

# REGULATORY SCIENCE

<https://www.pacific.edu/pharmacy/academics/regulatory-science-ms>

## Master of Science in Regulatory Science

The Master of Science in Regulatory Science (non-thesis) is 32 units and can be complete as quickly as 16 months (4 trimesters). It is designed to provide training in scientific and regulatory strategy to those who aim to pursue careers as regulatory scientists working on product development in Biotech, Pharma, the FDA and equivalent global regulatory agencies.

Graduates of the MS in Regulatory Science program will be able to develop protocols, evaluate and enforce existing guidance's and support regulatory filings as it relates the safety, efficacy, quality, and performance of FDA-regulated products. This MSRS program will have a STEM designation.

## Degree Program

- Master of Science in Regulatory Science

## Admission Requirements

- A bachelor's degree with a B average (GPA of 3.0) or higher is required in all upper-division coursework, including all official transcripts.
- The GRE® General Exam is required to determine an applicant's readiness for graduate school. The minimum combined score for the Verbal and Quantitative sections is 298. The minimum Analytical score is 3.0. Scores can be no older than five years old. Applicants must submit an essay or personal statement focusing on career objectives and personal ideals. Grammar and writing skills are an important part of the evaluation. A cumulative GPA of 3.5 may qualify for GRE waiver request.
- Three letters of recommendation, no more than one year old.

All international applicants must meet the following requirements:

- International students who attended schools outside of the United States must submit an evaluation of their academic records. Additionally, transcripts must be reviewed by one of the following outside evaluation agencies: World Education Services (WES) or Educational Credential Evaluators (ECE). Please request a course-by-course evaluation that includes a grade point average (GPA) and have an official copy sent directly to the Office of Graduate Admission. Student transcripts need to be translated into English before an evaluation can be processed. Please check with the evaluation agency for details on specific document requirements.
- A Certification of Finances form with all required documents must be completed and sent with the application materials or upon notification of admission by PCSP.
- Proof of English proficiency is required of all applicants whose native/principal language of instruction is not English. This requirement can be met by minimum scores of 80 (iBT) or 550 (paper) on the Test of English as a Foreign Language (TOEFL) or 6.5 on the International English Language Testing System (IELTS) or 105 on Duolingo. Official test score reports are required and can be no older than two years old.

## Learning Outcomes

This program is for individuals with a clear objective to cultivate a career in regulatory science in the pharmaceutical, biotech and drug device industries and those with an industry background desiring advanced education in regulatory science and/or management.

- Identify, Formulate & Solve Complex Scientific Problems.
- Conduct Appropriate Experimentation in Pure & Applied Research.
- Function in Multidisciplinary Teams.
- Recognize Ethical & Professional Responsibilities & Make Informed Judgments in Global, Economic, & Societal Contexts.
- Exhibit Behaviors Consistent with the Pharmaceutical Scientists Profession.

Master of Science in Regulatory Science

Students must complete a minimum of 32 units with a Pacific cumulative grade point average of 3.0 in order to earn the Master of Science degree in Regulatory Science.

### Requirements:

Regulatory Sciences in Drug Development

Biostatistics and Clinical Trial Design

Trends in Drug Design 3

API: Synthesis & Characterization Specifications

Formulation: Science & Drug Development (Preformulation and Product Development)

Lifecycle Management

GxP's

Pharmaceutical Marketing and Project Management

Reg Sci: Product Specifications

Reg Sci for device and drug combination

eCTD (electronic Common Technical Document)

Internship/CapStone Project/Development of a model filing

## Regulatory Science Faculty

Vijay K. Tammara, Director, MS Regulatory Sciences, Clinical Professor, Pharmaceutical Sciences, 2025, PhD, School of Pharmacy, Northeastern Louisiana University, Monroe, Louisiana, 1999.

## Pharm Chem Sciences Courses

### PCSP 201. Statistics and Experimental Design. 3 Units.

This course involves the study of the application and limitations of statistical methods of inference as they apply to the fields of chemistry and the pharmaceutical sciences. Topics include the use of parametric statistics for statistical inference, comparisons of means, analysis of variance and linear regression. Parametric statistics and nonparametric measures of association and elements of good experimental design are also included. Graduate standing.

### PCSP 202. GxP's: Drug, Drug Products and Maintaining their Quality. 2 Units.

An introduction to modalities of drugs (small molecules, peptides, gene therapies, cell therapies) and how to maintain their quality compliance. Prerequisites: Graduate standing or permission of instructor.

### PCSP 203. Information and Laboratory Management. 1 Unit.

This course covers basic knowledge of Information Management, Intellectual Property and Patenting, Research Laboratory Operations and Safety, Good Maintenance Practice (GMP) and Good Clinical Practice (GCP). Graduate standing.

**PCSP 204. Introduction to Nanotechnology. 4 Units.**

The course provides an overview of Molecular Nanotechnology. It shows that the nano regime is so different from other regimes because both classical and quantum effects can be active, thus leading to unique properties of nano devices. MNT is a highly interdisciplinary science, which will be reflected in the course by making reference to physics, chemistry, biology, pharmacy and engineering. Applications of MNT, as they are already in use today or as they are planned for the future, will be discussed. Graduate standing or permission of instructor.

**PCSP 205. Instrumental Analytical Chemistry. 4 Units.**

Lectures focus on the theory and physical principles of instruments for the analysis of matter. Laboratory lecturer describes the actual operation of instruments. Students gain hands-on experience with the operation of instruments. Graduate standing.

**PCSP 206. Models and Concepts in Chemistry. 4 Units.**

The course focuses on a general understanding of chemistry in terms of models and concepts that describe structure, stability, reactivity and other properties of molecules in a simple, yet very effective way. Many chemical problems from organic, inorganic, and transition metal chemistry and biochemistry are presented and the applicability of the various models and concepts as well as their limitations are demonstrated. Graduate standing or permission of instructor.

**PCSP 207. Bioanalytical Techniques. 3 Units.**

Students are introduced to techniques of bioanalysis for the pharmaceutical and chemical sciences. The course provides a conceptual understanding and practical familiarity with techniques used for analysis of proteins and nucleic acids. Recommended: Basic biochemistry.

**PCSP 208. Applied Pharmaceutical Analysis. 4 Units.**

Students study analytical methods applied for the assessment of pharmaceutical quality, and the identification and quantification of active pharmaceutical molecules and metabolites in biological samples. Prerequisite: any analytical Chemistry or Biology background and permission of instructor.

**PCSP 209. Technical Writing and Presentation. 1 Unit.**

This course covers common written and oral forms of communication and scientific material. Graduate standing.

**PCSP 210. Applied Physicochemical Principles in Pharmaceutical Systems. 3 Units.**

An introduction to physicochemical principles governing energy transfer, stability, behavior of small and large drug molecules in pharmaceutical systems from a microscopic and macroscopic perspective. Lecture and course examples are primarily taken from pharmaceutical sciences and industry to illustrate concepts. This is a hybrid distance-learning (<50% online)/Canvas course. Prerequisite: Graduate standing or permission of instructor.

**PCSP 211. Drug Design. 4 Units.**

Students study modern methods used in the design of new drugs. Target selection, lead compound discovery and molecular modifications to optimize activity are studied. Graduate standing or bachelor's degree and permission of instructor.

**PCSP 212. Methods in Bioanalytical, Physical and Biochemistry. 2 Units.**

As a general survey, this course is an introduction to the current methodologies commonly used in bioanalytical, physical and biochemistry labs. These methods will be investigated by understanding their use in the lab and through studies published in the primary scientific literature. Lecture will focus on the technique and instruments and a lab component will consist of a demonstration of the method. A mini project that using a single selected methodology will be performed by each student with a final report detailing the underlying technology and theory.

**PCSP 213. Biotransformation of Pharmaceutical Agents. 3 Units.**

This course teaches the graduate students the chemical and biological principles of the transformations of pharmaceutical agents in the body and the impact of such transformations on pharmacokinetics, pharmacodynamics, toxicity, drug design and drug delivery. Graduate standing in TJ Long School of Pharmacy & Health Sciences or in Chemistry Department, or permission of instructor.

**PCSP 214. Advanced Molecular Biochemistry. 4 Units.**

This course presents a conceptual study of cellular function and control mechanisms at the molecular level. Prerequisite: Graduate standing.

**PCSP 215. Molecular Modeling and Drug Design. 4 Units.**

The course presents a thorough and in-depth overview of methods and techniques in computer assisted drug design (CADD) where especially the needs of the pharmaceutical industry are considered. Graduate standing or permission of instructor.

**PCSP 216. Emerging Technologies in Drug Discovery. 2 Units.**

This course is designed mainly for graduate students, with emphasis on new concepts in the discovery of small molecules and biologic drugs. Graduate student standing with advanced molecular biochemistry background and interested Professional students who completed PHAR 116.

**PCSP 217. Drug Biotransformation. 3 Units.**

This course generally meets two times a week (two 75-minute lectures per week). In this course, a mechanistic approach is employed to study human drug metabolizing enzymes. Other aspects related to the differential expression of these enzymes are discussed. Students need to submit a research proposal at the end of the course. Graduate standing or permission of instructor.

**PCSP 218. Animal Techniques for Pharmaceutical Sciences. 2 Units.**

This course is designed to present an opportunity for graduate students to understand and apply animal techniques to pharmaceutical science research. Prerequisite: Graduate standing or permission of the instructor.

**PCSP 219. PK/PD Modeling and Simulation with Simcyp Simulator. 1 Unit.**

This course is designed to introduce the basic PK/PD modeling and simulation using the Simcyp simulator software. Students must not be on probation and must not have failed or received No Credit in any courses. Prerequisites: Graduate student standing with successful completion of PCSP 223 or Professional students with successful completion of PHAR 213 and PHAR 311, or instructor permission.

**PCSP 220. Cellular Signal Transduction Mechanisms. 2 Units.**

This course will examine and discuss the current literature in the field of cellular signal transduction mechanisms, including coverage of excitable & non-excitable cellular signaling systems involving hormone, neurotransmitter, growth factor, antigen and drug coupled pathways. Prerequisites: MS/PhD Student; PCSP 278 or Equivalent.

**PCSP 221. Fundamentals of Dosage Forms. 3 Units.**

In this course the fundamental physicochemical properties and composition of various dosage forms is taught. Graduate standing.

**PCSP 222. Thermodynamics of Pharmaceutical Systems. 3 Units.**

This is a classical course on the applications of thermodynamics to the study of pharmaceutical systems. The course includes a review of the basic principles of thermodynamics. These principles are used to describe and study physical and chemical transformations of pure substances and mixtures in pharmaceutical systems. Graduate standing or permission of instructor.

**PCSP 223. Pharmacokinetics and Pharmacodynamics. 3 Units.**

This course teaches critical concepts and basic principles of pharmacokinetics and pharmacodynamics. Such concepts and principles are required for the students to understand the drug behavior in the body. Graduate standing or permission of instructor.

**PCSP 224. Diffusion in Pharmaceutical Sciences. 3 Units.**

Students discuss diffusion theories, experimental methods, and application to pharmaceutical/biological systems. Prerequisites: CHEM 161 and MATH 033 or equivalent or permission of instructor.

**PCSP 225. Pharmaceutical Technologies. 2 Units.**

Students study theory and practice in industrial pharmacy that include pre-formulation, formulation and pharmaceutical manufacture. Prerequisites: PHAR 114, 123, 133. Graduate standing.

**PCSP 226. Industrial Pharmacy I. 4 Units.**

This course is the first part of Industrial Pharmacy series designed mainly for graduate students, with emphasis unit operations, technology and formulation of pharmaceuticals. This is also very useful to professional students who are interested to pursue careers in pharmaceutical and biopharmaceutical industry. The basic understanding of Preformulation, pharmaceutical operations as they are applied to solid dosage forms from laboratory scale to manufacturing scale will be discussed in lectures and all students will do hands on experiments. In addition, quality and regulatory processes will be outlined for solid dosage forms. Prerequisites: PHRM 114 and PHRM 124.

**PCSP 227. Industrial Pharmacy II. 3 Units.**

This course is the second part of Industrial Pharmacy course series designed mainly for graduate students, with emphasis unit operations, technology and formulation of pharmaceuticals. This is also very useful to professional students who are interested to pursue careers in pharmaceutical and biopharmaceutical industry. The basic understanding of pharmaceutical operations as they are applied to semi-solid and modified release dosage forms from laboratory scale to manufacturing scale will be discussed in lectures and all students will conduct hands on experiments. In addition, quality and regulatory processes will be outlined for semi-solid and modified release dosage forms. Prerequisites: PHRM 114; PHRM 124; PCSP 226.

**PCSP 228. Mathematical Modeling in Pharmaceutical Research. 3 Units.**

Students study the mathematical modeling theory and application to problems in pharmaceutical research. Modeling is applied to three major areas: drug delivery, metabolic/biological cascades and pharmacological response kinetics. Prerequisites: PHAR 113 or permission of instructor. Recommended: MATH 057; PHAR 114 and PHAR 134.

**PCSP 229. Advances in Drug Delivery Systems. 3 Units.**

In this course the design and formulation/fabrication of controlled release and other novel drug delivery systems for oral, transdermal, ocular and other routes of delivery are covered. The biopharmaceutical rational and evaluation of such systems is also discussed. Graduate standing.

**PCSP 233. Molecular Pharmacology III. 4 Units.**

This is the third course in the Molecular pharmacology series, effects of antimicrobial, hematologic and gastrointestinal therapeutic agents and the mechanism whereby these are induced. Drug classes are presented to illustrate the effects of drug classes in the treatment of diseases. The mechanisms of drug toxicity are also covered. Enrollment in the PCSP program is required.

**PCSP 234. Neurochemical Pharmacology. 3 Units.**

Students study neurobiology of nerve cells and the neurochemical pharmacology associated with function of central and peripheral nervous systems. Graduate standing.

**PCSP 238. Introduction to Thermodynamics in Physiological Systems. 1 Unit.**

The course aims at understanding of the energetics of basic physiological processes using fundamental concepts in thermodynamics. The course will make emphasis on those processes involving electrical and chemical signaling. Prerequisites: MS/PhD Student; PCSP 278 or Equivalent.

**PCSP 239. Introduction to Biophysics. 1 Unit.**

The course aims at learning and understanding the underpinning of commonly used and cutting edge biophysical techniques used to investigate structure-function relationship and pharmacology of proteins, in vitro and in situ. Prerequisites: MS/PhD Student; PCSP 278 or Equivalent.

**PCSP 240. Molecular Spectroscopy. 4 Units.**

The basic theory behind infrared, visible, ultraviolet, and magnetic resonance spectroscopy are studied. The course includes the quantum mechanics of light absorption, atomic absorption and emission spectroscopy, vibrational spectroscopy of diatomic and polyatomic molecules, absorption and emission electronic spectroscopy and magnetic resonance spectroscopy. Graduate standing or permission of instructor.

**PCSP 241. Advanced Organic/Bioorganic Chemistry. 4 Units.**

Synthetically useful organic reactions not normally covered in the introductory courses are emphasized. The reactions are grouped according to their mechanistic type and discussed in terms of their reaction mechanisms and synthetic utility. Prerequisites: CHEM 121 and CHEM 123 with a "C" or better.

**PCSP 242. Selected Topics: Advanced Organic Chemistry. 4 Units.**

Topics presented at various times under this course description include: Physical organic, natural products and structure elucidation, stereochemistry, heterocycles and carbohydrate chemistry. Prerequisites: CHEM 121 and CHEM 123 with a "C" or better.

**PCSP 243. Applied Computational Chemistry. 4 Units.**

Besides the normal laboratory experiments traditionally expected, modern chemists/biochemists, whether in the chemical/pharmaceutical industry or academia, perform "experiments" on the computer by calculating the outcome of chemical and biochemical reactions. This in silico chemistry has become an integral part of the education in chemistry and the present course will provide an introduction into this field by addressing a general audience of chemists/biochemists and students from neighboring fields.

**PCSP 244. High-Resolution NMR Spectroscopy. 4 Units.**

A study of one and two dimensional FT-NMR techniques used for structure elucidation of organic molecules. Emphasis is placed on understanding the capabilities and limitations of these techniques, the information they provide and the practical aspects of their implementation. Permission of instructor.

**PCSP 245. Proteins and Nucleic Acids. 3 Units.**

Students study the chemical, physical and biological properties of the proteins and nucleic acids and their constituents. Topics include isolation, determination of composition, sequence and structure; correlation of structure and biological properties. Prerequisite: CHEM 151 with a "C" or better.

**PCSP 246. Selected Topics in Advanced Biochemistry. 4 Units.**

The field of biochemistry is always developing in new and different directions; the purpose of this course is to expose graduates students to the newest and most cutting edge research topics in the field of biochemistry. The materials will primarily primary literature articles. Graduate students will learn to quickly process scientific papers and then, synthesize simple explanations of notable research areas in biochemistry. Graduate students will refine these skills in a series of lectures by the student and instructor as well as student led discussions.

**PCSP 247. Mass Spectrometry. 4 Units.**

Students study the fundamentals of mass spectrometry, theory, instrumentation and applications to organic and biological molecules. Prerequisite: PCSP 205.

**PCSP 248. Enzymology. 4 Units.**

This class gives an introduction into the biochemistry of the various classes of enzymes with emphasis on laboratory techniques. Prerequisite: CHEM 151 with a "C" or better.

**PCSP 249. Drug Target Discovery and Validation. 3 Units.**

An introduction to the discovery and validation of molecular targets for therapeutic intervention as part of the endeavors in drug discovery and drug development. This is a hybrid distance-learning (<50% online)/Canvas course. Prerequisite: Graduate standing or permission of instructor.

**PCSP 250. Product Development for New Drug Candidates. 3 Units.**

An introduction to the process of developing a product from drug candidates, with an emphasis on formulation, quality control, and regulation. This is a hybrid distance-learning (<50% online)/Canvas course. Prerequisite: Graduate standing or permission of instructor.

**PCSP 252. Lead Compound Identification and Optimization. 3 Units.**

An introduction to the identification and optimization of lead compounds as part of the endeavors in drug discovery and drug development. This is a hybrid distance-learning (<50% online)/Canvas course. Prerequisite: Graduate student standing in the PCSP program or permission by instructor.

**PCSP 253. PKPD for Drug Discovery and Drug Development. 3 Units.**

An introduction to pharmacokinetics (PK) and pharmacodynamics (PD) as part of the endeavors in drug discovery and drug development. This is a hybrid distance-learning (<50% online)/Canvas course. Prerequisite: Graduate standing or permission of instructor.

**PCSP 254. Research Processes: Publications, Presentations, Grants and IRB. 3 Units.**

This course prepares graduate students in Pharmacoeconomics and Health Care Outcomes and Services as a successful researcher by gaining experience in the development of a research plan, obtaining approval of the Institutional Review Board, submission of an extramural grant, dissemination of the student findings at a national or international meeting, and submission of a manuscript to a peer-reviewed journal. Prerequisite may be taken concurrently: PCSP 201, or other comparable statistics course at the discretion of the course coordinator. Permission of the instructor is required.

**PCSP 255. Long Term Care Practice. 3 Units.**

This class covers the clinical pharmacy component of a long term facility with special emphasis on opportunities and research needs. Students study the systematic approach to monitor the drug therapy of the long term care patient. Graduate standing.

**PCSP 256. Health Services Management and Finance. 2 Units.**

Health Care Finance offers an introduction to accounting, financial theory and practice in health care settings. It is designed to familiarize students with financial concepts and issues confronting managers in the health and pharmaceutical sectors. Prerequisites: Admission to the PCSP graduate program and permission of the instructor.

**PCSP 257. Ambulatory Care Practice. 3 Units.**

Students examine the application of clinical pharmacy to ambulatory care settings in an affiliated clinic or community pharmacy. Special emphasis is placed on opportunities and research needs. Graduate standing.

**PCSP 258. Teaching and Evaluation of Learning and Competency. 2 Units.**

Student abilities in development as a teacher are developed in an interactive, evidence-based manner covering the major components of teaching, learning, evaluation and assessment. Prerequisites: Admission to the PCSP graduate program and permission of the instructor.

**PCSP 259. Topics in Acute Care Practice. 3 Units.**

Students examine the application and investigation of clinical pharmacy in acute care setting with emphasis on medical management of common diseases and rational drug selection and dosing. Graduate standing.

**PCSP 260. Advances in Neuropsychiatric Pharmaceutical Care. 2 Units.**

Students examine pharmaceutical care for the patient with neurologic and psychiatric disorders. Emphasis is placed on appropriate use of drug therapy in the management of these disorders. Graduate standing. Permission of instructor.

**PCSP 261. Advances in Cardiovascular Pharmaceutical Care. 3 Units.**

Students explore the application of Drug Therapy to patient care with assignments that expand the students' knowledge of background material that support therapeutic guidelines. Permission of instructor.

**PCSP 262. Vascular, Renal and Pulmonary Care. 4 Units.**

Students study the pharmaceutical care for the patient with cardiovascular, respiratory and renal diseases. Emphasis is placed on appropriate use of drug therapy in the management of the disease. Prerequisites: Successful completion of all courses in semesters 1-3 of the Doctor of Pharmacy Program.

**PCSP 263. Analytical Techniques in Pharmacoeconomics and Health Care Outcomes and Services. 4 Units.**

This course prepares graduate students in Pharmacoeconomics and Health Care Outcomes and Services to meet the challenges of a broad assortment of health services related research by providing fundamental principles and tools for the discipline. The class uses real world examples of research design, statistical evaluations and database selection and use to assess therapeutic, economic and humanistic outcomes. Prerequisites: PCSP 201 and PCSP 203.

**PCSP 264. Applied Statistics in Health Services Research and Analysis. 3 Units.**

This course prepares graduate students in Pharmacoeconomics and Health Care Outcomes and Services to meet the challenges posed by the needed to rapidly and accurately review, critique and assimilate information from health care and economic literature and to complete a full, advanced statistical analysis such as that required for the introduction and discussion sections of a research article or dissertation in pharmacoeconomics and health care outcomes. Prerequisites: PCSP 201, 203, 263.



**PCSP 265. Health Care Economics. 2 Units.**

This course is a current medical literature based course and is designed to prepare graduate students in Pharmacoeconomics and Health Care Outcomes and Services to meet challenges associated with understanding microeconomics terms and tools used in health care, medical literature and health care decision making processes. Readings, lectures and discussions emphasize processes used in economic decisions made by health care consumers, providers and third party payers. Primary topics include the demand for health care, how it may vary based on payment/payer options and the scope and supply of care available. Prerequisites: PCSP 263, 264, and permission of the instructor.

**PCSP 266. Pharmacoeconomics and Microeconomics/Managerial Economics. 2 Units.**

This course is designed to prepare graduate students in Pharmacoeconomics and Health Care Outcomes and Services to evaluate the applicability, importance and relevancy of pharmacoeconomics, microeconomics and managerial economics in answering questions and solving problems within the US health care system. Additionally, after completion of this course, students can assess, apply, interpret and determine the appropriate utilization of pharmacoeconomics, microeconomic, and managerial economic principles to address relevant healthcare issues and questions. Prerequisites: PCSP 201 and permission of the instructor.

**PCSP 267. Research in Biochemistry and Chemistry. 2 Units.**

This course introduces students to the practical matters to accomplish research in biochemistry and chemistry. This includes introduction to scientific approaches, available laboratory equipment, research funding, and future employment paths. In this context, the research presented at the weekly Chemistry Department Seminar will be discussed and attendance required. Prerequisite: Graduate Standing.

**PCSP 268. Lab Management & Research Communication. 2 Units.**

Students will be introduced to the practical fundamental skills necessary to complete a graduate degree. Guidelines for the purpose of and the procedure to earn a graduate degree will be covered. Introduction to proper lab etiquette, production of research, presentation of data at lab meetings, on posters, in manuscripts, and for their thesis will be covered. Prerequisite: Graduate Standing.

**PCSP 270. Theory and Methodology of Simulation of Natural Rock Formation. 4 Units.**

This course is created particularly for PhD students of the Pharmaceutical and Chemical Sciences Program. It offers a comprehensive integration of multi-disciplinary sciences such as biology, life science, geoscience, ocean science, environment science, material science, etc. The course introduces some new breakthroughs and frontier discovery which reveal the mystery relationship between life science and geoscience. Upon completion of this course, PhD students are able to carry out professional lab and on-site tests and measurements. Graduate standing in chemistry, biology, geology, material science, environmental science or engineering or permission of instructor.

**PCSP 271. Design Thinking for Entrepreneurs. 2 Units.**

The course will examine aspects of an entrepreneur's journey and the elements that would be needed in his/her toolbox to tackle challenges - from ideation to economic viability. This course will benefit anyone interested in working in the industry as lead scientists, entrepreneurs, program champions, investors, technology transfer agents etc. Students will be introduced to the steps needed to form and grow a company including access to capital, collaborators, legal, and partners. Topics include an overview of the global biotechnology industry, idea generation, business plan formulation, intellectual property, raising capital, human resources including board composition, regulatory strategy, and company exits. Prerequisites: Graduate student standing with successful completion of PCSP 283 or Professional students that successfully completed first 3 semester, or instructor permission. Students must not be on probation and must not have failed or received No Credit in any courses.

**PCSP 272. Clinical Pharmacology in Drug Development. 2 Units.**

The course will cover important aspects of clinical pharmacology related to drug development. This course will benefit anyone interested in learning how to bring a compound to approval. The course will be delivered by leading experts in the field, with case studies presented for each topic covered. Prerequisites: student standing or Professional students that successfully completed the first 3 semesters, industry professionals or instructor permission. Students must not be on probation and must not have failed or received No Credit in any courses.

**PCSP 273. Marketing Principles and Applications for Pharma Entrepreneurs. 2 Units.**

The course will cover all of the basic marketing principles, including the 4 P's (Product, Promotion, Price and Place) and how to apply them to real world situations. This includes understanding and assessing markets for new pharma/biotech products. Key marketing elements that will be critical as components in product development process, forming a new company, gaining investor support, and ultimately in successful commercialization will be explored. Discussions will be structured for the stages of drug development from preclinical through to Phase 3 and the typical marketing elements that are needed for each stage. Factors relevant to the value proposition, the competitive landscape, and adoption of a new medical product and how to manage these factors in the early design and development phases will be also be covered. Guest speakers will be included to provide a heightened understanding and real world insights. Prerequisites: Graduate student standing or Professional students that successfully completed the first 3 semesters, industry professionals or instructor permission. Students must not be on probation and must not have failed or received No Credit in any courses.

**PCSP 274. Regulatory Science for Drug Development Scientists. 2 Units.**

The course will cover underlying scientific principles that forms the basis of federal regulations and guidance provided for drug development and approval. This course will benefit anyone interested in learning how to bring a drug product to approval. The course will be delivered by leading expert(s) in the field, with case studies for each topic covered. Prerequisites: Graduate student standing or Professional students that successfully completed the first 3 semesters, industry professionals or instructor permission. Students must not be on probation and must not have failed in any courses.

**PCSP 275. Molecular and Cellular Pharmacology. 3 Units.**

Students will learn the pharmacological principles, the mechanism of action of prototype drugs at the molecular and cellular levels and develop an appreciation of advanced research topics in current pharmacological science. Prerequisites: Graduate standing in Pharmaceutical and Chemical Sciences Program (PCSP).

**PCSP 276. Vital Sign Acquisition and Analysis. 1 Unit.**

The students will learn how to acquire, analyze and interpret data from electromyography, electrocardiography, thoracic ventilatory movement, pulmonary airflow, phrygmomanometry, body temperature, and other vital signs. Prerequisites: MS/PhD Student; PCSP 278 or Equivalent.

**PCSP 277. Laboratory Rotations in Physiology and Pharmacology. 2 Units.**

This course will utilize small but specific projects in a research laboratory. Specifically, this course will cover a variety of experimental approaches to address questions of physiological and/or pharmacological importance. This course will benefit entering doctoral trainees to the program by exposing them to the laboratory techniques and research in at least two specific areas, depending on the students' interests (e.g., Cancer, Stem cell biology, lipid biology, neuropharmacology, vascular biology and etc.). The course will be delivered by PHYP department faculty. Prerequisites: Graduate standing in Pharmaceutical and Chemical Sciences Program (PCSP).

**PCSP 278. Molecular Physiology. 5 Units.**

This course will cover physiological principles and molecular events that underlie the function of the nervous, cardiovascular, and respiratory systems at the organ and cellular levels. Prerequisites: MS and PhD Students.

**PCSP 283. Multidisciplinary Project. 1 Unit.**

Students in the Pharmaceutical and Chemical Science Graduate Program design an interdisciplinary project based upon the relevant contributions of their backgrounds. Enrollment in PCSP Graduate Program.

**PCSP 287. Internship. 1-4 Units.**

The internship offers an experiential learning program at a pharmaceutical/chemical/biotechnological industry, academic institution, government laboratory, or a clinical site that entitles the students to learn advanced techniques and practical application of the theoretical principles learned in a number of courses. Graduate students that have completed Category I course work, or obtained permission of coordinator shall enroll in this course. For students in thesis/dissertation tracks, concurrence of thesis/dissertation adviser(s) is required.

**PCSP 291. Independent Study. 1-4 Units.**

Independent Study is restricted to masters or doctoral (PhD) candidates. It may be repeated with permission as progress warrants. No more than eight credits may be used toward doctoral degree requirements. The student must be in good academic standing. Approval of the required contract for Independent Graduate Study is required. Graduate standing and permission of the instructor.

**PCSP 295. Graduate Seminar. 1 Unit.**

Seminar presentation on research-related topics given by M.S. graduate students. Enrolled students are required to (1) attend all seminars given throughout the pharmacy academic year (fall, spring, and summer semesters of the pharmacy calendar); (2) provide feedback on all seminars; and (3) give one seminar per year (20-min presentation followed by 4 min question/answer time). This course is required for all M.S. (non-thesis and thesis) graduate students for every year of their tenure in the PCSP. Prerequisite: Graduate standing in the PCSP.

**PCSP 297. Graduate Research. 1-4 Units.**

Graduate Research is limited to masters or doctoral (PhD) candidates. It may be repeated with permission as progress warrants. No more than eight credits may be used toward doctoral degree requirements. Admission to the graduate program and permission of research director.

**PCSP 299. Thesis. 1-6 Units.**

This course provides one-to-one work by student with faculty research mentor to plan, organize, conduct, evaluate and write an original research project as a thesis for partial fulfillment of the MS degree. Admission to MS thesis program (PCSP) and permission of research advisor.

**PCSP 387. Internship. 1-4 Units.**

This internship offers an experiential learning program at a pharmaceutical/chemical/biotechnological industry, academic institution, government laboratory, or a clinical site that entitles the students to learn advanced techniques and practical application of the theoretical principles learned in a number of courses. Graduate Standing with completed Category I course work or permission of coordinator. For students in thesis/dissertation tracks, concurrence of thesis/dissertation adviser(s) is required.

**PCSP 391. Independent Study. 1-4 Units.**

Independent Study is restricted to masters or doctoral (PhD) candidates. It may be repeated with permission as progress warrants. No more than eight credits may be used toward doctoral degree requirements. The student must be in good academic standing. Approval of the required contract for Independent Graduate Study is required. Graduate standing and permission of the instructor.

**PCSP 395. Graduate Seminar. 1 Unit.**

Seminar presentation on research-related topics given by Ph.D. graduate students. Enrolled students are required to (1) attend all seminars given throughout the pharmacy academic year (fall, spring, and summer semesters of the pharmacy calendar); (2) provide feedback on all seminars; and (3) give one seminar per year (20-min presentation followed by 4 min question/answer time). This course is required for all Ph.D. graduate students for every year of their tenure in the PCSP. Prerequisite: Graduate standing in the PCSP.

**PCSP 397. Graduate Research. 1-4 Units.**

Graduate Research is limited to masters or doctoral (PhD) candidates. It may be repeated with permission as progress warrants. No more than eight credits may be used toward doctoral degree requirements. Admission to the graduate program and permission of research director.

**PCSP 399. Dissertation. 1-6 Units.**

This course is only open to doctoral (PhD) candidates. No more than eight credits may be used toward doctoral degree requirements. Admission to PhD program (PCSP) and permission of research advisor.