USC Mann

Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences

FA-2025:
RXRS-422: Regulation, Guidance, & Control of Medical Products

Instructors: Terry David Church, DRSc, MA, MS

Associate Professor, Department of Regulatory and Quality Sciences
Assistant Director, Pharmacy Undergraduate Programs
USC Mann School of Pharmacy and Pharmaceutical Sciences
tdchurch@usc.edu
(323) 442-0241
Office: HSC campus CHP-140

Office Hours: Details available via link in Brightspace

Course Weight: **2** units

Days/Time/Location: Mon, Wed | 2:00-2:50PM | DMC 158

Catalogue description: *Overview of the regulatory, guidance, and compliance activities with federal, state, and local governments as well as pharmaceutical industry.*

Introduction

Regulatory and quality sciences are comprised of the rules and regulations that govern product development and post-approval marketing. In the United States, the FDA establishes and oversees the applicable regulations under several statutes, many regulations, and partnerships with legislators, patients, and customers. Biotechnology products may be classified as drugs, biologics, or medical devices. Each type is regulated by a different center within the FDA.

This course seeks to provide students with an in-depth knowledge and understanding of the core areas of pharmaceutical science and associated regulatory frameworks for the use of therapeutic agents in society. This entails the development of an understanding of how the regulatory framework is intertwined with practical and scientific considerations. This course will emphasize the development of a strong framework of regulations, guidances, and quality practices, addressing scientific methods needed to ensure safety, efficacy, quality, and consistent performance.

This course will focus on pharmaceutical, medical device, and biologics industries. Students will be exposed to historical issues that have framed our current regulatory processes. This course will help establish a framework for developing the critical set of quality-compliance skills necessary for the practice of safe and effective pharmaceutical science.

Objectives

This course will develop core competencies in dealing with the regulations, guidances, and control mechanisms in healthcare and research settings amidst a growing industry focused on pharmaceutical, medical device, and biologics industries. This will include a discussion of the legal, regulatory, and compliance strategies of the pharmaceutical industry, including clinical drug trials and studies, research, and marketing and promotion. This course will also provide a discussion of basic principles of business conduct in other healthcare industries.

Students will be presented with case studies to help explore and understand the principles guiding the conduct of pharmaceuticals, medical devices, and biologics. Topics including development of new tools, standards, and approaches to adequately assess the safety, efficacy, quality, and performance of regulated medical products.

Upon successful completion of this course, the student should be able to –

- Distinguish between regulations, guidance, and standards
- Describe the regulatory and quality review processes for medical products
- Summarize current gaps in regulatory knowledge
- Evaluate key issues in regulatory affairs and formulate arguments in defense and interrogation of those issues
- Appraise the consequences of improper drug use and abuse and its relationship to health, economy, wellbeing, and society as presented in the literature

This course will encourage students to be critical of current regulatory and quality processes, with the hope that one day they may help change the regulatory landscape for medical product development.

Evaluation and Grading:

Evaluation will be based on case study discussions and a final.

Description	Points	Weight
Case Study Debates 5 (@ 20 pts each)	100 pts	45%
Final exam (partially cumulative)	100 pts	55%
Total	**200 pts**	**100%**

Attendance at all classes is expected. Participation will include asking and answering questions and being actively involved in the discussion. It is expected that the students read the assigned materials prior to the lecture and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture. Due to the nature of regulatory science, it is expected that we will not always agree, and a richness of perspectives often helps illuminate the issues at hand.

45% Case Study Debates (each worth 9% of the class grade): The debates will be related to the weekly topic. Students will select regulatory guidelines, professional standards, or legal precedents related to the weekly lecture topic to be presented. These presentations will be used to guide the topical discussions. Students will need to research their topics and debate based on a journal article, legal case, ethical issue, or policy review they researched. The discussion will be driven by the weekly lecture. Specific information on the presentations can be found on pages 8-11.

55% Final: The Final Exam will be in the form of a take home test during exam week. The final exam will allow students to express their ideas based on facts derived from the course.

Please note, below is the "Approximate" grading scale breakdown. However, this scale is not set in stone and may slightly shift up or down based on overall scores. There are no pluses (+) or minuses (-) assigned to grades in this course.

Percent	Letter Grade
90-100%	A
80-89%	B
70-79%	C

60-69%	D
Below 60%	F

There are no make-up exams. If exceptional circumstances prevent you from attending an exam, your reason for missing it must be accompanied by a written statement from a third party (e.g. a note from a medical doctor).

Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

Students will be asked to complete an anonymous critical evaluation of the course at its completion.

Course Readings

This course is designed to be current and as such will rely on journal articles, book chapters, and other materials relevant to the weekly topics.

Other topical materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on http://brightspace.usc.edu/.

Course Outline

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session, the instructor will engage the students with questions and draw comments or interpretations primarily based on the assigned reading. Students are expected to ask questions and participate in an interactive fashion. Because this is an area of rapid change in policies, the readings may vary from one term to the next. Additional readings for each section that may be of added use are listed in the table below.

Schedule of Topics

Week	Date	Topic	Assigned Reading(s)
1	25 Aug 27 Aug	Introduction and Expectations	N/A
2	1 Sep 3 Sep	No Class, 1 Sep History of Regulatory Sciences	Woosley, R. L. (2013). One hundred years of drug regulation: where do we go from here? *Annual Review of Pharmacology and Toxicology, 53*, 255-273.
3	8 Sep 10 Sep	Regulatory Agencies	Hamburg, M. A. (2010). Innovation, regulation, and the FDA. *New England Journal of Medicine, 363*(23), 2228-2232.
4	15 Sep 17 Sep	Regulatory Information Discussion	Arya, H., & Nimesh, S. (2021). An overview of IND, NDA, approval agencies and FDA post-marketing surveillance. In T. K. Bhatt & S. Nimesh (Eds.), *The Design & Development of Novel Drugs and Vaccines* (pp. 267-273). New York, NY: Elsevier.
5	22 Sep 24 Sep	Drug Submissions Discussion	Paradise, J. (2018). 21st Century Citizen Pharma: The FDA & Patient-Focused Product Development. *American Journal of Law & Medicine, 44*(2-3), 309-327.
6	29 Sep 1 Oct	Biologics Submissions Discussion	Klonoff, D. C. (2020). The new FDA real-world evidence program to support development of drugs and biologics. *Journal of diabetes science and technology, 14*(2), 345-349.
7	6 Oct 8 Oct	Medical Device Submissions Discussion	Schlauderaff, A., & Boyer, K. C. (2019). An Overview of Food and Drug Administration Medical Device Legislation and Interplay with Current Medical Practices. *Cures, 11*(5), 1-6.

Week	Date	Topic	Assigned Reading(s)
8	13 Oct 15 Oct	Good Practices and Standards Discussion	TBA
9	20 Oct 22 Oct	International Perspectives Discussion	TBA
10	27 Oct 29 Oct	Risk Management Discussion	Song, W., Li, J., et al (2020). Human factors risk assessment: an integrated method for improving safety in clinical use of medical devices. *Applied Soft Computing, 86*, 1-21.
11	3 Nov 5 Nov	Wearable Devices – Student Debates 01	Student Selected
12	10 Nov 12 Nov	Cell and Tissue Based Therapies – Student Debates 02	Student Selected
13	17 Nov 19 Nov	Direct to Consumer Advertising – Student Debates 03	Student Selected
14	24 Nov 26 Nov	Dietary Supplement Regulation – Student Debates 04 Thanksgiving Recess – 26 Nov	Student Selected
15	1 Dec 3 Dec	Precision Medicine and Informatics – Student Debates 05	Student Provided
		Final Exam **Friday, 12 Dec 2025, 2pm-4pm**	

Academic Conduct:

Plagiarism – presenting someone else's ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Part B, Section 11, "Behavior Violating University Standards" policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct, http://policy.usc.edu/scientific-misconduct.

Support Systems:

Student Counseling Services (SCS) – (213) 740-7711 – 24/7 on call
Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention. engemannshc.usc.edu/counseling

National Suicide Prevention Lifeline – 1 (800) 273-8255
Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. www.suicidepreventionlifeline.org

Relationship and Sexual Violence Prevention Services (RSVP) – (213) 740-4900 – 24/7 on call
Free and confidential therapy services, workshops, and training for situations related to gender-based harm. engemannshc.usc.edu/rsvp

Sexual Assault Resource Center
For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: sarc.usc.edu

Office of Equity and Diversity (OED)/Title IX Compliance – (213) 740-5086
Works with faculty, staff, visitors, applicants, and students around issues of protected class. equity.usc.edu

Bias Assessment Response and Support

Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. studentaffairs.usc.edu/bias-assessment-response-support

The Office of Disability Services and Programs

Provides certification for students with disabilities and helps arrange relevant accommodations. dsp.usc.edu

Student Support and Advocacy – (213) 821-4710

Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. studentaffairs.usc.edu/ssa

Diversity at USC

Information on events, programs and training, the Diversity Task Force (including representatives for each school), chronology, participation, and various resources for students. diversity.usc.edu

USC Emergency Information

Provides safety and other updates, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible. emergency.usc.edu

USC Department of Public Safety – UPC: (213) 740-4321 – HSC: (323) 442-1000 – 24-hour emergency or to report a crime. Provides overall safety to USC community. dps.usc.edu

Presentation Topics

Week Number	General Topic
11	Wearable Devices – Student Debates 01
12	Cell and Tissue Based Therapies – Student Debates 02
13	Direct to Consumer Advertising – Student Debates 03
14	Dietary Supplement Regulation – Student Debates 04
15	Precision Medicine and Informatics – Student Debates 05

Debate Structure

Students will take on a role during each of the weeks listed above. Each student will have the opportunity to participate in the lead debater, and jury roles throughout the semester.

1. **Lead Debater Pro** – responsible for selecting, disseminating, and presenting the paper based on the weekly topic to the group. Prepares arguments that are pro debate topic.

2. **Lead Debater Con** – prepares arguments that are con debate topic.

3. **Jury** – all remaining students form the jury and are responsible for preparing jury cross examination and verdict.

Debate Team

The Lead Debaters and Patient Advocate will prepare their cases after reading the article selected by the Lead Debater Pro. Usually, ethical debates focus on topics that involve *moral dilemmas*. Recall, in a moral dilemma, there are two or more moral positions that support contradictory judgments or decisions. In a debate, one is expected to support one of these moral positions over the other. Thus, in general, preparing for an ethical debate can be divided into the following steps:

1. Identify the key issue.
    - Identify, in detail, the key regulatory issue.

- Provide potential ways the issue can be resolved that takes into account, time, difficulty of intervention, and risk-management factors to be considered.

2. Identify the arguments in favor of your position.
    - Identify those *regulatory processes* that support your position.
    - Identify those reasons why the regulatory processes involved in your position are more important or stronger than those of your opposition.

Two main kinds of reasons can be offered as evidence to justify a regulatory decision. You can offer reasons based on

(a) the effects of the decision, and

(b) reasons based on relevant regulatory processes.

A responsible decision regarding a regulatory issue or problem should emerge from careful evaluation of both kinds of reasons both for and against all the available options.

The Jury's Verdict Document

The jury consisting of the remaining students in the class must submit a verdict document. This document must include an analysis and criticism of each position. The verdict document (1 page, double spaced maximum) will be handed in by the next class day. It should include the following:

- An analysis of each regulatory issue or problem.

- An analysis of the strengths of each solution or hinderance discussed. What arguments support each position? What arguments can be found in the assigned articles to support each position?

- An analysis of the weaknesses of each position. What arguments might be used to undermine each position?

- A set of questions to be asked in the debate. These questions should be challenging to each position. What problems or questions must each side address to persuade you?

The Debate Structure

Our debate structure will be modeled after the L-D debate format, also known as a "values" debate. L-D is an acronym for "Lincoln-Douglas", referring to the famous debates between Abraham Lincoln and Stephen Douglas. For those familiar with this type of debate, our format is similar, but not identical to the classic LD format.

The debate focuses on a *resolution*. For instance, "Resolved: The government should give up its war on drugs and focus on legalizing and regulating drugs and drug use". Usually, the resolution is the judgment supported by the pro-position.

Part 1: The Pro-position: This is where the pro-debater gives a brief speech supporting the regulatory solutions or application of guidances / standards for a given case, or resolution. Use your key regulatory process arguments in formulating the pro-position. This should be, at most, five minutes in length.

Part 2: Cross Examination of Pro-Position: The members of the con-position can make objections and ask critical questions of the pro-position members. Pro-position members give responses (based on their regulatory position and reading material). The con debater can then object to these responses. This will be, at most, fifteen minutes in length.

Part 3: The Con-Position: This is the same as part 1, but for the con-position. As with the pro-position, the speech should be at most five minutes in length.

Part 4: Cross Examination of Con-Position: This is the same as part 2, but for the pro-position (fifteen minutes in length).

Part 5: Jury Cross Examination: The jury asks critical questions of each group. These questions should be both pre-prepared and based on comments or arguments made during the debate. This will be no more than fifteen minutes in length.

Part 6: Jury Decision: The jury will be given a total of five minutes to speak as a group and then will vote individually and give reasons for their vote. The jury will be judged on how well they justify their decision. Decisions should be thoughtful, reflective and make substantive reference to the arguments given during the debates.

Grading Rubric

The following criteria are used to evaluate preparation for and participation in the debate.

NOTE: The number values are not used in the computation of the grade. The numbers are used to give you a general idea of your areas of strength and the areas in which improvement is needed.

Criteria	Excellent (3)	Good (2)	Needs Improvement (1)
Participation*	Substantial, informed participation by all group members.	Adequate participation by each member, but with varying degrees of substance.	Inadequate participation. Either no participation by some group members or obvious "token" participation.
Cross Examination*	Excellent, relevant criticisms and questions of the opposition's constructive.	Adequate criticisms and questions of opposition's constructive.	Less than adequate criticisms and questions.
Response to Jury	Excellent, confident response to questions and criticisms.	Adequate response to questions and criticisms.	Inadequate response. Either fumbled or unconvincing.
Jury Decision (jury only)	Decision based on insightful comments, making substantive reference to the debate. Each jury member offers unique insights into decision.	Decision based on adequate comments. Some repetition in jury member insights. Possible moderate reference to debate.	Less than adequate justification of decision. Repetition in jury insights. No real substantive reference to debate.