Health product regulation

RA 601 Introduction to the Health Product Industry
This introduction to the industry is intended to provide a common basic level of understanding, whether the student comes directly from an undergraduate program, another graduate program, or from industry experience in limited types of products or associated activities. It includes:

- The health product industry (pharmaceutical, biotechnology, and devices)
- Typical company structures
- Laws, regulations, and standards
- The government structures, agencies, organizations, and societies that influence and produce them
- Regulatory agencies that enforce them
- Third party organizations (product testing, quality system auditing, clinical research organizations)
- The healthcare industry (providers, such as hospitals and clinics, and reimbursers, such as insurance companies, HMOs, government health plans)

RA 602A Introduction to Health Production Regulatory Regulation
This overview of the Food and Drug and Cosmetic Act describes the basis for regulation of the development, production, and the approval processes for drugs and biologics, foods, and cosmetics. The primary focus is United States regulation, but examples of foreign laws and regulations are included.

RA 603A Pharmaceutical Product Regulation
Current information on the laws and U.S. Food and Drug Administration (FDA) regulations regarding the control and regulation of drugs and biologics, the manufacturing processes, marketing, and compliance procedures. An overview of classic drug development process model, including pre-clinical, clinical (Phases 1, 2, 3, and 4), and post-marketing surveillance are addressed. Case studies are used so that actual examples can be examined first-hand.

RA 604A Medical Device Regulation
A survey of the principles of medical device regulation focused on United States, European Union, and Canadian regulations. Students select a hypothetical product as a semester-long project and apply what they learn about each of the issues covered, including classification, quality systems, design controls, standards, software, biocompatibility, infection control and sterilization, production control, and postmarket activities.

RA 605 Field Experience in Regulatory Affairs
A coordinated field experience at a product company or clinical research organization. Students apply the principles learned in classes to produce results of value to the host organization. The experience can occur where the student is employed or at organizations found by the student. Assistance from faculty and fellow students can help identify appropriate sites and projects. Project locations and the nature of the experience must be approved by the Regis faculty and by the host organization.

RA 608 Clinical Research Methods
An introduction to common clinical research and analysis methods used in product development for:

- Proof of concept or technology including: device feasibility studies and exploration of new applications, indications for use, or modified methods of use
- Demonstration of safety and effectiveness for regulatory approvals
- Human factors engineering including: usability by medical personnel and proper use of over-the-counter, home use, or direct-to-consumer products
- Demonstration of clinical value to qualify for reimbursement

The student learns methods for different products and applications, such as, pharmaceuticals, biologics processing (e.g., blood processing), in-vitro diagnostics, clinical laboratory instruments, and monitoring, diagnostic, therapeutic, or preventive devices.

Factors in the design of clinical research methods include:
- Statistics methods and power analysis
- Quantitative versus qualitative methods
- Protocol design and inclusion/exclusion criteria
- Selection of sites and investigators, including the choice of foreign or domestic sites
- Regulatory and ethical restrictions

**RA 609 Clinical Trial Management**
An introduction to the fundamentals of clinical trials, including The Code of Federal Regulations as they pertain to clinical trials, the role of the FDA, basics of drug and medical device trials, FDA submission process, Good Clinical Practices, Institutional Review Boards, managing and monitoring clinical trials, and ethical principles including informed consent and conflict of interest.

**RA 610 Medical Reimbursement**
A survey of the general elements of medical product reimbursement and commercialization in both the U.S. public and private payer markets. The course examines the role of the Centers for Medicare and Medicaid Services (CMS) and their relationship with the various sectors of medical industry. Each session builds on the understanding of the importance of reimbursement for products and services and the regulatory control CMS exerts over the marketplace.

**RA 615 Quality Systems and Risk Management**
The student learns requirements and industry practice associated with the Medical Device Quality System Regulation, pharmaceutical Good Manufacturing Practice, Good Clinical Practice, Good Laboratory Practice, and associated international standards. Principles of quality system auditing are learned and practiced in role-playing case studies. The principles of risk management and related regulations and standards are taught exercised in case studies. Risk management is applied to situations throughout the product life cycle.

**RA 616 Project Management**
The student learns project management terminology, key concepts, and ideas for planning and scheduling projects; assess projects, manage cost, time, scope, risk, and quality of projects. The role of an effective project leader is a demanding one that requires a clear understanding of the five project processes: initiating, planning, executing, controlling and closing. Effective project management and its concurrent need to establish defined scope, within budget and completion dates is key to success in today's dynamic biotech, pharmaceutical and healthcare environment.

**RA 617 Combination Products and Advanced Product Regulation Issues**
This elective course is intended for advanced students who have completed the prerequisites, RA 603A and RA 604A. RA 617 provides advanced studies in currently evolving medical product regulation issues. To tackle future medical problems, medical devices will be used in combination with drugs and biologics (hence, combination products) to treat a wide range of diseases. A well-known example of a combination product is the drug-eluting stent. More advanced combination products may be tissue-engineered, composed of cells (biologics) producing proteins (biotech drugs) growing on polymer substrates (medical devices). Course participants learn about examples of combination products on the market and on the drawing board. The course concludes with a look at the future of medicine, including tissue engineering, nanotechnology and beyond.

For courses provided by other graduate programs, that is, that do not have the “RA” course prefix, please see the course description in the corresponding section of this website:

**CO Organizational and Professional Communication**
**MT Leadership and Organizational Change**
**NU Nursing**

For additional information, including a schedule of day and evening classes:
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