Pharmacy Quality Assurance (QARA)

Course information contained within the Bulletin is accurate at the time of publication in June 2025 but is subject to change. For the most up-to-date course information, please refer to the Course Catalog.

QARA 5000. Special Topics in Regulatory Affairs and Quality Assurance. 1 to 4 Credit Hour.
Topics vary.

Repeatability: This course may be repeated for additional credit.

QARA 5401. Fundamentals of Pharmacology and Pharmacokinetics. 3 Credit Hours.
This introductory course to general pharmacology includes discussions of the mechanisms of action of selected drug classes. It covers pharmacokinetics, including clearance, bioavailability, compartment models, extravascular dosing, nonlinear pharmacokinetics and pharmacodynamics as they apply to the drug development process. Note: Not open to students who have taken the former PHARMACEUTICS 400 or those in the Non-Thesis M.S. program who have taken PHARMACEUTICS 5401.

Repeatability: This course may not be repeated for additional credits.

QARA 5408. Pharmacoeconomics. 3 Credit Hours.
The economic methodologies used to evaluate the cost effectiveness of drug therapy are reviewed. Cost effectiveness is examined in terms of outcome assessment and quality of life measurements. The course explores the dynamic environment of health care and the process of drug product selection in managed care. Not open to students who completed QARA 0480.

Repeatability: This course may not be repeated for additional credits.

QARA 5451. Statistical Quality Control. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5458. Global Biopharmaceutical Industry. 3 Credit Hours.
What social and economic factors contributed to the development of innovator and generic pharmaceutical companies, and what are their current and future trends? This course introduces students to the basic structure of the pharmaceutical industry, examining the growth and relationships among various sectors, including the fully-integrated companies of big pharma, the generic and biotech industry, and specialty and service companies, such as CROs and CMOs. Social, political, demographic, economic, and technological influences will be examined not only in the US domestic market, but also across major world economies, including the differences between national health and single-payer systems. A segment of the course focuses on the impact of the Waxman-Hatch Act on drug price competition and patent term restoration.

Repeatability: This course may not be repeated for additional credits.

QARA 5459. Drug Development. 3 Credit Hours.
This course studies the drug development process from discovery through FDA marketing approval. It reviews the process of development and the interrelationships linking the various disciplines, introducing students to regulations governing the process, including the interactions with FDA, ICH, and other regulatory agencies. Note: This course is required for the M.S. in RA and QA, the Drug Development Certificate, and the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5468. Validation of Facilities, Utilities and Equipment (FUE). 3 Credit Hours.
The production of FDA regulated products (pharmaceutical, medical device, food, etc.) is highly dependent on both the initial qualification of facilities, utilities, and equipment (FUE) along with the ongoing efforts to maintain the qualified/validated state meeting current user and regulatory needs. This course focuses on the key validation elements specific to qualifying and validating facilities, utilities, and equipment. In practice, validation of these items is also a prerequisite for other validation efforts including process, cleaning and test method. The class will examine the key concepts of FUE qualification/validation as well as the life-cycle through retirement of the FUE.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B in QARA 5477.

QARA 5471. Biotechnology: Bioprocess Basics. 3 Credit Hours.
This course emphasizes regulatory and control aspects of biologics manufacturing as well as Quality by Design principles. It provides students with a basic understanding of the major steps involved in the manufacture of biologics/biopharmaceuticals, including preparation of media, fermentation, harvesting/recovery, purification, and formulation. Included is a review of basic bioscience topics (e.g., microbiology, biochemistry, and molecular biology) with particular relevance to the study of bioprocessing techniques. Note: Not open to students who have taken the former PHARMACEUTICS 481 or those in the Non-Thesis M.S. program who have taken PHARMACEUTICS 475 or PHARMACEUTICS 5471.

Repeatability: This course may not be repeated for additional credits.

QARA 5472. Pharmaceutical Marketing. 3 Credit Hours.
This course describes the marketing dynamics of the healthcare industry and the ways in which pharmaceutical companies can better meet the changing needs of patients and managed care. Focusing on individual marketing techniques, it stresses the development of multidisciplinary marketing teams. The product attributes discussed in the selling process are efficacy, safety, cost effectiveness, compliance, and treatment outcomes.

Repeatability: This course may not be repeated for additional credits.

QARA 5473. Generic Drug Regulation (ANDAs). 3 Credit Hours.
By examining specific case studies of Abbreviated New Drug Applications (ANDAs) which document the bioequivalence of generics to an original product, this course gives students an overview of regulatory requirements for generics, introducing problems unique to this segment of the industry.

Repeatability: This course may not be repeated for additional credits.

QARA 5474. Process Validation. 3 Credit Hours.
Since the concept of "validation" originally appeared in GMP regulations, it has extended to every step in product manufacturing from building the plant to the methods used for testing and releasing its products. The course exposes students to all aspects of validation. FDA Guides and Guidelines, as well as the current emphasis on validation concerns by FDA (as identified in 483 and Warning Letter observations), will be incorporated. Students develop acceptable validation protocols and learn what constitutes an acceptable validation report.

Repeatability: This course may not be repeated for additional credits.

QARA 5476. Good Laboratory Practices. 3 Credit Hours.
This course explores the regulatory and quality assurance issues pertinent to pre-clinical safety research. Research study design and processes will be analyzed by pharmacologic and toxicologic methods and for carcinogenicity and reproductive toxicology. Some time is devoted to mutagenicity and pharmacokinetics, discussed in the context of developing a safety profile and determining the potential risk to humans in subsequent clinical trials. Note: This course fulfills the GxP requirement for M.S. in RA and QA students and for the Drug Development Certificate.

Repeatability: This course may not be repeated for additional credits.

QARA 5477. Good Manufacturing Practices. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5478. High Purity Water Systems. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5479. Advanced Good Manufacturing Practices - Defining "c". 3 Credit Hours.
This course brings students from the basic GMP concepts presented in QARA 5477 to a fuller understanding of the concepts of current good manufacturing practices. Discussions include how to evaluate FDA 483s and Warning Letters, the routine review of periodicals, including the Pink Sheet, Gold Sheet, and other GMP-oriented documents, and how to evaluate information provided by the FDA. Recalls are discussed.

Repeatability: This course may not be repeated for additional credits.

QARA 5491. Pre-Approval Inspections. 3 Credit Hours.
This course provides a detailed overview of Pre-Approval Inspections and how to conduct audits of facilities based on the responsibilities delineated in a pending drug application, including NDAs, ANDAs and NADAs. Emphasis is placed on reviewing the Pre-approval audit process, Pre-Approval laboratory issues (including analytical and microbiological), technology transfer, case studies involving various dosage forms, and outsourcing issues. This course stresses key areas for Pre-Approval inspection audits. Case studies help prepare students for issues arising during a Pre-Approval inspection. The history and evolution of the Pre-Approval program are discussed. Note: Not open to students who have taken the former PHARMACEUTICS 490.

Repeatability: This course may not be repeated for additional credits.

QARA 5492. Production of Sterile Parenterals. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5493. Sterilization Processes. 3 Credit Hours.
A study of the theory and application of sterilization processes in the preparation of sterile pharmaceutical products. The course will cover basic principles and current sterilization technology. The course will focus on moist heat sterilization using autoclaves which is the predominant sterilization method employed in the production of pharmaceuticals. A case study will be used in the course demonstrating the specification, installation, qualification and regulatory approval of a new autoclave facility. An overview of gas and radiation sterilization will be provided. Specific pharmaceutical product examples using radiation and gas sterilization will be reviewed in detail. Not open to students who have completed QARA 0493.

Repeatability: This course may not be repeated for additional credits.

QARA 5494. Quality Audit. 3 Credit Hours.
This course covers topics in quality assurance principles, audit techniques, audit types, audit presentation and reports, auditing procedures for GMPs, GCPs, and GLPs. Note: This course is required for the MS in RA and QA; however, students interested in RA may substitute IND/NDA Submissions. Not open to students who have completed QARA 0494.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B in (QARA 5476, QARA 5477, QARA 5479, or QARA 5536)

QARA 5495. Investigational New Drug/New Drug Application Submissions. 3 Credit Hours.
This course covers the development of Investigational New Drug (IND) and New Drug Application (NDA) submissions for FDA review. The major emphasis is directed toward developing an understanding of the philosophies and requirements FDA imposes on data submitted to support INDs and NDAs. It covers the process of producing INDs and NDAs (managing the teams, producing the submission, using electronic media) and emphasizes how to work with FDA to gain approval of a submission. FDA meetings, advisory panel hearings, appeals, strategies for review and approval of NDAs, use of Orphan drug status, and the various avenues of expedited review are discussed. Note: This course is required for the MS in RA and QA; however, students interested in QA may substitute Quality Audit. Not open to students who have completed QARA 0495.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in (QARA 5459 or QARA 5592)

QARA 5496. Regulation of Medical Devices: Compliance. 3 Credit Hours.
This course examines the broad scope of the medical device industry and its quality assurance practices, covering the preclinical, clinical, manufacturing, postmarket reporting, and device-tracking compliance regulations in the U.S. and other major world markets.

Repeatability: This course may not be repeated for additional credits.

QARA 5497. Statistics for Clinical Trials. 3 Credit Hours.
Assuming no previous courses in statistics, this introductory course reviews topics of interest in statistical evaluation of clinical trials.

Repeatability: This course may not be repeated for additional credits.

QARA 5498. Computerized System Validation. 3 Credit Hours.
This course studies the regulatory history and background for computerized system validation (CSV). The current FDA and global CSV relevant regulations including the predicate rules will be discussed. The course will also address compliance with 21 CFR Part 11. The course will introduce students to software development methods and deliverables as they relate to CSV. A wide range of computerized systems typically employed in regulated environments will be examined and their unique challenges will be discussed. Students will have the opportunity for hands-on practice in the development of key validation deliverables and will complete an assigned project. Software development experience is not needed, but a better than average understanding of technology and the systems used in Life Sciences is expected. Not open to students who have taken QARA 0498.

Repeatability: This course may not be repeated for additional credits.

QARA 5499. Drug Dosage Forms. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5502. Regulation of Medical Devices: Submissions. 3 Credit Hours.
This course provides an overview of medical device submissions. The course begins with a review of laws specific to medical devices such as the requirement for pre-market submissions. Specific topics include device classification, investigational device exemption (IDE) applications, pre-market notification submissions [510(k)s], pre-market approval applications (PMAs), humanitarian device exemptions (HDEs), product development protocols (PDPs), STED and an overview of Global Harmonization Task Force recommendations.

Repeatability: This course may not be repeated for additional credits.

QARA 5503. Design Controls for Medical Devices and Combination Products. 3 Credit Hours.
This course focuses on design control requirements and practices in the medical device and combination products industry. Class discussions will include design control requirements as they apply to medical devices and combination products. Current regulations and practices will be discussed and utilized to provide students with experience in executing design control activities for a range of products.

Repeatability: This course may not be repeated for additional credits.

QARA 5504. Patient-Focused Regulatory Policy for Medical Products. 3 Credit Hours.
This course provides an overview of patient-focused regulatory policy that impacts the global regulation of medicines and medical devices. This course will cover the legislative and regulatory history of patient-focused policy at U.S. FDA, such as Patient Preference Information and Patient Focused Drug Development. This course will also survey patient-focused policy efforts around the world in countries such as Canada, Australia, and the European Union, among others. Students will have the opportunity to review literature related to patient engagement, patient preference, and patient experience to understand the subtle methodological and policy-specific differences between these concepts. Topics will include evidence for the value of patient engagement in product development, examples of medical products cleared or approved using patient input, and expectations by regulators for the use of patient-generated data to support regulatory submissions. The value of including the patient voice in regulatory decision-making, the impact of patient-focused policy on regulatory decisions, and current policy issues, challenges, and opportunities will also be discussed.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in (QARA 5459 or QARA 5592)

QARA 5505. Global Regulation of Medical Devices. 3 Credit Hours.
This course provides an overview of international medical device regulations. Beginning with a discussion of the similarity of global requirements (including both voluntary and mandatory standards and directives and progressing to in-depth analyses of market specific requirements), the course provides students with resources to meet the regulatory requirements for the largest world markets. The Medical Device Directive, the In Vitro Diagnostic Directive and the Active Implantable Medical Device Directive will be discussed, as well as initiatives by the Global Harmonization Task Force related to the classification, development, and complaint handling for medical devices. As part of this course, the student will learn the quality system requirements of ISO13485, risk management according to ISO14971 and how to CE mark their product. Country-specific regulatory requirements for Canada, EU, Australia and Japan are included.

Repeatability: This course may not be repeated for additional credits.

QARA 5507. Regulation of Non-Prescription Healthcare Products. 3 Credit Hours.
This course examines non-prescription healthcare products in the U.S., including their legal status (both past and present). Starting with discussions of how non-prescription healthcare products are classified, the course will focus on the Food and Drug Administration's OTC Monograph system and the OTC Monograph User Fee (OMUFA). Students will learn how non-prescription labeling evolved (including discussions on Drug Facts Labeling) and examine cases where prescription products were switched to OTC, including the impact of FDA's NSURE Initiative, a draft guidance that will facilitate Rx-to-OTC switches. A brief overview of Non-Prescription classifications outside the U.S. will also be included.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in QARA 5592.

QARA 5508. Good Pharmacovigilance Operations. 3 Credit Hours.
This course provides a solid foundation for understanding/managing the complexities of the lifecycle of an individual case safety report (ICSR). It reviews the process from receipt of the ICSR to reporting to regulatory authorities (both as an expedited ICSR and within a periodic safety update report). It compares US and EU regulations and ICH guidances in this area. It also covers the requirements for a validated safety database to process ICSR and Quality Systems in a Pv department. The course discusses the management of a Pv department and the business decisions required to manage the volume of cases received. Also discussed is the role of Pv agreements and preparation for a Pv inspection.

Repeatability: This course may not be repeated for additional credits.

QARA 5509. Pediatric and Orphan Drug Regulations. 3 Credit Hours.
This course introduces students to pediatric and orphan disease drug development, which includes defining these two populations, discussing where they overlap, and the historical and current challenges in developing therapeutic products for them. Biopharmaceutical medications and aspects of medical device development for these populations will also be included. Discussions focus on legislative changes and the importance of legislative advocacy during the past three decades for pediatric and orphan disease drug development, as well as incentives to make drug development in these areas profitable. While the primary focus of the course will be on the United States and the FDA, the course will include similar activities in the European Medicine Agency (EMA) and other relevant regulatory agencies around the world. Specific examples of successful pediatric and orphan drug development programs are included as well as guest lecturers presenting current issues and trends in these areas.

Repeatability: This course may not be repeated for additional credits.

QARA 5512. Microbiological Concepts in Pharmaceutical Manufacturing. 3 Credit Hours.
This course addresses essential microbiology concepts and contamination control of manufacturing and quality control that form the basis of Good Manufacturing Practices (GMPs) for both sterile and non-sterile pharmaceuticals. Emphasis is placed on a review of the following from a microbiological perspective: basic microbiology and microbial awareness, cleanroom design and microbiology, cleaning and disinfection, aseptic techniques, microbial identification, objectionable microorganisms, environmental monitoring, importance of risk assessment, manufacturing technologies and techniques, building quality into processes and contamination control strategy, influence of raw material quality on finished product, microbial deviation investigations 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. Not open to students who have taken QARA 0512.

Repeatability: This course may not be repeated for additional credits.

QARA 5513. Active Pharmaceutical Ingredients (APIs). 3 Credit Hours.
This course provides a working background on Active Pharmaceutical Ingredients (APIs) used in pharmaceutical dosage forms with focus on the development, manufacture and global regulations that impact successful marketing approval of products. The primary focus is on small molecule synthetic APIs.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in QARA 5459.

QARA 5514. Regulatory eSubmissions. 3 Credit Hours.
This course will explore the evolution of global regulatory submissions from the original paper format to the current electronic common technical document (eCTD) and non-eCTD electronic submissions (NeeS). This course will primarily focus on current regulations, tools, and specifications associated with electronic submissions and electronic requirements of included documentation.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B in QARA 5459.

QARA 5515. Biologics/Biosimilars: A Regulatory Overview. 3 Credit Hours.
Since the first biopharmaceutical product approval in 1982 (recombinant human insulin), the biotechnology derived product market has been rapidly growing with introduction of a number of promising advances in medicine such as therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors. As with traditional drugs (small molecules), the regulatory framework for approval of a biotechnology derived product (biologics) is complicated. In addition, there has been much debate about the introduction of biosimilars using an abbreviated approval process. An overall biologics-based process map beginning with pre-clinical through the post-marketing stage will be discussed. Topics such as therapeutic proteins/peptides, gene therapy, stem cells, vaccines, interference RNAs, PK-PD, world-wide regulatory filings, pre-clinical IND-enabling studies, BLA/CTD filing, biosimilars/follow-on-biologics, selected case studies, immunogenicity, comparability studies, manufacturing challenges, clinical trials, market exclusivity, and related regulatory guidelines will be discussed.

Repeatability: This course may not be repeated for additional credits.

QARA 5516. Cleaning Validation. 3 Credit Hours.
This course will review the different aspects of a pharmaceutical cleaning validation program and the criteria for each. The course will go from protocol to final report with emphasis on the regulatory risks and consequences. FDA and other regulatory agency observations will be highlighted to reinforce class material.

Repeatability: This course may not be repeated for additional credits.

QARA 5532. Global Labeling Regulation: Principles and Practices. 3 Credit Hours.
Provides a detailed analysis of corporate labeling practices in the U.S. and E.U., comparing and contrasting FDA, EU, and International Congress on Harmonization regulations. Special focus is devoted to new FDA guidelines and pharmacovigilance guidelines.

Repeatability: This course may not be repeated for additional credits.

QARA 5533. Requirements for Product Labeling and Advertising. 3 Credit Hours.
This course examines strategies for creating drug labeling during new product development, for updating existing product labeling, and for creating "harmonized" core data sheets for products marketed globally. Students gain insight and awareness of current trends in advertising and promotional regulation.

Repeatability: This course may not be repeated for additional credits.

QARA 5534. Regulatory Aspects of Biomedical/Technical Communication. 3 Credit Hours.
This course reviews regulatory requirements of biomedical/technical writing in the pharmaceutical industry. Students research, summarize, and organize typical scientific data. Issues of content (relevancy, accuracy, balance, and currency), organization, and style (e.g., American medical Association Manual of Style and current FDA and ICH guidelines) are addressed. Writing exercises include topics such as the Physician's Desk Reference, developing product label package inserts, and summarizing studies in pharmacokinetics, pharmacodynamics, efficacy and safety, product development, and stability.

Repeatability: This course may not be repeated for additional credits.

QARA 5535. Advanced Topics in Labeling Development. 3 Credit Hours.
This course reviews the regulatory and legal fundamentals of labeling FDA-regulated products, specifically, prescription pharmaceuticals, emphasizing the direct application of the regulations to actual practice. It analyzes case studies and current practices, providing an overview of legal, regulatory, and marketing concepts affecting labeling. It discusses the application of current knowledge and explores new trends in the legal and regulatory framework surrounding the development and implementation of drug labeling. As a class project, students are assigned to drug development teams (Regulatory Affairs, Marketing and Clinical) and provided with the known data of their compounds. Teams determine what information is needed to complete the draft labeling for NDA submission, and develop a final label; they hold mock negotiations (internal and with the Agency) and propose changes to labeling in response to post-marketing surveillance.

Repeatability: This course may not be repeated for additional credits.

QARA 5536. Good Clinical Practices. 3 Credit Hours.
This course examines the federal regulatory requirements and processes necessary to conduct valid drug trials on human volunteers. Emphasis is placed on managing the clinical drug study and auditing its processes and generated data. The course also addresses ethical issues and volunteer informed consent. Note: This course fulfills the GxP requirement for the M.S. in RA and QA students and for the Drug Development Certificate. It is required for the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5537. Clinical Trial Management. 3 Credit Hours.
This course is designed to help the clinical research department member and those familiar with the industry working in related fields become more effective members of the clinical research team, whether at a company or an investigator's office. This course covers the day-to-day operations of a clinical trial, from site and investigator selection through monitoring and data retrieval. It covers key topics such as budgeting, protocol preparation, site and investigator selection, monitoring, document and file creation and maintenance, and the participation of key members of the principal investigator's team. Note: This course is required for the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5538. Clinical Drug Safety and Pharmacovigilance. 3 Credit Hours.
This course provides students with an in-depth understanding of what pre-marketing Clinical Safety and Risk Management (CSRM) means in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. Beginning with an historical overview of IND and international safety requirements, it examines the processes and systems in place to support compliance and the strategic documentation required for applications. It also looks at the role of risk management and epidemiological methods used to identify the signals used to quantify, assess, and communicate adverse drug reactions (ADR). Topics include clinical trial policy, the roles of the investigator, patient, and IRBs, privacy issues, informed consent, DSMB, and other related matters. Note: This course may be substituted in place of Clinical Data Management in the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5539. Global Clinical Drug Development. 3 Credit Hours.
This course focuses on the specific regulatory requirements of clinical development in the European Union, Easter Europe, Latin America, Canada, India, China and Japan. It will review the efforts of the International Conference on Harmonization (ICH) to unify Good Clinical Practices (GCPs) in these global areas, exploring the differences between cultures, races, and societies and the impact of socialized medicine. Upon successful completion of this course, students will: gain an overview of multinational clinical drug development; gain a basic understanding of cultural differences towards GCPs in various regions of the world; understand key regulatory bodies and concepts governing clinical development in various global markets; and become familiar with the ICH and its legal requirements for global clinical development. Note: This course may be substituted in place of Clinical Trial Management in the CTM certificate.

Repeatability: This course may not be repeated for additional credits.

QARA 5541. Pharmaceutical Packaging: Technology and Regulation. 3 Credit Hours.
This course focuses on the complexities of packaging for the pharmaceutical industry, covering commonly used packaging systems (bottle/blister packaging for Oral solids) as well as niche applications (such as sterile/parenteral, inhalation, and nasal systems). In addition to the container/closure systems, some of the packaging processing methods will be covered. A review of the applicable regulatory environment and the submission requirements for drug products will be included. The submission needs will be covered, with a focus on the needs of the newly implemented Common Technical Document (CTD). A visit to a manufacturing facility of one of the industry's suppliers will be required.

Repeatability: This course may not be repeated for additional credits.

QARA 5542. Pharmacopoeia Compliance: Understanding the Global Impact on RAQA. 3 Credit Hours.
Compliance with requirements published by pharmacopoeias around the world is a legal and regulatory requirement in those countries and regions in which the pharmacopoeia is applicable. This fundamental (and often misunderstood) principle is an important consideration throughout the drug product life cycle across the bio/pharmaceutical industry. This course provides an in-depth look at the interplay of pharmacopoeias, quality assurance, and regulatory affairs to assist companies in establishing effective processes, partnerships, and tools to maintain appropriate and timely compliance. Topics include why pharmacopoeia compliance is necessary and why it is difficult; a history of pharmacopoeias and harmonization efforts; the revision process for global and national pharmacopoeias and the associated surveillance process used by industry to identify pharmacopoeia changes; the process for monograph development including real-world case studies; and new topics that are on the horizon as the pharmacopoeias continue to evolve. Additionally, the course provides compendial touchpoints during each stage of product development and its importance to regulatory decision making throughout a development program and lifecycle management of a therapeutic product, including innovator, generic, virtual, OTC, and start-up companies who discover, develop, manufacture, and distribute small-molecule drug products, biotherapeutic products, and vaccines, as well as the drug substances and excipients used in these products. Class discussion and hands-on exercises will provide insights on the complexity encountered and possible solutions that companies face every day. The class will focus on small molecule drugs and biotherapeutics and will not include an in-depth overview of herbals or dietary supplements. Note: Science background required. Suggested prerequisites (but not required): Drug Development (5459), Good Manufacturing Practices (5477), and Generic Drug Regulation: ANDAs (5473).

Repeatability: This course may not be repeated for additional credits.

QARA 5543. Good Distribution Practices. 3 Credit Hours.
Students will study the organizational, managerial and technology issues related to the supply chain, logistics, and distribution functions of the pharmaceutical industry, particularly generic pharmaceuticals. They will be introduced to the tools and technologies that companies use to optimize their supply chain, logistics, and distribution functions, with specific emphasis on how generic companies configure and operate these aspects. Topics include: supply chain operations; integration with distributors, wholesalers, and other channels; WHO/FDA regulations and guidelines; supply chain security (counterfeiting, RFIDs, etc.); inventory considerations (management, turns, cost); demand and capacity planning; lean operations; postponement; supply constraints; and technologies.

Repeatability: This course may not be repeated for additional credits.

QARA 5544. Regulatory Intelligence. 3 Credit Hours.
This course examines the fundamentals of Regulatory Intelligence, including what it is, how it is conducted, and how it is used to influence regulatory decision making throughout the development and lifecycle management of a therapeutic product. Students will learn to monitor the legislative and regulatory landscape by assessing accessible information data.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in (QARA 5459 and QARA 5592)

QARA 5545. Post Approval Changes (PAC). 3 Credit Hours.
This course reviews SUPAC guidelines developed by CDER to maintain product safety, efficacy, and quality while giving manufacturers substantial regulatory relief and flexibility. A basic review of formulation development of various dosage forms provides a complete understanding of the guidelines and of regulatory strategies for formulation development.

Repeatability: This course may not be repeated for additional credits.

QARA 5546. Global Pharmaceutical Excipient Regulation. 3 Credit Hours.
An integral part of almost all pharmaceutical dosage forms, excipients play an important role in drug development. This course discusses the function of excipients, providing an in-depth examination of their unique yet globally diverse regulatory requirements in major world markets. Excipient selection, assessment, and supplier qualifications will be discussed, as well as Adverse Events (AEs) related to excipient quality. This course stresses how global pharmaceutical excipient regulation is critical in developing formulations that have the potential for international approvals.

Repeatability: This course may not be repeated for additional credits.

QARA 5547. Project Management for Clinical Trials. 3 Credit Hours.
Creation of clinical development plans to better lead, manage and operate clinical trials. Combines basic project management methodology and drug development best practices needed for leading and managing a clinical trial time.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B in (QARA 5459 or QARA 5536)

QARA 5548. Risk Management of Pharmaceutical and Medical Devices. 3 Credit Hours.
This course focuses on risk management requirements and practices in the pharmaceutical, medical device, and biotech industries. Current regulations and risk management tools will be discussed and utilized to provide students with experience in executing risk assessments.

Repeatability: This course may not be repeated for additional credits.

QARA 5571. Post-Marketing Safety Surveillance. 3 Credit Hours.
This course provides an in-depth understanding of post-marketing safety surveillance (PMSS) in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. It begins with a historical overview of PMSS and then reviews the role of epidemiological methods in identifying signals and quantifying, assessing, and preventing adverse drug reactions (ADR). Medical/legal issues, benefits and limitations of safety surveillance systems, labeling changes, the ability to refute false signals, and social and ethical obligations inherent in the conduct of PMSS are discussed.

Repeatability: This course may not be repeated for additional credits.

QARA 5572. Vaccines: Regulatory Affairs and Quality Assurance Issues. 3 Credit Hours.
This course addresses the history, research and development, manufacture, marketing, and medical impact of vaccines. Various public policy, regulatory, ethical, and legal issues in this area are discussed as they pertain to the U.S. and, to some extent, international markets. Beginning with the eradication of smallpox, this course covers the development of widely used vaccines against once common diseases (e.g., polio, mumps, varicella, etc.), to the development of vaccines against HIV, anthrax, and certain types of cancer.

Repeatability: This course may not be repeated for additional credits.

QARA 5573. Pharmacoepidemiology. 3 Credit Hours.
This course introduces students to principles of study design, concepts of causal inference, and major types of epidemiological studies. These principles are applied to the distribution and determination of the effects (expected and unintended, beneficial and adverse) of pharmaceuticals on human populations. Risk-benefit analyses, cost-benefit assessments, regulatory issues, and legal and public health concerns are discussed.

Repeatability: This course may not be repeated for additional credits.

QARA 5574. Pharmaceutical Quality Management Systems. 3 Credit Hours.
This course presents a comprehensive Quality Management Systems approach to the pharmaceutical industry based on Q10 regulations. SOPs, Deviation/Non-conformance, Corrective and Preventative Action, Supplier Management, Change Management, Validation, and Process controls via Key Performance Indicators are explored. Focus is placed on the key areas for inspection readiness and robust Quality Systems development.

Repeatability: This course may be repeated for additional credit.

QARA 5575. Regulatory Sciences: Managing the Guidelines to Quality. 3 Credit Hours.
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.

Repeatability: This course may not be repeated for additional credits.

QARA 5576. Global CMC Issues and Regulatory Dossier. 3 Credit Hours.
The course provides students with an in-depth knowledge of the major chemistry, manufacturing. and controls (CMC) issues facing the global pharmaceutical industry. Students learn the practical and theoretical skills necessary to develop successful CMC dossiers from the initial clinical application through marketing and post-marketing support. The class emphasizes long range CMC planning to combine technical and regulatory knowledge with strategic thinking. The class is designed for regulatory professionals, managers, and scientists with significant responsibility for CMC dossiers.

Repeatability: This course may not be repeated for additional credits.

QARA 5577. Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics. 3 Credit Hours.
This course provides an introduction to the chemistry, manufacturing and controls (CMC) topics involved in the development and licensure of biologic products (biopharmaceuticals, vaccines) in the US, Europe and other highly regulated world regions. Topics will be discussed from the perspective of Regulatory and QA requirements and expectations. Basic microbiology, cell biology and chemistry concepts will be reviewed with an emphasis on their practical application to product development and RA/QA. The class orients RA/QA professionals, managers and scientists responsible for biopharmaceutical CMC development and preparation of dossiers to the CMC content matter and technical issues that must be addressed in biologic product development and registration globally. Topics include adventitious agents testing, cell and seed bank testing methods and requirements, drug substance production via cell culture, protein and virus purification methods, control and analysis of process impurities, analytical methods and potency testing for characterization and release, strategy for specification setting for release and stability, comparability studies for biologics.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B in QARA 5459.

QARA 5578. Benefit Risk Management and Safety Signaling of Healthcare Products. 3 Credit Hours.
This course provides students with a basic understanding of the principles involved in developing, negotiating, and implementing Benefit-Risk Management Plans. While the focus will be on risk management plans intended for the EU and USA markets, the general principles are applicable across most regulatory jurisdictions in the world.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in (QARA 5571 or QARA 5538)

QARA 5579. Regulatory and Legal Basis of Pharmacovigilance. 3 Credit Hours.
This course reviews key regulations and the regulatory framework that influence the development and management of a pharmacovigilance system. While the main emphasis is on ICH regions, systems in emerging countries are also included, including the impact of the changing regulatory landscape on both manufacturers and regulators. Discussions include partnership agreements, pharmacovigilance aspects of due diligence, licensing and acquisitions, and product liability issues. In addition, students learn key aspects of drug safety and pharmacovigilance; FDA and EMA guidances that shape pharmacovigilance practices; the merits and deficiencies in the U.S. AERS database system in comparison to the European Eudravigilance data base; differences between the U.S. periodic reports (including periodic safety update reports, development safety update reports, and others as mandated); the impact of key regulatory reforms on pharmacovigilance (Brexit and GDPR); and product liability issues.

Repeatability: This course may not be repeated for additional credits.

QARA 5591. Global Regulatory Affairs. 3 Credit Hours.
This course provides a detailed analysis of the regulatory processes for new drug approvals outside of North America. Students gain experience in comparing the European and Japanese registration trends with those of the United States. Future regulatory structures in the major world markets are explored.

Repeatability: This course may not be repeated for additional credits.

QARA 5592. Food and Drug Law. 3 Credit Hours.
This course examines the governance of intra- and interstate commerce in foods, drugs, cosmetics, and medical devices and the effects of the Federal Food, Drug and Cosmetic Act upon research, manufacture, marketing, and distribution of FDA-regulated products. Note: This course is required for the M.S. in RAQA and several certificates (Drug Development, Medical Devices, and Labeling, Advertising and Promotions).

Repeatability: This course may not be repeated for additional credits.

QARA 5594. Regulation of Dietary Supplements and Functional Foods. 3 Credit Hours.
Functional foods and dietary supplements have been a fast growing segment of the food market for the last half a decade owing to the aging demographics and scientific research demonstrating their effect on health. Regulation and judicial decisions have been influential for dietary supplement companies in producing and marketing their products. An understanding of how these regulation work and what influence they have on dietary supplement regulatory policy is critical. This course will provide information on the history of the regulation in the US and an in-depth look at the current regulatory outlook for these products in the US and in other select countries/regions.

Repeatability: This course may not be repeated for additional credits.

QARA 5595. Food Law. 3 Credit Hours.
While Food and Drug Law (QARA 5592) briefly touches on food law, this course examines the major federal statutes and regulations applicable to food in more detail through class discussion and workshops. While emphasis is placed on the role, policies, and regulations of FDA, the practical working relationships and obligations between the food industry, the USDA, and other government agencies at the state and local level are also examined. Pertinent landmark judicial decisions and concepts are presented relating to regulation of food and enforcement action against adulterated food. The Food Safety Modernization Act (FSMA), the most sweeping reform of U.S. food safety laws in more than 70 years, is studied, including new enforcement tools granted to FDA. Preventive Controls for Human and Animal Food, which are revolutionizing food safety programs across the globe, are extensively studied and illustrated. The student project focuses on conducting a Hazard Analysis for a particular food product.

Repeatability: This course may not be repeated for additional credits.

QARA 5596. Food Labeling and Regulatory Affairs. 3 Credit Hours.
This course provides students with an in-depth understanding about how food marketed in the U.S. must be labeled. Students learn about the food label and its mandatory elements, as well as problems associated with incorrect or deceptive labeling. Workshops illustrate important labeling concepts. The course also describes regulatory affairs functions in the food industry including food facility registration, importing, recordkeeping, reporting, and recalls. Tips and insights for navigating an FDA inspection are explored. Select rules issued under the Food Safety Modernization Act (including Produce Safety, Intentional Adulteration, Sanitary Transportation, and Foreign Supplier Verification Program) are studied. This is one of three required courses for the Food Regulatory Affairs and Quality Assurance Certificate (Food RA and QA Certificate), which non-matriculated students may pursue. Matriculated students are welcome to pursue the Food RA and QA Certificate along with another certificate before receiving the MS in RAQA.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in (QARA 5592 or QARA 5595)

QARA 5597. Food Good Manufacturing Processes. 3 Credit Hours.
This course covers FDA-enforced cGMPs (current Good Manufacturing Practices) through class discussion and workshops. Food safety regulations under the Food, Drug, and Cosmetic Act are covered as well as their impact on personnel, facilities, equipment, and production. Major foodborne pathogens are discussed, followed by control strategies, such as formulation and thermal processing. Emphasis is placed on preventing foodborne hazards via an understanding of sanitation measures, allergen control, acidification and low-acid canning. A risk-based approach to controlling hazards is presented using HACCP (Hazard Analysis and Critical Control Points) principles, from which new Preventive Controls regulations were derived. The student project focuses on evaluating food safety concerns when an FDA inspection reveals a total quality failure.

Repeatability: This course may not be repeated for additional credits.

QARA 5598. Regulatory and Safety Requirements for Developing New Innovative Food Ingredients. 3 Credit Hours.
Many innovative and new food ingredients are being introduced for use in the food industry. Each new ingredient must meet current regulatory and safety requirements. This course provides an overview of the regulatory and safety evaluation of food ingredients, including the regulatory approval processes. Topics include the requirements and submission process for innovative ingredients in the U.S., Canada, EU and other global regions. Discussions include global strategies for food ingredient approval, including petition procedures for JECFA and the Codex Alimentarius Commission. The course emphasizes the U.S. Generally Recognized as Safe (GRAS) system, exploring the controversial issues associated with this unique regulatory process. Self-regulatory schemes for ingredients such as flavors and enzymes will also be discussed.

Repeatability: This course may not be repeated for additional credits.

QARA 5601. Industry Interactions with FDA/Health Authorities. 3 Credit Hours.
Presenting a global perspective by reviewing the drug approval process in the European Union (EU), this course introduces students to the importance of establishing liaisons with officials with the U.S. FDA and other world health authorities. The rapport developed with health authorities frequently lessens the time it takes to get a new drug to market. How a firm presents its data can contribute as much to the successful relationship with health authorities as the quality of data presented. Areas include: FDA organization, average workload analysis with FDA, FDA review and drug approval process, national versus mutual recognition versus centralized approval process in the EU, user fees, company "personalities," FDA/Industry meetings, inspections, Advisory Committees, IND/NDA classification system, FDA initiatives to speed drug approval including electronic submissions, and notable internet regulatory addresses.

Repeatability: This course may not be repeated for additional credits.

QARA 5605. Advanced Topics in Food and Drug Law. 3 Credit Hours.
This course expands the regulatory concepts covered in QARA 5592. Each semester the specific topics change.

Repeatability: This course may not be repeated for additional credits.

QARA 5606. Regulatory Strategy: Discovery to Approval. 3 Credit Hours.
A regulatory strategy is a key component of a therapeutic product's development. It is imperative to create a regulatory strategy early in the development process to consider such critical factors as the correct indication, size of the treatment population, cost and extent of clinical studies, and potential market for the product under consideration. The regulatory strategy should be developed as soon as the target product profile (TPP) is determined. Considering the enormous investments companies incur when launching new products, any regulatory strategy must be well thought out, reviewing existing patents, current regulatory intelligence, and pricing issues. This course covers the development and execution of product approval strategy from discovery to marketing approval. Class discussions include analyses of successful product launches as well as ones that failed due to insufficient regulatory strategies.

Repeatability: This course may not be repeated for additional credits.

QARA 5611. Regulation of Advertising and Promotions. 3 Credit Hours.
This course reviews the regulatory and legal fundamentals of advertising and promotion of FDA-regulated prescription products. Emphasis will be placed on prescription pharmaceuticals and the current regulatory and legal environment. Discussions include how prescription drug regulations differ from those applicable to OTCs (over-the-counter drugs), biologics and restricted medical devices.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in QARA 5533.

QARA 5612. Bioethics for Pharmaceutical Professionals. 3 Credit Hours.
This course focuses on bioethical issues arising in the regulation and conduct of research. It instills a basic understanding of bioethics and the theories and principles underlying its practices and application to research. It also discusses how bioethical theories and principles provide the foundation for many research regulations. Starting with a brief history of research ethics and regulation, it explores past and present ethical research controversies. Note: This course is required for the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5615. Project Management for Pharmaceutical Professionals. 3 Credit Hours.
This course discusses the strategic positioning of drugs, specifically focusing on domestic and international registration strategies. It explores why a company seeks a particular indication in labeling and how RA/QA professionals play a critical role in understanding and developing regulatory intelligences. It covers how project teams should be created, including the effective clarification of roles and responsibilities, so regulatory timeliness can be achieved. Workshops include an overview of project planning tools, techniques and critical path management, including negotiating registration strategies with the FDA and foreign agencies.

Repeatability: This course may not be repeated for additional credits.

QARA 5616. Accelerated Regulatory Pathways: From Fast Track to Reliance. 3 Credit Hours.
Facilitated Regulatory Pathways (FRPs) are regulatory approaches used by ministries of health to accelerate the development and assessment of new products or reduce the burden of duplicative regulatory activities, helping to make the development and assessment of safe, effective, quality medicines more efficient and timelier often through reliance or recognition mechanisms, thereby promoting efficient access to important medicines worldwide. This course has been designed to help the student understand the evolution of and distinguish the characteristics of FRPs used by ICH and maturing regulators. Participants will learn how to apply these to real-world global drug development programs. Students will investigate how to apply the concept of Return on Investment for the use of FRPs, as these apply to companies and agencies and will gain an understanding of how the data requirements for FRPs and the acceleration of authorizations through these pathways have implications for agencies, patients, payers and health technology assessment bodies. A combination of presentation styles will be used: lecture by the instructor and invited international speakers; interactive questions will be posed by the presenter to the students; each week selected students will be asked to prepare a 10-minute overview of a recently published manuscript/ research paper/policy document that will relate to the topic of the session and will help students familiarize themselves with important advances in the field of FRPs; and an in-session discussion will be presented by the course instructor based on the reading homework, and practical applicability of the learnings from the publication will be stressed.

Repeatability: This course may not be repeated for additional credits.

Pre-requisites: Minimum grade of B- in QARA 5459.

QARA 5618. Clinical Data Management (CDM). 3 Credit Hours.
Data management is the activity of collecting, reviewing, organizing, and analyzing data from clinical research studies. The data from clinical research studies are the crux of a regulatory submission for a new drug or biologic. There is no basis for a therapeutic claim without data. Thus the success of a submission depends on quality data management practices and strict adherence to regulatory requirements. This course teaches students how to go from collecting data for the first protocol to ultimate submission to a regulatory agency from data collection, management, and reporting perspectives. Note: This course is required for the Certificate in Clinical Trial Management.

Repeatability: This course may not be repeated for additional credits.

QARA 5621. Regulatory Bioanalysis. 3 Credit Hours.
This course covers several broad topics: (1) a high-level quantitative analysis of biological samples that provide date to support pharmaceutical drug/biological product approval, (2) detailed instruction of FDA and EMA regulations and guidances that govern bioanalytical method development, validation and application in routine sample analysis, (3) "best practices" recommended for implementing quality management systems in a bioanalytical laboratory, and (4) discussion of approaches to address common problems that may arise during method validation and sample analysis.

Repeatability: This course may not be repeated for additional credits.

QARA 5622. Unit Operations. 3 Credit Hours.
This course will expose students to the current process steps common to the manufacture of modern pharmaceuticals. In particular, the key variables for each step of a process will be discussed. Each class will feature a specific process common to pharmaceutical processing. Specific variables will be discussed, including an analysis of each process. At the end of the course the student should be able to describe a process by a series of smaller operations, describe the key variables for each small operation, identify key limitations of time and resources in proposed processes, and provide constructive improvements to complex processes.

Repeatability: This course may not be repeated for additional credits.

QARA 5625. Process Analytical Technology (PAT). 3 Credit Hours.
The course focuses on state-of-the art utilization of process controls, including multivariate methods and feed-back loops. It will investigate analytical tools, including thermal conductivity, NIR, and Raman spectroscopy. It will also cover process analysis and feedback, as well as batch record analysis.

Repeatability: This course may not be repeated for additional credits.

QARA 5627. Statistical Design of Experiments (DOE). 3 Credit Hours.
This course exposes students to the use of statistical methods for designing optimal processes used in industry, extensively using data sets and data charting. At the end of the course the student should be able to: create an experimental plan to optimize a process; create a screening study to limit the number of experiments; use surface methodology to set process specifications; and use specialized methodology for material analysis.

Repeatability: This course may not be repeated for additional credits.

QARA 5629. Process Monitoring. 3 Credit Hours.
This course reviews Control Charting, Six Sigma, Root Cause Analysis, Risk/Benefit Analysis, Process Capability, and Process Efficiency/Lean Manufacturing.

Repeatability: This course may not be repeated for additional credits.

QARA 5650. Special Topics in Regulatory Affairs and Quality Assurance. 3 Credit Hours.
Special topics as announced.

Repeatability: This course may be repeated for additional credit.

QARA 5655. Analytical Chemistry in Pharmaceutical Laboratories. 3 Credit Hours.
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.

Course Attributes: SI

Repeatability: This course may not be repeated for additional credits.

QARA 8001. Principles of Drug Action/PK. 3 Credit Hours.
This course presents the fundamental principles of pharmacology, medicinal chemistry, and pharmacokinetics needed to understand their application in drug discovery and developmental processes. The material, presented in an integrated manner, includes the molecular mechanisms of drug action, structure-activity relationships, and the time-course of drug absorption and disposition.

Repeatability: This course may not be repeated for additional credits.

QARA 8002. Pharmaceutical Analysis. 3 Credit Hours.
Application of chemical analysis as it relates to pharmaceuticals and pharmaceutical manufacturing. Classical separation methods including GC and HPLC, as well as hyphenated techniques (GS-MC and HPLC-MC) will be explored. Students will also be introduced to newer immunologic antibody-based procedures and emerging technologies.

Repeatability: This course may not be repeated for additional credits.

QARA 8003. Preformulation - Small Molecules. 3 Credit Hours.
Preformulation research of small molecules is the foundation of pharmaceutical manufacturing. Inadequate understanding of the physical/chemical and biophysical properties of drug substance or excipient can lead to the development of formulations and manufacturing processes that are not robust. The ability of a company to demonstrate to health agencies a firm understanding of the "manufacturing science" related to the production of each dosage form is essential. This course describes the evolution of preformulation from a science dedicated to primarily characterizing basic drug substance and excipient attributes as they relate to the finished product to the science of understanding, utilizing and controlling such properties to optimize the manufacture and bioavailability of a dosage form. The influence of preformulation data in the era of Quality by Design (QbD) and expectations for outstanding science from global health authorities will be incorporated throughout the course.

Repeatability: This course may not be repeated for additional credits.

QARA 8004. Solid Dosage Forms: Small Molecules. 3 Credit Hours.
This course presents the comprehensive, integrated, and most up-to-date methods, processing, and principles as they apply to solid dosage form design and product development. Conventional and specific techniques of industrial pharmacy, including direct compression, wet and dry granulation, fluid bed and coating operations, tableting machine instrumentation and compatibility measurements, and solid product evaluation will be presented. Novel oral dosage forms and technologies associated with solid products as well as product quality and performance assessment will be covered.

Repeatability: This course may not be repeated for additional credits.

QARA 8006. Physical Pharmacy I. 3 Credit Hours.
The emphasis of this course is to form a 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.

Repeatability: This course may not be repeated for additional credits.

QARA 8007. Applied Biopharmaceutics. 3 Credit Hours.
This course considers the interrelationship of the physicochemical properties of the drug, the dosage form, and the route of administration on the rate and extent of systemic drug absorption. Drug absorption mechanisms, physiological and GIT constraints on dosage form transit and bioavailbility, effect of formulation parameters, dissolution methodologies, in-vitro/in-vivo correlation of drug product performance as well as PAC, 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.

Repeatability: This course may not be repeated for additional credits.