

Regulatory Affairs - CPS (RGA)

RGA 6000. Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation. 2 Hours.

Offers students an overview of pharmaceutical and biologic product clinical and regulatory development in addition to a description of the Food and Drug Administration's (FDA's) involvement in the process. Through course work and participation, offers students an opportunity to develop an understanding of fundamental pharmaceutical and biologic regulatory affairs from a U.S.-centric perspective. Reviews the historical development of U.S. pharmaceutical legislation and statute development, FDA and industry functions, as well as significant case law that has shaped the present state of regulation.

RGA 6001. Introduction to Food and Drug Administration Medical Device Regulation. 2 Hours.

Provides an overview of the medical device development process and the function of the Food and Drug Administration (FDA) as it relates to device product commercialization. Through course work and participation, offers students an opportunity to develop an understanding of fundamental medical device regulatory affairs from a U.S.-centric perspective. Reviews the historical development of significant U.S. medical device legislation, including the Medical Device Amendments of 1976. In addition, introduces the subject of quality system regulation (QSR) as it relates to device product design, clinical development, and compliance.

RGA 6002. Regulatory Compliance Culture. 2 Hours.

Offers a general overview of imperatives for regulatory compliance (judicial, economic, and public health, to name a few). Offers students an opportunity to gain competencies in the areas of agency, advocacy, ethics, mitigation laws, and corporate social responsibility. The various state, federal, and international agencies; their authorities; and how they became established help students understand the scope and scale of the regulatory landscape.

RGA 6100. Introduction to Drug and Medical Device Regulation. 4 Hours.

Provides an overview of drug, biologics, and device development and the FDA. Through course work and discussion, offers students an opportunity to gain the foundations necessary to build a strong understanding of regulatory affairs. Topics include the historical development of U.S. drug laws, law vs. regulation, FDA and industry functions, policy-guided science, and cases shaping history into the present state of regulation.

RGA 6101. Therapeutic Product Development: A Regulatory Overview. 4 Hours.

Examines every step of the therapeutic development and regulation process within the Center for Biologic Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER), from preclinical testing through postmarketing adverse experience reporting. Offers students an opportunity to conduct a comprehensive and up-to-date analysis of the complete U.S. pharmaceutical and biological products approval processes. Considers FDA standards for nonclinical testing-quality assurance issues and good laboratory practice, investigational new drug (IND) applications, therapeutic market applications and review process initiatives designed to speed therapeutic product review, as well as current good manufacturing practice regulations to assure quality of marketed products.

RGA 6112. Biomedical Intellectual Property Management Strategy: Patents and Trade Secrets. 4 Hours.

Emphasizes the practical uses and financial benefits of sound patent, licensing, and trademark practices. One of the primary functions of the biomedical industry is to produce intellectual property (IP) in the forms of drugs, biologics, and medical devices. To protect these resources, industry leaders must make prudent IP decisions at the beginning of any product development. Through a careful examination of case studies and through multiple group projects, offers students an opportunity to become familiar with the relevant legal issues (e.g., pertinent case law and statutes), the "how-to-gets" involving IP protection, and the strategies employed to license proprietary technology.

RGA 6200. Biologics Development: A Regulatory Overview. 4 Hours.

Offers students an opportunity to conduct a comprehensive and up-to-date analysis of the post-reform FDA Center for Biologics Evaluation and Research (CBER) and the complete U.S. biological product approval process, from preclinical testing to postmarketing regulatory requirements. Includes both CBER official and industry expert perspectives on quality assurance issues and related regulatory topics in successfully bringing biologics to market, as well as current good manufacturing practice regulations to assure quality of marketed products.

RGA 6201. New Drug Development: A Regulatory Overview. 4 Hours.

Examines every step of the drug development and regulation process, from preclinical testing through postmarketing adverse experience reporting. Considers FDA standards for nonclinical testing-quality assurance issues and good laboratory practice, investigational new drug application (NDA) and review process initiatives designed to speed drug review, and the Prescription Drug User Fee Act (PDUFA).

RGA 6202. Medical Device Development: A Regulatory Overview. 4 Hours.

Analyzes U.S. medical device development and approval requirements. Features detailed analysis of quality assurance issues and recent regulatory reforms implemented under the Food and Drug Modernization Act (FDAMA), in addition to providing a step-by-step guide through the Center for Devices and Radiological Health (CDRH). Covers CDRH's reengineering initiatives and evolving investigational device exemptions, premarket approval, 510(k) application process, and product development protocol and review processes. Provides practical, in-depth analyses on how emerging developments and trends are reshaping medical device regulation in the United States. Offers students an opportunity to demonstrate an appreciation of the subjective and interpretive aspects of the regulations and an ability to think critically about the interaction between regulatory and development processes.

RGA 6203. Pharmaceutical and Medical Device Law: Topics and Cases. 5 Hours.

Analyzes current food, drug, and medical device laws. Reviews legislation and landmark cases, as well as laws governing development, manufacture, and commercial distribution of drugs, biologics, and medical device products and how they relate to the biotechnology, pharmaceutical, and medical device industries.

RGA 6204. Legal Issues in International Food, Drug, and Medical Device Regulation. 4 Hours.

Explores international laws related to the regulation of food, drugs, and medical devices with a focus on the European Union. Draws comparisons between international laws and corresponding U.S. laws, as well as considerations necessary for international biotechnology, pharmaceutical, and medical device industries.

RGA 6205. Emerging Trends and Issues in the Medical Device Industry. 4 Hours.

Focuses on trends expected to have a significant effect on the future of the medical device industry, including the aging population; the need for devices that treat chronic illnesses such as renal failure, congestive heart failure, heart abnormalities, arthritis, and diabetes; reimbursement issues arising from the huge financial burden placed on Medicare and insurance companies in picking up the increased cost of healthcare; lifestyle changes with an increased demand for devices that improve one's quality of life or appearance; reuse of single-use disposable devices to cut costs; group purchasing practices, outpatient treatment; telemedicine, regulatory/legal requirements; and the movement of devices into new areas, such as coating stents with pharmaceutical/biological agents and using patches to deliver pharmaceutical agents.

RGA 6206. Practical Aspects of Regulatory Compliance. 4 Hours.

Uses a series of practical exercises and discussions designed to offer students an opportunity to develop the ability to translate regulatory requirements for pharmaceutical, biologic, and medical device products into practical documents and broadly applicable research solutions. Topics include how to create practical documents based on regulations and guidelines; how to complete production batch records; how to conduct product testing and perform inspections; and, in general, how to effectively utilize Current Good X Practices (cGxP) requirements. Includes assignments that require students to research applicable regulatory and industry information as well as activities designed to aid in the comprehension of the regulations and in the review of real-life industry issues.

RGA 6207. Global Impact of Electronic Common Technical Document (eCTD) Submissions. 4 Hours.

Examines the structure of the Common Technical Document (CTD) format through study of both regulatory requirements as well as example submissions. Offers students an opportunity to develop an understanding of FDA's geographically specific eCTD submission requirements. Also reviews the basic structure and format of an eCTD submission and the differences between the electronic format and former paper-based CTD submissions.

RGA 6210. Strategic Planning and Project Management for Regulatory Affairs. 4 Hours.

Introduces the core concepts of strategic planning and project management. Seeks to equip regulatory professionals with the skills needed to join upper corporate management in choosing which products to pursue and how best to pursue them. Offers students an opportunity to learn how to guide medical device teams through the design and development stages. Emphasizes the role of product classifications in demonstrating the safety, efficacy, and performance of medical devices for human use. The curriculum and assignments offer a chance to carefully study the function and format of presubmission meetings with U.S. and other global regulatory agencies, as well as understand their role in gaining regulatory approval for market sale.

RGA 6211. Combination Products and Convergence. 4 Hours.

Examines the development of combination products, with an eye toward understanding FDA and international agency oversight, regulatory classifications, and interpretations of guidance documents. Medical products, no matter how well designed, can only do so much to address clinical problems today. In order to satisfy the therapeutic needs of the future, medical devices will be used in combination with drugs and biologics. This category of products covers everything from transdermal patches to drug-eluting stents. Tissue engineering, for example, employs cells (biologics) producing proteins (biotech drugs) growing on polymer substrates (medical devices). Through a detailed study of real-world case studies, offers students an opportunity to weigh the larger economic, social, political, and clinical dimensions of combination products.

RGA 6212. Introduction to Safety Sciences. 4 Hours.

Introduces safety and surveillance regulations and principles for drugs, biologics, and medical devices. Offers students an opportunity to become familiar with the U.S. and global safety regulations, as well as related guidance from FDA, ICH, WHO, and CIOMS. Adopts a life-cycle perspective, beginning with use of preclinical data to anticipate human safety issues and continuing through clinical development and postmarketing. Examines combination products, safety information in regulatory documents (INDs, clinical study reports, NDA submissions), safety data analysis, quality management and CAPAs, and global safety initiatives (e.g., the WHO Uppsala Monitoring Centre).

RGA 6215. Project Management in Early Drug Discovery and Development. 4 Hours.

Provides an overview of the processes common to researching and developing a new drug. Focuses on the early stages of this progression, from identifying active molecules to completing Phase 1 safety trials. Surveys the predominant biological and chemical techniques used in these efforts. Offers students an opportunity to prepare standard operating procedures and a pre-IND package. The lectures and reading materials focus on how to incorporate key data in writing the IND. Examines the procedures used to execute a Phase 1 safety study and the strategies available to prepare a persuasive clinical study report. Throughout the term, course material highlights the applicability and utility of project management tools.

RGA 6216. The Medical, Social, and Financial Dimensions of Orphan Drugs. 4 Hours.

Examines the orphan drug development process, from discovery to FDA regulatory approval to postapproval marketing and distribution. Using selected case studies, offers students an opportunity to gain a strong understanding of how novel biomedical discoveries are translated into products used to treat relatively rare diseases. Topics include the role of patient advocacy groups in lobbying for research and development, the influence of gender and racial considerations on policy decisions, and the capacity of the federal government to support the research and commercialization of orphan drugs. The course situates its study of orphan drugs within the context of pharmaceutical firms' reluctant shift away from big blockbuster drugs in favor of more personalized medicines.

RGA 6217. Biomedical Product Development: From Biotech to Boardroom to Market. 4 Hours.

Examines the evolution of the medical device and pharmaceutical landscape from a technological, regulatory, and financial perspective, as well as from a societal and cultural framework. Begins by recognizing that significant differences exist between small and mid-to-large medical device and pharmaceutical companies with regard to key variables in the current business environment. These differences extend to the opportunities available as well as the limitations and challenges faced by each. Discusses the symbiotic and potentially synergistic relationship that has developed between small, yet established, biotechnology companies and large medical device and pharmaceutical firms, as well as the impact of these relationships on the general economic environment.

RGA 6219. Advanced Topics in Advertising and Promotion of Drugs and Medical Devices. 4 Hours.

Covers current trends, regulations, and issues in digital advertising, including mobile applications, social media, and Twitter; FDA's and FTC's role in the regulation of OTC products and certain mobile digital applications; patient engagement; FDA regulation of advertising and promotion of veterinary drugs; recent FDA and government enforcement actions and court cases; proactive communications about medical products between manufacturers and payers, including use of real-world evidence; global perspective on regulation of advertising and promotion, including Canada, Latin America, Asia, and the European Union; decision making and risk assessments in advertising and promotion.

RGA 6220. Global Biotechnology Product Registration: E.U., U.S. Product Regulation. 5 Hours.

Provides a comprehensive and up-to-date analysis of the biotechnology product approval process within each of the world's three most critical biopharmaceutical markets. From preclinical product development to postmarketing approval, explores aspects of biopharmaceutical regulatory analyses in the three regions of the world that together represent more than 75 percent of the global market for biopharmaceuticals.

RGA 6221. European Union Compliance Process and Regulatory Affairs. 4 Hours.

Provides a clear-cut picture of the European Union (EU) and how EU directives impact international business. By illustrating how companies need to approach compliance, offers students an opportunity to be guided through compliance issues and to gain an understanding of the relationship between compliance and CE marking. Discusses the risks and rewards of CE marking and an overview of liability laws in the EU.

RGA 6222. European Medical Device Regulations. 4 Hours.

Covers European Commission directives and guidance documents; European Agency for the Evaluation of Medicinal Products, medical device guidance documents, and notified body guidelines and recommendations; Global Harmonization Task Force final reports; and mutual recognition agreements. Topics include biological and biotechnological products, CE marking, conformity assessment and notified bodies, the Global Harmonization Task Force, clinical trials, and standardization.

RGA 6223. Introduction to Canadian, Asian, and Latin American Regulatory Affairs. 4 Hours.

Covers the Common Technical Documents; General Guidance and GMPs; Global Harmonization Task Force documents; and regulatory affairs dealing with drugs, medical devices, biologics, and natural products. Examines multinational documents from Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), MERCOSUR, and Pan American and World Health Organizations. Discusses Latin American governmental regulations and guidance, as well as the guidance and regulations from FDA and General Agreement on Tariffs and Trade (GATT/WTO).

RGA 6224. Regulation of Biomedical Product Commercialization by Health Canada. 4 Hours.

Studies the regulatory requirements associated with all phases of biomedical product commercialization in the Canadian market by manufacturers. The Canadian market represents a significant opportunity for biomedical product manufacturers to export their goods into foreign geographies. Several factors have led patients in Canada to seek treatment modalities for their clinical symptoms and disease from both Canadian and non-Canadian sources. Reviews the Common Technical Document format for market approval applications, general Health Canada Guidances, good manufacturing practices (GMPs), and Global Harmonization Task Force documents. Examines multinational requirements and recommendations, including those issued by the North American Free Trade Agreement, the World Health Organization, and the U.S. Food and Drug Administration. Reviews the requirements of submissions to Health Canada by biomedical product manufacturers.

RGA 6225. Japanese Medical Device Regulations and Registration. 4 Hours.

Offers new and experienced regulatory professionals the opportunity to gain the knowledge and insight needed to successfully obtain Japanese medical device approvals. Japan is the second largest medical device market in the world, generating more than US\$18 billion in device sales per year. As Japanese regulations and guidelines become more transparent, U.S. and EU manufacturers are flocking to this lucrative market.

RGA 6226. Canadian and Australian Medical Device Regulations. 4 Hours.

Explores the Common Technical Documents, General Guidance, GMPs, and Global Harmonization Task Force (GHTF) documents for medical device requirements in Canada and Australia. Offers students an opportunity to learn how to put together a medical device submission, identify two key submission pathways per product classification, and outline the postmarket requirements in both the Canadian and Australian markets.

RGA 6227. Emerging Medical Device Markets. 4 Hours.

Covers the Common Technical Documents, General Guidance, GMPs, and Global Harmonization Task Force (GHTF) documents for medical device requirements in emerging markets. The United States, European Union, Japan, Canada, and Australia comprise the five founding member countries of the GHTF. Yet, the most vibrant and challenging regulatory arenas of medical device development are those in emerging markets (e.g., the Pacific Rim, East Asia, the Middle East, and South America). Offers students an opportunity to practice putting together a medical device submission, identify two submission pathways per product classification, and outline the postmarket requirements. These practical lessons and regulatory skills are an asset to any regulatory professional in the global marketplace.

RGA 6228. Managing International Clinical Trials. 4 Hours.

Focuses on initiating, collecting, and managing data from multicountry clinical trials. The assigned material documents the growing internationalization of clinical research in biomedicine. For example, even trials carried out under the aegis of the U.S. FDA are likely to involve investigators in the European Union, China, India, Africa, or Latin America. The global nature of this research is due to the advantages that certain countries offer, including lower costs, flexible health infrastructures, and the presence of treatment-naïve populations. Multisource studies, however, present their own practical, legal, and ethical challenges. Offers students an opportunity to study the steps needed to conduct regulatory-compliant international trials. Through case studies and group projects, examines strategies to integrate clinical sites along common protocols and deadlines.

RGA 6229. Biomedical Product Regulatory Affairs in Emerging Markets: Russia and Kazakhstan. 4 Hours.

Studies basic requirements that medical device and other types of biomedical product manufacturing companies need to commercialize products in the Russian and Kazakhstan markets. Today Russia, together with other former Soviet countries such as Kazakhstan, remain some of the world's fastest-growing export markets. In spite of recent economic difficulties, these geographic areas present many opportunities for biomedical product manufacturing companies that seek to expand into new markets. Offers students an opportunity to develop a practical understanding of the associated regulatory processes, through focus on real-world examples, the types of obstacles that companies may face, as well as how to overcome them.

RGA 6230. Clinical Laboratory Management in Clinical Trials. 4 Hours.

Provides an overview of the management elements of the clinical laboratory aspect of clinical research. Offers students an opportunity to study the configuration of visits and identify the differences between safety-related testing, esoteric testing, and end-point testing. Identifies the challenges of qualifying a clinical laboratory and managing a clinical laboratory during the conduct of a clinical trial: protocol kits, logistics, local laboratory data, reference ranges, inspections, and regulatory requirements. Covers global aspects, such as data and method harmonization, blinding of data, transmission of data, and data amendments.

RGA 6233. Application of Quality System Regulation in Medical Device Design and Manufacturing. 4 Hours.

Introduces the Food and Drug Administration's (FDA) Quality System Regulations (QSRs) and describes how these regulations can improve the safety and efficacy of medical device products. Discusses the legislative origins of QSRs, their historical evolution, as well as the details of how they are implemented. Examines case studies and empirical examples of QSRs that have been employed by individual medical device manufacturers during the product commercialization process. Offers students an opportunity to develop an understanding of FDA's expectations for product design control; the structuring of quality system documentation; and principles of practical QSRs within the context of medical device manufacturing, packaging, and distribution. Encourages students to develop strategies for customizing QSRs to particular companies, device products, and manufacturing environments.

RGA 6234. Drug and Device Supplier Risk Management: Compliance and Processes. 4 Hours.

Seeks to provide a comprehensive overview of current supply chain risk-management practices and their impact on patient safety, product quality, and clinical effectiveness. Analyzes supplier oversight guidance documents, demonstrates how life-science companies strive to ensure compliance, and discusses the responsibilities of regulatory professionals in supply chain risk-management systems and regulatory issues stemming from poor supplier performance and management. Using case-based investigations and real-world examples, examines how to evaluate supply chain management systems as they relate to particular categories of biomedical products manufactured in specific contexts. Offers students an opportunity to obtain the skills and knowledge they need to customize effective supply chain risk-management methods within various global settings.

RGA 6235. Emerging Product Categories in the Regulation of Drugs and Biologics. 4 Hours.

Examines the development and commercialization pathways for several product categories, including new over-the-counter (OTC) products, nutraceuticals, nanotechnology products, and personalized medicine-based therapies. These emerging categories of drug and biologic products are not formally classified by FDA from a regulatory perspective. Evaluates the reasons why the regulatory paradigms for these products are not well established and analyzes how the relatively amorphous nature of these paradigms has impacted commercialization of these product categories in the U.S. market. Offers students an opportunity to gain a better understanding of how and why new product categories continue to emerge as existing regulatory classifications continue to evolve.

RGA 6241. Working in Multicultural Environments: Challenges and Opportunities. 2 Hours.

Offers a general overview of and guidelines for working in multicultural teams with particular reference to the pharmaceutical industry. There is an increasing need for pharmaceutical companies to not only seek international marketing rights but to conduct international clinical trials. This quest does not come without obstacles. Examines the challenges and opportunities of various cultural models. Defines culture, studies working behaviors, and sheds light on cross-cultural misunderstandings, relationship building, and verbal and nonverbal communications in various cultures.

RGA 6242. Preparing EU Medical Device Clinical Evaluations. 2 Hours.

Examines the process of writing European Union medical device clinical evaluations. Clinical evaluations are complex regulatory documents that are needed for every class of medical devices in Europe. These evaluations have a strong component of research and technical writing. This course offers students hands-on experience with the stages involved in performing a clinical evaluation (scoping, identification, appraisal, analysis of clinical data, and report creation). The term assignment is a completed clinical evaluation.

RGA 6243. Medical Device Product Development in Canada. 4 Hours.

Explores the general requirements for medical device regulation globally and the details of medical device regulation in Canada. Familiarizes students with the International Medical Device Regulatory Forum goals and objectives, and explores the medical device regulatory model developed by Global Harmonization Task Force that is in use in many countries today. Studies the Canadian medical device regulations, covering topics such as postmarket topics of adverse event reporting, recalls and inspections, classification, device licensing, establishment registration, design change, license amendments, and annual renewal processes. Explores the use of standards globally and in Canada related to the regulation of medical devices. Offers students a project-based learning opportunity to learn how to prepare portions of a sample submission for Canada.

RGA 6244. Therapeutic Product Development in Canada. 4 Hours.

Examines every step of the Canadian drug development and regulation process, from preclinical testing through postmarketing drug adverse reaction (DAR) reporting. Considers Canadian standards for nonclinical testing-quality assurance issues and good laboratory practice, good clinical practices, GMP, and use of ICH guidelines. Examines various Canadian drug submissions and their timelines, including New Drug Submission (NDS), Abbreviated New Drug Submission (ANDS), and Clinical Trial Applications (CTA).

RGA 6245. Regulation of Generic Pharmaceutical and Biosimilar Products. 4 Hours.

Describes the contrasting history and implementation of generic drug and biologic legislation in the U.S. market. Explores the specific technical differences between drug and biologic products and highlights areas where regulatory approval of generic products must differ between the two categories. Offers students an opportunity to better understand how the nonclinical and clinical development programs of generic drug and biologic products are constructed. Examines the relatively advanced state of the regulatory paradigm for biosimilars in the European Union.

RGA 6247. Medicines Regulatory Harmonization in Africa. 2 Hours.

Examines the regulatory landscape on the continent of Africa and focuses on the progress made in Medicines Regulatory Harmonization efforts. Africa's emerging economic powerhouse on the world market has been brought to the limelight. The value of Africa's pharmaceutical industry is estimated to increase from \$20.8 billion (2013) to between \$40.0 and \$65.0 billion (2020). In essence, Africa has become the "new global pharmaceutical giant," making the continent an attractive emerging market for pharmaceutical companies seeking to expand their market base.

RGA 6248. Global Regulatory Operations. 2 Hours.

Explores the fundamentals of various operational aspects of regulatory professional responsibilities. Regulatory operations is a vital function within biomedical product manufacturing organizations. Global regulatory operations professionals have responsibility for a diverse set of FDA and other global regulatory agency requirements, ranging from premarket submissions to maintenance of postmarketing compliance standards. Includes, but not limited to, the electronic Common Technical Document (eCTD) submission format, structures of Clinical Trial Applications (CTAs) from various geographical regions, EU Marketing Authorization Applications (MAAs), as well as documentation management and publishing compliance standards. Project work includes development of a regulatory document based on current guidelines for submission of FDA- and/or EMA-compliant marketing approval or postmarket surveillance standards.

RGA 6249. Chinese Food and Drug Administration Regulation of Biomedical Product Commercialization. 4 Hours.

Studies the biomedical product commercialization regulations and compliance standards implemented by the Chinese Food and Drug Administration (CFDA). As many of these regulations and compliance standards have been developed or updated within the past two to three years, case studies illustrate how the CFDA enforces these regulations. Additionally, examines how the regulatory documentation submission processes set up by the CFDA are operationalized. Reviews the impact of the eCTD standard utilized by ICH and other non-ICH geographies on CFDA submissions.

RGA 6250. Financing and Reimbursement in Biomedical Product Development. 4 Hours.

Introduces the complex discipline of market access and pricing strategy for medical device, drug, and biologic products. As cost and relative efficacy drivers become increasingly important to market biomedical products successfully, life-sciences regulatory professionals must evaluate regulatory compliance criteria in relation to reimbursement and product pricing concerns. Regulatory professionals must also be involved in demonstrating that utilization of new biomedical products is comparatively cost-effective when measured against standards of clinical care. Using specific case studies from the United States and abroad, offers students an opportunity to analyze these market developments, as well as their resulting implications for biomedical product development, manufacturing, and commercialization, with an overall objective to develop comparatively and financially informed regulatory systems.

RGA 6255. Global Convergence of Regulatory Science and Reimbursement/Market Access. 2 Hours.

Studies the evolution of convergence drivers between global regulatory science and reimbursement/market access paradigms. Outlines the similarities and differences between "safety and efficacy" and "reasonable and necessary" and explores how cost-effectiveness variables can be evaluated concomitantly during the biomedical product marketing approval process. Students explore both the opportunities, as well as the mechanistic challenges, associated with the ongoing global requirement for biomedical product manufacturers to obtain marketing approvals from specific geographic regulators, along with associated payer organizations, to obtain full market access for new healthcare products.

RGA 6280. Advanced Writing on International Biomedical Topics. 4 Hours.

Seeks to hone the research and composition skills of regulatory affairs professionals. Offers students an opportunity to develop a highly efficient ability to craft accurate and detailed summaries, analytic essays, and research papers. Each term the course focuses on a particular country or region of the world. Specific topics include healthcare epidemiology; healthcare delivery and financial systems; progress in biomedical research; government involvement in the healthcare industry; regulatory systems governing drugs, biologics, and medical devices; and the conduct of clinical trials. Concludes by asking students to provide recommendations on how to improve biomedical research and markets in the focused country or regions.

RGA 6300. Practical Applications in Biomedical Product Global Regulatory Affairs. 4 Hours.

Uses a series of practical exercises and discussions designed to offer students an opportunity to exercise their ability to translate global regulatory requirements for pharmaceutical, biologic, and medical device product commercialization into submission-ready documents and broadly applicable regulatory science solutions. Topics include creating practical documents based on regulations and guidelines, completing production batch records, conducting product testing, performing inspections, and effective utilization of GxP requirements. Incorporates both group and/or individual assignments that require students to research applicable regulatory and industry information, as well as activities designed to aid in the comprehension of global regulatory issues. Uses case-based methodologies to enable real-world application of topics and regulatory issues discussed during the course.

RGA 6310. Regulatory Documentation Processes. 4 Hours.

Examines the nexus of professions, practices, and institutions that constitute the field of biomedicine. Explores the historical roots and cultural foundations of biomedicine. Maps the industrial terrain and identifies opportunities and issues for professional communicators. Students research and report on current changes in the biomedical industry, focusing on identifying new opportunities for writers in biomedicine. Offers students an opportunity to acquire research and writing skills and to develop the ability to think in terms of complex institutions so as to locate and articulate opportunities for professional communication.

RGA 6370. Advanced Regulatory Writing: Medical Device Submissions. 4 Hours.

Examines the process of writing medical device submissions for regulatory agencies both nationally and internationally. Topics include device regulations, the device development process, and clinical study documents. Offers students an opportunity to practice communicating complex scientific information in various documents, including investigators' brochures, clinical trial reports, and investigational device exemption (IDE) 510(k) submission components.

RGA 6380. Advanced Regulatory Writing: New Drug Applications. 4 Hours.

Examines the process of writing drug submissions for regulatory agencies both nationally and internationally. Topics include drug regulations, the drug development process, and clinical study documents. Offers students an opportunity to practice communicating complex scientific information in various documents, including investigators' brochures, clinical trial reports, and Investigational New Drug (IND) application submission components.

RGA 6385. Operational Aspects of Electronic Common Technical Document (eCTD) Submissions. 4 Hours.

Studies the processes and specific software programs utilized to compile FDA-compliant Electronic Common Technical Document (eCTD) submissions. Reviews the IT security issues that manufacturers must comply with when submitting INDs and marketing applications for new products in the eCTD format. Through detailed study of the operational aspects of the FDA eCTD submission process, offers students an opportunity to master the submission of similar regulatory documentation to regulatory agencies in several other key global markets.

RGA 6410. Fundamentals of CMC Regulations and Methods. 4 Hours.

Discusses components of the Common Technical Document Module 3 and describes how regulatory affairs professionals support compliance with CMC regulation. Offers students an opportunity to design and evaluate core elements of an effective CMC compliance strategy, ensuring alignment with ICH guidelines, FDA Guidances, pharmacopeia, and 21 CFR. Chemistry, manufacturing, and controls (CMC) regulatory affairs professionals must use technical, analytical expertise and problem-solving abilities to ensure only quality product is distributed to patients.

RGA 6420. Global IVD Regulations and Submissions. 4 Hours.

Examines in-depth regulations governing in vitro diagnostic medical devices. Covers the IVD regulations for the four major economic markets—United States, European Union, Australia, and Canada—as well as other markets that have specific IVD regulations—these countries could include China, Brazil, Mexico, etc. Topics include IVD classification schemes, regulatory strategy, regulatory submission routes (including harmonization), regulatory review processes, performance evaluation, clinical trial requirements, labeling, and postmarketing. Also explores IVD testing methodologies. Covers emerging trends in IVDs, such as the advent of companion diagnostics and their relationship to personalized medicine.

RGA 6423. Medical Device Product Development in Canada. 4 Hours.

Explores the general requirements for medical device regulation globally and the details of medical device regulation in Canada. Familiarizes students with the International Medical Device Regulators Forum goals and objectives and explores the medical device regulatory model developed by the Global Harmonization Task Force that is in use in many countries today. Studies Canadian medical device regulations, covering topics such as postmarket topics of adverse event reporting, recalls and inspections, classification, device licensing, establishment registration, design change, license amendments, and annual renewal processes. Offers students an opportunity to participate in a project to learn how to prepare portions of a sample submission for Canada.

RGA 6430. Clinical Trial Quality Oversight. 2 Hours.

Examines systemic reviews of audits in regions and trends in reported issues across regions, including evaluating previous experiences with investigators as well as other approaches. In the ever changing world of conducting clinical research, there is a need for quality oversight of activities. Offers students an opportunity to learn how all of this information collates and reports out to be used in the full quality oversight of a research study.

RGA 6431. Clinical Trial Agreements and Other Key Contracts in the Life Sciences. 4 Hours.

Describes the legal principles involved with clinical trial agreements and contracts in the life sciences of all types. Clinical trial agreements address high-risk legal areas like subject injury, indemnification, confidentiality, ownership of data, patent rights, and publication rights. Other important contracts used in the life sciences industry include manufacturing and supply agreements, sponsored research agreements, services agreements, consulting agreements, and licensing agreements. Clinical trials typically involve a complex matrix of roles and responsibilities defined by the different contracts entered into by the sponsor, investigator, contract research organization, and clinical trial site. Explores the meaning of different clauses and reviews the key issues faced in negotiating these contracts. Discusses some of the pitfalls to look out for when structuring agreements with healthcare professionals and academic institutions.

RGA 6432. Real-World Evidence in Biomedical Research. 2 Hours.

Provides an overview of real-world evidence (RWE), discusses challenges in implementing an effective RWE strategy, and reviews the implications of RWE on regulatory decision making. Topics include observational studies/pragmatic clinical trials, comparative effectiveness research, registries, patient reported outcomes, primary vs. secondary data collection, medical claims and electronic health record data, social media, wearable devices, and artificial intelligence.

RGA 6460. Intellectual Property in the Life Sciences. 2 Hours.

Reviews each of the main types of intellectual property (patents, trademarks, copyrights, and trade secrets) and explains the role they have in protecting the intellectual assets of life science companies. Intellectual property is at the heart of all products in the life sciences and plays a central role in the business strategy used by companies developing their pipeline of products. Also explains how regulatory affairs professionals can assist with the creation and protection of intellectual property and ways for them to work collaboratively with intellectual property counsel to ensure that the intellectual property delivers maximum value.

RGA 6461. Cybersecurity and Regulation of Digital Health Technologies by the FDA. 2 Hours.

Explores the increasing reliance on electronically based media to warehouse patient clinical data, as well as the need to protect it and maintain individual privacy with respect to patient healthcare data. Includes detailing the specifics of what types of patient clinical data new cybersecurity compliance regulations are designed to address, as well as a study of how these regulations impact the development of new biomedical products. Offers students an opportunity to study how these issues are addressed in other geographies, including the European Union, Canada, and the Asia-Pacific nations.

RGA 6462. Regulatory Compliance in the Pharmaceutical Industry: A Collaborative Approach. 4 Hours.

Offers students a historical overview of the compliance function in the pharmaceutical industry, covers the basic components of an effective compliance program, and describes the consequences associated with a weak compliance culture. In addition, advocates for compliance to become a collaborative partnership to different stakeholders in the business and help achieve important goals at the individual, department, and company levels. The rapid evolution of regulatory changes at the U.S. Food and Drug Administration (FDA) and foreign counterpart agencies like the European Medicines Agency (EMA) have increased the importance of regulatory compliance management for pharmaceutical companies. Companies must continuously adapt their compliance practices to conform to the changing regulatory landscape.

RGA 6463. Regulatory Strategy for Product Development and Life-Cycle Management. 4 Hours.

Examines the preparation of regulatory strategies to support product development and life-cycle management while providing students the opportunity to examine domestic and international processes relevant to regulatory strategy. In developing target product profiles, strategic regulatory plans, and life-cycle management plans, students appraise key components of regulatory strategies, evaluate core elements of product life cycle in the generation of those strategies, and integrate business needs into regulatory planning. Upon completion of the course, successful students should possess the fundamentals to formulate regulatory strategies supporting product development and life-cycle management and be equipped with a stronger understanding of the high-visibility role regulatory professionals serve in developing sound regulatory strategy.

RGA 6470. Research Ethics. 2 Hours.

Covers many of the ethical and regulatory issues that must be considered when conducting a clinical trial. Reviews the history and tragedies of conducting human experimentation and how such events shaped the regulatory framework we have today. Students analyze and discuss current and specific ethical research topics such as trials concerning pediatrics, women, elderly and the terminally ill, prisoners, embryos and fetuses, stem cell research, and genetic testing.

RGA 6920. Internship Reflection. 1 Hour.

Offers an independent study designed to allow students to reflect on both the theoretical knowledge that they have learned while pursuing their degree at Northeastern University and the practical experience that they have gained in an internship. Students should aim to create a unique, original, and ultimately applicable project that demonstrates an in-depth understanding of current markets, future trends, and global shifts in regulatory affairs.

RGA 6962. Elective. 1-4 Hours.

Offers elective credit for courses taken at other academic institutions. May be repeated without limit.

RGA 7962. Elective. 1-4 Hours.

Offers elective credit for courses taken at other academic institutions.

RGA 7978. Independent Study. 1-4 Hours.

Offers independent work under the direction of members of the department on a chosen topic.

RGA 7983. Topics. 1-4 Hours.

Covers special topics in regulatory affairs. May be repeated without limit.