UNIVERSITY OF WYOMING
PHCY 5241
Biopharmaceutical Regulatory Compliance, 3 Credit Hours

Online Delivery, Primarily Asynchronous Through WyoCourses
Spring, 2022
This Course Meets Daily on the Discussion Board and Live Online Selected Sunday Evenings
The First Day of Class is March 6, and the Last Day of Class is April 24 (7 Weeks)

Background: The pharmaceutical industry is among the most heavily regulated industries in the country. Success in the field of pharmacy, medicine, and pharmaceuticals requires a thorough understanding of regulatory requirements and the systems through which regulatory compliance can be accomplished. The failure to comply with regulatory requirements can doom a practice or a business. An overly conservative approach to regulatory compliance can cause a practice or business to be non-competitive as compared to other practitioners and businesses. The successful practice or business will balance economic interests with public safety interests.

Course Description: This course considers the role of regulatory agencies that prescribe conduct in the pharmacy profession, other health professions, and the pharmaceutical industry. The focus of the course is on the federal Food and Drug Administration. The functioning of other agencies, such as the federal Drug Enforcement Administration, state boards of pharmacy and state departments of health are also considered, primarily through their relationship with the FDA.

Course Purpose: The basic theme of this course is the Central Principle of Balance. Regulatory compliance requires "getting it right" when interpreting regulatory requirements and implementing systems to promote compliance. This is much easier to say than to do. The course begins with an overview of regulatory theory, it moves to a study of regulatory agency identity and behavior, and ends with case studies in regulatory compliance.

Place and Time of Class Sessions
This course will be taught primarily in asynchronous fashion. One live virtual classroom sessions will be held live on Sunday afternoon/evening at the end of the first week of class, and on Sundays thereafter as deemed necessary and convenient. Students will be responsible for completing course materials as their time permits, each week, during the 7 weeks of the course, with quizzes and exams being administered on weekends. Discussion board sessions will be held around the clock during the course. Students are expected to actively participate in discussion board on a regular basis. If there are fewer than 6 students enrolled in the course, then live classes will not be held and class participation will take place through the discussion board.

Course Instructor
David Brushwood, RPh, JD
Phone: 307-399-3372

Email: dbrushwo@uwyo.edu
Office Hours: TBD

Course Objectives

Upon successful completion of this course, the student will be able to:

1. Describe the importance of the "organizational reputation" of a drug regulatory agency.
2. Discuss the influence of "audiences" (the judiciary, Congress, nongovernmental organizations, the regulated industry, the public) on regulatory agency behaviors.
3. Describe how performative, technical, procedural, and moral reputation influence the policies of drug regulatory agencies.
4. Discuss how drug regulatory agencies utilize directive power, gatekeeping power, and conceptual power to influence behaviors of the regulated.
5. Discuss how FDA leadership has unilaterally, and perhaps extra-legally, introduced new requirements for drug development and distribution.
6. Discuss the problem of "information cascade" through which incorrect ideas gain acceptance by being parroted until eventually they are assumed to be true even in the absence of evidence.
7. Consider whether over the past 20 years, drug regulators have become increasingly risk-averse, hyper-regulatory, and problematic to practitioners and the industry.
8. Discuss the willingness of agency leadership to accede to undue political influence on product-specific and practice-specific regulatory decisions.
9. Consider why there is so much judicial deference to FDA and other drug regulatory agencies.
10. Discuss how public attention affects the speed and content of agency procedures and policies.
11. Discuss how the tenure of a regulatory agency director matters for how the decisions of the agency are treated.
12. Discuss the potential consequences of inappropriately lax or inappropriately harsh enforcement activity by the FDA (the so-called "Goldilocks Principle").
13. List the requirements for establishing the level of evidence necessary to support the approval of a new molecular entity under the Food, Drug, and Cosmetic Act.
14. List the required elements of approved drug labeling and the effect this labeling has on product promotion and professional practice.
15. Describe the traditional role of pharmacy compounding and the regulatory controversies that continue to address the appropriate methods of assuring the safety of pharmacy compounded products.
16. Discuss the regulatory distinction between Prescription-Only and OTC drugs.
17. Describe the regulatory responsibilities of manufacturers, distributors, and health professionals during the marketing and use of an approved drug.
18. List the characteristics of the "closed system" of controlled substance distribution under the Controlled Substance Act.

19. Discuss the challenges posed by the recent epidemic of prescription drug abuse, and the appropriate regulatory approach to addressing this epidemic.
20. Describe how federal payment systems indirectly restrict and control the use of safe and effective medications through payment conditions established by the Medicare and Medicaid programs.
21. Discuss the practices that must be adopted to ensure compliance with the False Claims Act, and with the requirements of the Medicare and Medicaid programs.
22. Describe the attributes of programs that can successfully manage liability for harm caused to patients by adverse drug events.

Course Learning Resources:

- Required Textbook:
    - Carpenter D. Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA, Princeton University Press (2010).
- Posted Video Lectures
- Posted Expert Videos
- Journal Articles

Course Structure & Outline

Interactive learning will occur on the discussion board 24/7, with multiple choice quizzes following weeks 1, 2, 3, 5 and 6, and short answer/essay exams following weeks 4 and 7. We will hold live classes online if there are 6 or more students enrolled in the course.

Evaluation Techniques:

Class participation	30%
Quizzes & Exams	70%

Grading:

A:	90 - 100
B:	80 – 89
C:	70 – 79
D:	60 – 69
F:	<60

Class Attendance Policy

Each student is expected to initiate two original discussion board threads per week and three responsive threads that follow the original thread posted by another student. All threads, whether original or responsive, must relate directly to the course material for that week, and must indicate reflective consideration of the material.

Quiz/Exam Policy

Inquiries regarding quizzes and exams should be directed to the course coordinator, preferably prior to the assessment, and always within a week following the assessment.

Make-up Quiz/Exam Policy

Students who are excused from a quiz or exam will not be required to make up that

assessment and their final grade will be calculated without consideration of the missed assessment. Students who are not excused from a missed quiz or exam will receive a grade of zero on that missed assessment. Any student who misses quizzes and/or exams of a sufficient number that indicate the student has not completed enough coursework to achieve the objectives of the course will be given an incomplete (I) grade for the course.

Policy on Old Quizzes and Assignments
All quizzes and exams will be posted, with answers, to the course discussion board, and these materials may be shared with anyone who wishes to have them.

Academic Dishonesty Statement:
The University of Wyoming is built upon a strong foundation of integrity, respect and trust. All members of the university community have a responsibility to be honest and the right to expect honesty from others. Any form of academic dishonesty is unacceptable to our community and will not be tolerated. Teachers and students should report suspected violations of standards of academic honesty to the instructor, department head, or dean. Other University regulations can be found at:
http://uwadmnweb.uwyo.edu/legal/universityregulations.htm

Disability Support Statement:
The University of Wyoming is an affirmative action/equal opportunity educator and employer. If you have a physical, learning, or psychological disability and require accommodations, please let the instructor know as soon as possible. You will need to register with, and provide documentation of your disability to University Disability Support Services (UDSS) in SEO, room 330 Knight Hall. The University Disability Support Services website, which may be found at:
http://uwadmnweb.uwyo.edu/udss/facultyandstaff/tipsforteaching.asp or you may contact UDSS for more information at (307) 766-6189, TTY: (307) 766-3073

Class Schedule-All times are Wyoming times-Class meets at 6pm on Sundays. (There will be no live classes if enrollment falls below 6 students—In that situation, the class participation will be entirely on the discussion board with a lively interaction between students and faculty.)

Module	Topic	Assignments	Course Activities	Assessment
I	The Regulatory Craft	-Lecture: "Foundations of Health Regulation"; -Monograph: "Regulatory Problem-Solving"; -Selected Journal Articles	-Discussion Board	Exam I.
II	Effective Health Regulation	-Lecture: "Theories of Health Care Regulation," -Monograph: "The Regulation/Ethics Interface." -Selected Journal Articles	-Discussion Board	Exam II
III	Foundational Authority for Drug Regulation	Carpenter, Chapters 1 & 2	- Discussion Board	Exam III
IV	Science-Based Regulatory Authority for Pharmaceuticals	Carpenter, Chapters 3 & 4	- Discussion Board	Exam IV.
V	The Aggregation of Federal Power in Drug Regulation	Carpenter, Chapters 5 & 6	-Discussion Board	Exam V.
VI	Public Influence on Pre-Marketing Drug Regulatory Decisions	Carpenter, Chapters 7 & 9	-Discussion Board	Exam VI
VII	Public Influence on Post-Marketing Drug Regulatory Decisions	Carpenter, Chapters 10 & 12	-Discussion Board	Exam VII

Syllabus Changes: I will alert you to any possible course format changes in response to UW decisions about community safety during the semester.

HyFlex, Zoom, and WyoCourses expectations:

As with all UW coursework, this course will be educational and useful to you. I will respond to questions, concerns, and feedback in a timely manner.

Your responsibilities:

- Give and receive feedback from me and your classmates respectfully and constructively in all interactions. This includes in Zoom chats, on WyoCourses boards, and within physical classroom spaces.
- Actively engage in civil discourse in a respectful manner. Use professional language in all course related forums.
- Communicate professionally. Whenever you send class-related email or messages, please include a clear, specific subject line and use the body of the email or message to explain the purpose for the email and any attached materials. Conduct yourself professionally.
- Meet assignment deadlines. We expect that you're interacting with course material multiple times during the week.
- Ask for help when you need it. For academic assistance for this course please contact me for available resources. For Dean of Students assistance please see: https://www.uwyo.edu/dos/student-resources/covid-19-student-resources.html
- Please let us know if you notice another student who needs help in our (anonymous) WyoCares referral option (https://www.uwyo.edu/dos/students-concern/index.html).

Information Technology (IT): If you have any IT related challenges, please contact the UWIT Service Center:
https://uwyo.teamdynamix.com/TDClient/1940/Portal/Requests/ServiceDet?ID=8890