generate solutions to current problems in pharmaceutical care, the pharmaceutical industry and public policy, and support their views with

evidence that reflects concepts, principles, theories and philosophies from the

social/behavioral/administrative sciences. Based upon their research, students will prepare written reports, give multimedia class presentations and conduct class discussions.

Credits: 3

Every Fall and Spring

# PHA 654 FDA Regulation of Over-the-Counter Drugs, Medical Devices and Dietary Supplements

Provides the participants with an understanding of, and an appreciation for, the regulation of over-thecounter drugs, medical devices, cosmetics and animal health drugs as legislated by the Federal Food, Drug, and Cosmetics Act and its amendments and the Fair Packaging and Labeling

The pre-requisite of PHA 603 is required. Credits: 3

Every Spring

# PHA 655 Chemistry, Manufacturing and Controls (CMC) Regulatory Affairs

This course describes various aspects of CMC regulatory affairs as they relate to the development, approval and marketing processes for drugs in the U.S. Topics include: FDA vs. pharmaceutical industry viewpoints on CMC regulatory affairs; quality issues related to CMC regulatory affairs; organization of the CMC regulatory function and role of the CMC regulatory professional; CMC regulations and guidance; format, required, required content and scientific considerations for the CMC sections of INDs and NDAs for traditional dosage forms; and an overview of CMC requirements and considerations for other submissions (i.e. generics, biologics, animal drugs, drug master files, devices and international dossiers). Offered on occasion.

The pre-requisite of PHA 603 is required. Credits: 3

On Occasion

### PHA 656 Current Enactments, Regulations and Guidances

In the last few years, there has been a plethora of new and revised congressional acts and FDAadministered rules and guidance towards the development and approval of drugs in the U.S. This course will focus upon these current requirements. There will be extensive discussion of the Food and Drug Administration Modernization Act (FDAMA); selected Safety, Efficacy and Quality International Conference on Harmonization (ICH) Guidance; selected FDA Guidance prepared under the auspices of the various FDA Coordinating Committees; and selected Post-Approval Changed (PAC) Guidance. Current draft requirements and the resulting future regulatory direction will also be considered.

The pre-requisite of PHA 603 is required. Credits: 3

On Occasion

# PHA 657 Principles and Practices of Regulatory Compliance and Enforcement

This course emphasizes the history, development, implementation, monitoring, operational procedures and audit techniques of investigation and enforcement. Enforcement issues and problems are addressed.

The pre-requisite of PHA 603 is required. Credits: 3 Every Spring

#### PHA 658 International Drug Regulatory Affairs

The increasing globalization of product development and marketing means that companies that manufacture and market products in many different countries must comply with an everincreasing spectrum of laws and regulations. The borders that divide nations seem to be shrinking as the means of rapid communication increase. But the lack of regulatory consistency across the globe makes it extremely difficult for pharmaceutical manufacturer's to implement a globally acceptable product design. The purpose of this course is to provide an overview of global regulatory requirements for U.S. and EU for product registration. Topics covered will include the understanding of the ICH (International Conference on Harmonization) and CTD (Common Technical Document) as well as some basic understanding of international product registration requirements. Following this course. students should be able to understand the fundamentals of global regulatory issues.

Credits: 3

On Occasion

# PHA 660 Mechanics of Preparing INDs and **NDAs**

This course provides an in-depth assessment and analysis of the requirements of the investigational new drug (IND) and new drug applications (NDA). Component parts, appropriate format, assembly and submission of each is emphasized.

The pre-requisite of PHA 603 is required.

Credits: 3

Every Fall

# PHA 661 The American Pharmaceutical Industry

This course provides a comprehensive view of the key activities in which major pharmaceutical companies are involved, e.g., research and development, pilot manufacturing, manufacturing and packaging, quality assurance, marketing, sales, distribution, regulatory affairs and pharmacy relations.

Credits: 3

On Occasion

# PHA 662 Ethics in Pharmaceutical Industry

A comprehensive course designed to investigate the role ethics play in today's pharmaceutical industry. Students will explore case studies related to past, present, and potential future ethical dilemmas concerning clinical trials, patient safety, intellectual property rights, and marketing and advertising

practices. Course will also examine issues concerning drug pricing and other public interests that challenge current industry practices worldwide. Credits: 3 On Occasion

#### PHA 663 Food and Drug Law

This course is designed to provide a basic working knowledge of the domestic laws regulating food, drugs, cosmetics, biologics/blood and medical devices. It has a practice related direction providing a grass roots understanding of the legislative and regulatory processes through a comprehensive review of the relationships between FDA, the health care industry, consumers and their interest groups and the U.S. Congress.

Credits: 3

On Occasion

# PHA 665 Healthcare Data Management and

Students will learn data management and the most commonly used analysis techniques utilizing SAS or SPSS. Various type of data employed in pharmacyrelated evaluation and its advantages and disadvantages will be discussed. Readings and assignments will provide hands-on experience in dealing with data from randomized clinical trials, hospital and pharmacy administrative issues, payer claims, and large surveys. Data analysis to address issues in areas such as pharmacotherapy effectiveness, adverse drug effects, health care utilization, and health care cost will be discussed and practiced.

The pre-requisite of PHA 010 is required. Credits: 3

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