

# Regulatory Affairs and Quality Assurance (M.S.)

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## About The Program:

Since its establishment in 1968, Temple's Regulatory Affairs and Quality Assurance program has played a significant role in training pharmaceutical company personnel in regulations and quality principles and practices. Its courses meet the career requirements of professionals in the pharmaceutical and related industries. The program provides students with a broad knowledge of the industry, fostering their professional development and preparing them for supervisory and managerial positions.

**Career Options:** Students find positions in all areas of the pharmaceutical industry, including big Pharmaceutical Research and Manufacturers of America (PhRMA) and generic companies, biotechnology, clinical research organizations, and medical devices and packaging. Employment is also found with government agencies, including the FDA, and healthcare providers.

**Prerequisites for Admission:** A B.S. degree in Biochemistry, Biology, Chemistry, Physics, or a health-related discipline is required.

**Affiliation(s):** Each year the program sponsors a major conference with the pharmaceutical industry and the U.S. FDA, focusing on current regulatory and quality issues.

**Areas of Specialization:** This is a non-thesis M.S. program. Faculty members are specialists in many areas, such as auditing; clinical trial management and operations; global regulation; IND/NDA submissions; manufacturing; pharmaceutical, food, and device law; pharmaceutical labeling and advertising; quality assurance; regulatory affairs; and validation.

## Requirements of Programs:

- **Total Credit Hours:** 36
- **Culminating Events** This program has no culminating events beyond completion of coursework.

## Core Courses (Thesis Option)

**Drug Development** - 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.

**Quality Audit** - 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 M.S. in RA and QA; however, students interested in RA may substitute IND/NDA Submissions. **OR Investigational New Drug/New Drug Application Submissions** - 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 M.S. in RA and QA; however, students interested in QA may substitute Quality Audit.

**Food and Drug Law** - This course studies 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 drugs. Note: This course is required for the M.S. in RA and QA and for the Drug Development Certificate.

## **Good Practices Courses**

*Select one of the following:*

**Good Laboratory Practices** - 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.

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

**Advanced Good Manufacturing Practices - Defining "c"** - 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.

**Good Clinical Practices** - 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.

## **Electives (24 Credits)**

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## Courses:

Click [HERE](#) for more information on the courses below.

- Special Topics in Regulatory Affairs and Quality Assurance
- Fundamentals of Pharmacology and Pharmacokinetics
- Pharmacoeconomics
- Statistical Quality Control
- Global Biopharmaceutical Industry
- Drug Development
- Pharmaceutical Laboratory Quality Systems and Operations
- Biotechnology: Bioprocess Basics
- Pharmaceutical Marketing
- Generic Drug Regulation (ANDAs)
- Process Validation
- Pharmaceutical Biotechnology
- Good Laboratory Practices
- Good Manufacturing Practices
- High Purity Water Systems
- Advanced Good Manufacturing Practices - Defining "c"
- Pre-Approval Inspections
- Production of Sterile Parenterals
- Sterilization Processes
- Quality Audit
- Investigational New Drug/New Drug Application Submissions
- Regulation of Medical Devices: Compliance
- Statistics for Clinical Trials
- Computer Validation
- Drug Dosage Forms
- Regulation of Medical Devices: Submissions
- Design Controls for Medical Devices and Combination Products
- Global Regulation of Medical Devices
- Environmental Law and Regulation (EPA)
- Good Pharmacovigilance Operations
- Advanced Audit Workshop of Quality Systems
- Advanced Audit Workshop of Quality Systems
- Active Pharmaceutical Ingredients (APIs)
- Regulatory Electronic Submissions
- Biologics/Biosimilars: A Regulatory Overview
- Cleaning Validation
- Quant Methods-Benefit/Risk
- Regulatory Issues in Pharmacogenomics
- Global Labeling Regulation: Principles and Practices
- Requirements for Product Labeling and Advertising
- Regulatory Aspects of Biomedical/Technical Communication
- Advanced Topics in Labeling Development
- Good Clinical Practices
- Clinical Trial Management
- Clinical Drug Safety and Pharmacovigilance
- Global Clinical Drug Development
- Pharmaceutical Packaging: Technology and Regulation
- Good Distribution Practices
- Regulatory Intelligence
- Post Approval Changes (PAC)
- Global Pharmaceutical Excipient Regulation
- Project Management for Clinical Trials
- Risk Management of Pharmaceutical and Medical Devices
- Post-Marketing Safety Surveillance
- Vaccines: Regulatory Affairs and Quality Assurance Issues
- Pharmacoepidemiology
- Pharmaceutical Quality Management Systems
- Regulatory Sciences: Managing the Guidelines to Quality
- Global CMC Issues and Regulatory Dossier
- Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics
- Benefit Risk Management and Safety Signaling of Healthcare Products
- Regulatory and Legal Basis of Pharmacovigilance
- Global Regulatory Affairs
- Food and Drug Law

- Regulation of Dietary Supplements, Botanicals, and Nutraceuticals
- Food Law
- Food Labeling and Regulatory Affairs
- Food Good Manufacturing Processes
- Clinical Aspects of Pharmaceutical Medicine
- Industry Interactions with FDA/Health Authorities
- Clinical Aspects of Pharmaceutical Medicine II
- Advanced Topics in Food and Drug Law
- Regulation of Advertising and Promotions
- Bioethics for Pharmaceutical Professionals
- Project Management for Pharmaceutical Professionals
- Clinical Data Management (CDM)
- Regulatory Bioanalysis
- Unit Operations
- Process Analytical Technology (PAT)
- Statistical Design of Experiments (DOE)
- Process Monitoring
- Special Topics in Regulatory Affairs and Quality Assurance
- Analytical Chemistry in Pharmaceutical Laboratories
- Principles of Drug Action/PK
- Pharmaceutical Analysis
- Pharmaceutical Manufacturing I: Preformulation/Formulation
- Pharmaceutical Manufacturing II: Solid Dosage Forms
- Physical Pharmacy I
- Applied Biopharmaceutics