Regulatory Affairs - CPS (RGA)

Courses

RGA 5000. Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation. (1.5 Hours)
Offers an overview of biopharmaceutical product formulation, development, and commercialization regulation by the U.S. Food and Drug Administration (FDA) and other regulatory agencies. Through course work and didactic technical instruction, offers students an opportunity to develop the foundations necessary to build a strong scientific and technical understanding of biopharmaceutical design and commercialization compliance. Topics include the dynamic progression of U.S. biopharmaceutical laws, differentiation between law vs. regulation, FDA and industry compliance functions, policy-guided science, and cases that shape the evolution of regulatory compliance.

RGA 5001. Introduction to Food and Drug Administration (FDA) Medical Device Regulation. (1.5 Hours)
Offers an overview of the medical device engineering, development, and commercialization process and its regulation by the U.S. Food and Drug Administration (FDA). Through course work and didactic technical instruction, 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. Introduces the subject of quality system regulation (QSR) as it relates to device product design, clinical development, operations management, and compliance.

RGA 5002. Introduction to Regulatory Compliance and Practice. (1.5 Hours)
Presents a detailed overview of critical scientific, technical, engineering design, manufacturing, and operational drivers for regulatory compliance. Offers students an opportunity to gain competencies in the areas of regulatory agency, advocacy, ethics, mitigation laws, and corporate compliance responsibility. A study of the various state, federal, and international agencies, their authorities, and how they became established is designed to enable students to understand the scientific and technical scope of the global regulatory compliance landscape.

RGA 5101. Therapeutic Product Development: A Regulatory Overview. (3 Hours)
Examines every step of the biotherapeutic development and regulation process within the U.S. FDA's Center for Biologic Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). Enrolled students receive didactic instruction from product formulation, product development, and preclinical testing perspectives through postmarketing adverse experience reporting. Offers students an opportunity to study FDA standards for nonclinical testing-quality assurance issues and good laboratory practice, investigational new drug (IND) applications, therapeutic market applications and review processes designed to speed therapeutic product review, as well as current good manufacturing practice and operations management regulations.

Prerequisite(s): RGA 5000 with a minimum grade of C-

RGA 5202. Medical Device Development: A Regulatory Overview. (3 Hours)
Analyzes U.S. medical device engineering development, marketing approval, and commercialization compliance requirements from scientific, technical, and engineering-based perspectives. Features analysis of quality assurance issues and recent regulatory reforms implemented under the Food and Drug Modernization Act (FDAMA). Provides 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. Offers practical, in-depth analyses and didactic instruction on how emerging technical trends and the application of statistical modeling to analyze product complaints are reshaping medical device regulation in the United States. Offers students an opportunity to learn how to think critically about the interaction between regulatory and development processes.

RGA 5203. Pharmaceutical and Medical Device Law: Topics and Cases. (3.75 Hours)
Analyzes current food, drug, and medical device laws. Reviews legislation and landmark cases, as well as laws governing formulation development, engineering design, manufacture, and commercial distribution of drugs, biologics, and medical device products. Studies how these variables relate to operations management in the biotechnology, pharmaceutical, and medical device industries.

RGA 5204. Legal Issues in International Food, Drug, and Medical Device Regulation. (3.75 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 5212. Introduction to Safety Sciences. (3 Hours)
Introduces safety and surveillance regulations and principles for products developed and commercialized in regulated industries. Covers global safety regulations as well as related guidance from agencies such as the FDA, International Conference on Harmonization (ICH), the World Health Organization (WHO), and the European Commission (EC). Adopts a life-cycle perspective, beginning with use of precommercialization data to anticipate human safety issues, and continuing through prototype development and postmarketing issues. Offers students an opportunity to review combination products; safety information in regulatory documents (for example, INDs, clinical study reports, NDA submissions); safety data analysis; quality management and CAPAs; safety plans; and global safety initiatives (e.g., the General Data Protection Regulation).

RGA 5463. Regulatory Strategy for Product Development and Life-Cycle Management. (3 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 6000. Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation. (2 Hours)
Offers an overview of biopharmaceutical product formulation, development, and commercialization regulation by the U.S. Food and Drug Administration (FDA) and other regulatory agencies. Through course work and didactic technical instruction, offers students an opportunity to develop the foundations necessary to build a strong scientific and technical understanding of biopharmaceutical design and commercialization compliance. Topics include the dynamic progression of U.S. biopharmaceutical laws, differentiation between law vs. regulation, FDA and industry compliance functions, policy-guided science, and cases that shape the evolution of regulatory compliance.

RGA 6001. Introduction to Food and Drug Administration (FDA) Medical Device Regulation. (2 Hours)
Offers an overview of the medical device engineering, development, and commercialization process and its regulation by the U.S. Food and Drug Administration (FDA). Through course work and didactic technical instruction, 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. Introduces the subject of quality system regulation (QSR) as it relates to device product design, clinical development, operations management, and compliance.

RGA 6002. Introduction to Regulatory Compliance and Practice. (2 Hours)
Presents a detailed overview of critical scientific, technical, engineering design, manufacturing, and operational drivers for regulatory compliance. Offers students an opportunity to gain competencies in the areas of regulatory agency, advocacy, ethics, mitigation laws, and corporate compliance responsibility. A study of the various state, federal, and international agencies, their authorities, and how they became established is designed to enable students to understand the scientific and technical scope of the global regulatory compliance landscape.

RGA 6101. Therapeutic Product Development: A Regulatory Overview. (4 Hours)
Examines every step of the biotherapeutic development and regulation process within the U.S. FDA's Center for Biologic Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). Enrolled students receive didactic instruction from product formulation, product development, and preclinical testing perspectives through postmarketing adverse experience reporting. Offers students an opportunity to study FDA standards for nonclinical testing-quality assurance issues and good laboratory practice, investigational new drug (IND) applications, therapeutic market applications and review processes designed to speed therapeutic product review, as well as current good manufacturing practice and operations management regulations.

Prerequisite(s): RGA 6000 with a minimum grade of C- ; BTC 6210 with a minimum grade of C-

RGA 6202. Medical Device Development: A Regulatory Overview. (4 Hours)
Analyzes U.S. medical device engineering development, marketing approval, and commercialization compliance requirements from scientific, technical, and engineering-based perspectives. Features analysis of quality assurance issues and recent regulatory reforms implemented under the Food and Drug Modernization Act (FDAMA). Provides 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. Offers practical, in-depth analyses and didactic instruction on how emerging technical trends and the application of statistical modeling to analyze product complaints are reshaping medical device regulation in the United States. Offers students an opportunity to learn how to think critically about the interaction between regulatory and development processes.

Prerequisite(s): BTC 6210 (may be taken concurrently) with a minimum grade of C- ; RGA 6001 (may be taken concurrently) with a minimum grade of C-

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 formulation development, engineering design, manufacture, and commercial distribution of drugs, biologics, and medical device products. Studies how these variables relate to operations management in the biotechnology, pharmaceutical, and medical device industries.

Prerequisite(s): RGA 6101 (may be taken concurrently) with a minimum grade of C- or RGA 6202 (may be taken concurrently) with a minimum grade of C-

RGA 6204. Legal Issues in International Food, Drug, and Medical Device Regulation. (5 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.

Prerequisite(s): RGA 6101 (may be taken concurrently) with a minimum grade of C- or RGA 6202 (may be taken concurrently) with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C-

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. Students review and receive didactic instruction in the basic structure and technical format of an eCTD submission, the use of statistical models to present data, and the differences between the electronic format and former paper-based CTD submissions.

Prerequisite(s): RGA 6101 with a minimum grade of C- ; BTC 6210 with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C- or RGA 6101 with a minimum grade of C-

RGA 6212. Introduction to Safety Sciences. (4 Hours)
Introduces safety and surveillance regulations and principles for products developed and commercialized in regulated industries. Covers global safety regulations as well as related guidance from agencies such as the FDA, International Conference on Harmonization (ICH), the World Health Organization (WHO), and the European Commission (EC). Adopts a life-cycle perspective, beginning with use of precommercialization data to anticipate human safety issues, and continuing through prototype development and postmarketing issues. Offers students an opportunity to review combination products; safety information in regulatory documents (for example, INDs, clinical study reports, NDA submissions); safety data analysis; quality management and CAPAs; safety plans; and global safety initiatives (e.g., the General Data Protection Regulation).

Prerequisite(s): RGA 6002 with a minimum grade of C- ; RGA 6463 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6203 with a minimum grade of C- or RGA 6204 with a minimum grade of C-

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.

Prerequisite(s): RGA 6203 with a minimum grade of C- or RGA 6204 with a minimum grade of C-

RGA 6223. Introduction to Australian, Asian, and Latin American Regulatory Affairs. (4 Hours)
Covers the applicable regulatory agency guidance and GMPs associated with biopharmaceutical and medical device product design, quality assurance, and commercialization specifically in Australia, Asia, and Latin America. 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 government regulations and guidance, as well as the guidance and regulations from the General Agreement on Tariffs and Trade (GATT/WTO).

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C- or RGA 6101 with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): BTC 6210 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

RGA 6234. Risk Management: Compliance and Processes. (4 Hours)
Seeks to provide a comprehensive overview of current risk-management practices, including supply chain management, as well as their impact on safety, product quality, and effectiveness. Analyzes regulatory oversight guidance documents, demonstrates how organizations in regulated sectors strive to ensure compliance, and discusses the responsibilities of regulatory professionals in supply chain risk-management systems. Studies the regulatory issues that originate from poor supplier performance and management. Using case-based investigations and real-world examples, analyzes how to evaluate risk-management systems as they relate to particular categories of regulated products manufactured in specific contexts. Offers students an opportunity to obtain the skills and knowledge they need to customize effective risk-management methods within various global settings.

Prerequisite(s): RGA 6000 with a minimum grade of C- or RGA 6001 with a minimum grade of C-

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, neutraceuticals, 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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6001 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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).

Prerequisite(s): RGA 6002 with a minimum grade of C-

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.

Prerequisite(s): RGA 6200 with a minimum grade of C- or RGA 6101 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

RGA 6275. Product Development and Process Validation. (2 Hours)
Studies the compliance standards associated with commercializing new biopharmaceutical and medical device products. Focuses on U.S. regulations, although discusses compliance with standards in other major geographical areas as well, including those in Canada and the European Union. Offers practical instruction in the product design control process, setup of small-batch manufacturing processes, scale-up to large-scale manufacturing processes, as well as the regulatory requirements for manufacturing process validation. Includes a detailed analysis of process flow, incoming raw material and work-in-progress testing, stability testing, sterility testing, and handling requirements. Other topics include creation of design history files, establishment of master validation plans, and compliance with ongoing facility and manufacturing equipment standards.

Prerequisite(s): RGA 6002 with a minimum grade of C- ; (RGA 6000 with a minimum grade of C- or RGA 6001 with a minimum grade of C-)

RGA 6300. Practical Applications in Global Regulatory Affairs. (4 Hours)
Offers students an opportunity to exercise their ability to translate global regulatory requirements for globally regulated product commercialization into submission-ready documents and broadly applicable regulatory science solutions. Uses didactic instruction and a series of practical exercises and discussions. Topics include creating practical documents based on regulations and guidelines, formulation development, 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 scientific and technical application of topics and regulatory issues discussed during the course.

Prerequisite(s): RGA 6203 with a minimum grade of C- or RGA 6204 with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C-

RGA 6405. Nonclinical Regulations in Biomedical Product Commercialization. (4 Hours)
Examines the nonclinical regulatory processes involved in commercializing biomedical products within FDA's CBER, CDER, and CDRH. Offers students an opportunity to conduct a comprehensive analysis of FDA's quality standards for biomedical products, including gene and cellular-based therapies, with respect to ICH Common Technical Document (CTD) Module 4. Provides an overview of preclinical investigational new drug (IND) requirements and good manufacturing practice (GMP) regulations that must be fulfilled by biomedical product manufacturers in support of CTD Module 3. Additionally, offers students an opportunity to study biocompatibility testing requirements for medical devices according to FDA guidance and ISO 10993 standards to support 510(k) and PMA submissions.

Prerequisite(s): RGA 6002 with a minimum grade of C- ; RGA 6463 with a minimum grade of C-

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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.

Prerequisite(s): RGA 6202 with a minimum grade of C

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.

Prerequisite(s): RGA 6101 with a minimum grade of C or RGA 6202 with a minimum grade of C

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.

Prerequisite(s): BTC 6210 with a minimum grade of C ; (RGA 6101 with a minimum grade of C or RGA 6000 with a minimum grade of C)

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.

Prerequisite(s): BTC 6210 with a minimum grade of C ; (RGA 6101 with a minimum grade of C or RGA 6000 with a minimum grade of C)

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.

Prerequisite(s): RGA 6101 with a minimum grade of C- or RGA 6202 with a minimum grade of C-

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 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 7983. Topics. (1-4 Hours)
Covers special topics in regulatory affairs. May be repeated without limit.