

REGENERATIVE MEDICINE ENTREPRENEURSHIP (RGME)

RGME 467. Commercialization and Intellectual Property Management. 3 Units.

This interdisciplinary course covers a variety of topics, including principles of intellectual property and intellectual property management, business strategies and modeling relevant to the creation of start-up companies and exploitation of IP rights as they relate to biomedical-related inventions. The goal of this course is to address issues relating to the commercialization of biomedical-related inventions by exposing law students, MBA students, and Ph.D. candidates (in genetics and proteomics) to the challenges and opportunities encountered when attempting to develop biomedical intellectual property from the point of early discovery to the clinic and market. Specifically, this course seeks to provide students with the ability to value a given technological advance or invention holistically, focusing on issues that extend beyond scientific efficacy and include patient and practitioner value propositions, legal and intellectual property protection, business modeling, potential market impacts, market competition, and ethical, social, and healthcare practitioner acceptance. During this course, law students, MBA students, and Ph.D. candidates in genomics and proteomics will work in teams of five (two law students, two MBA students and one Ph.D. candidate), focusing on issues of commercialization and IP management of biomedical-related inventions. The instructors will be drawn from the law school, business school, and technology-transfer office. Please visit the following website for more information: fusioninnovate.com. Offered as EBME 467, ECSE 467, GENE 367, GENE 467, LAWS 5341, MGMT 467, and RGME 467.

RGME 525. Current Topics in Regenerative Medicine. 2 Units.

Current Topics in Regenerative Medicine, will be an elective course in the newly approved Master's Program in Regenerative Medicine and Entrepreneurship. The objective of this course is for each student to develop a general understanding of concepts and current topics related to Regenerative Medicine, Stem Cell research, entrepreneurship and product development. -To expose students to principles in Cell Biology and Tissue Engineering relevant to the field -To review the current landscape and spectrum of topics which makes up the field of regenerative medicine -To explore current and emerging technologies supporting regenerative medicine research -To discuss federal regulatory and compliance issues related to clinical research and the development of therapeutics -To explore cellular manufacturing approaches for regenerative medicine products -Discuss ethical and societal issues related to regenerative medicine research and technologies

RGME 529. FDA Regulation in Entrepreneurship and Clinical Research. 1 - 3 Units.

The FDA Regulation in Entrepreneurship and Clinical Research course is designed to provide foundational knowledge in the FDA approval and regulatory process while highlighting scientific, clinical, ethical, and other related emergent factors for consideration. The course includes a series of lecture-based classes delivered by content experts and interdisciplinary team-based learning discussions of case studies designed for the application of lecture content. Students who elect to take the course for three credits as opposed to one credit will go through the process of reviewing an example Investigational New Drug (IND) or Investigational Drug Exemption (IDE) Application (midterm project) and preparing an IND or IDE for submission (final project) with the guidance of nationally renowned experts in FDA regulation and law. The primary goal of this course is that upon completion, students will be able to take the knowledge gained from content experts and apply it to facilitate the movement of their current or future technologies through the FDA approval process. Offered as CRSP 529 and MGRD 529 and PHRM 529 and RGME 529.

RGME 535. Foundations in Regenerative Medicine. 3 Units.

Foundations in Regenerative Medicine is a team-taught course using multiple faculty content experts. The objective of this course is for each student to develop a general understanding of the foundations and concepts related to Regenerative Medicine and Stem Cell research. -To expose students to foundational principles in Cell Biology and Tissue Engineering relevant to the field -To review the current landscape and spectrum of topics which makes up the field of regenerative medicine -To explore current and emerging technologies supporting regenerative medicine research -To discuss federal regulatory and compliance issues related to clinical research and the development of therapeutics -To explore cellular manufacturing approaches for regenerative medicine products -Discuss ethical and societal issues related to regenerative medicine research and technologies

RGME 545. Stem Product Biology, Bench to Bedside Development and Therapeutic Translation. 3 Units.

This course is a team - taught course using multiple faculty content experts. The objective of this course is for each student to understand the concept of stem cell biology from procurement to therapeutic development. This course will provide an overview of the regulatory framework, concepts, lab operations, and biologic techniques to support cell and regenerative medicine product manufacturing. To work in this emerging field, students must understand the scientific and regulatory development of biologic therapies as well as operational issues related to manufacturing in the cleanroom space under quality systems. The goals are to: 1) Develop an understanding of the infrastructure and compliance required to manufacture biologics for clinical use of stem cells. 2) Identify and critically analyze key operational issues related to clinical development and use of biologics from expansion to pre-clinical validation and therapeutic use. 3) Perform hands on activities using current techniques. 4) Discuss ethical and societal issues related to regenerative medicine research and technologies.

RGME 547. Gene Therapy and Concepts in Regenerative Medicine. 3 Units.

This course focuses on the principles of gene therapy for disease treatment or drug delivery. Technical aspects associated with the development of the therapeutic approach will be covered along with the concepts related to the legal, ethical, economic, religious, and philosophical consequences of implementing gene-editing technologies for common and rare (often childhood) diseases. The "agora" will define ethical considerations of risk/benefit, informed consent, priority therapy targets, optimal technologies and delivery, costs, FDA regulation, and desired outcomes across disciplines. This course will be available to all students at CWRU, with consent of instructor. Students must have a foundational understanding in cell biology, exposure to regenerative medicine and genetics. Recommended Preparation: RGME 535 or RGME 525.

RGME 549. Advanced Regenerative Medicine: Innovation and Applications. 3 Units.

This course is a literature based class. The review of regenerative medicine literature with presentations by students so that they learn how to interpret literature critically.

RGME 550. Basic Laboratory Exposure and Techniques. 3 Units.

This course is a laboratory exposure class which allows students to explore different regenerative medicine labs for the course of a semester, to learn how to be in a lab and the important dynamics of successful, productive involvement. Students will have the opportunity to get exposure and learn basic techniques in the laboratory to aid in facilitating transition to their research proposal or commercial internship. The course will include issues related to professionalism in the laboratory, maintenance of good notes and books and laboratory, administrative dynamics. Regardless of the activities, the work must culminate in a final paper that will outline the experiences and the professional networks established. Course Learning Objectives: 1. Students are expected to learning basic laboratory skills for reproducibility and attention to details. These will include but are limited to pipetting techniques, management of basic equipment for weighing, pH and making reagents. Sterile technique will also be incorporated. 2. Refine a detailed attention to good laboratory notebooks, computer skills and basic data analysis. 3. Provide the foundation for professionalism, in the laboratory and in potential employee interactions. For students pursuing an independent study while continuing their work experience as a part-time student, the focus of the independent study project may not be the result of a project in the same laboratory or on a project being undertaken within their specific department. Prereq: Enrolled in the Regenerative Medicine & Entrepreneurship Masters Program.

RGME 560. Regenerative Medicine Independent Study, Research Project. 1 - 3 Units.

The RGME 560 Independent Study-Research Project allows students to explore a topic of interest under the close supervision of a RGME program director and mentor. The course may include directed readings, applied work, assisting a faculty member with a research project, carrying out an independent research project, or other activities deemed appropriate. Regardless of the activities, the work must culminate in a formal paper. The specific course requirements are described in the Independent Studies Proposal form to be completed by the student, project mentor and program director prior to enrollment in the course. Prereq: RGME 535 and RGME 545.

RGME 565. Regenerative Medicine Independent Study, Internship. 1 - 3 Units.

The RGME 565 Independent Study-Industry Internship provides students with the opportunity to gain practical experience within an industry environment. Course objectives are: -Acquire knowledge of the industry sector in which the internship is completed. -Translate knowledge and skills learned in the classroom into a work environment. -Explore additional career options available with the designated industry sector. -Identify areas for future knowledge and skill development. Prereq: RGME 535 and RGME 545.