

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

**Online Delivery, Primarily Asynchronous Through WyoCourses**  
**This Course Meets Daily on the Discussion Board and Live Online Selected Sunday Evenings**

**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. Two live virtual classroom sessions will be held live on Sunday afternoon/evening at the end of the first and second weeks 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 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.

**Course Instructor**

David Brushwood, RPh, JD

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**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 Videos
- Journal Articles

**Course Structure & Outline**

Interactive learning will occur on the discussion board 24/7, short answer/essay exams will weeks 4 and 7. We will hold live classes online during the first two weeks of the course, and as needed thereafter.

**Evaluation Techniques:**

Class participation	30%
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 Exam Policy**

Students who are excused from an exam may choose not 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 exam will receive a grade of zero on that missed assessment.

**Policy on Old Exams and Assignments**

Exams are provided to students without restriction on redistribution.

**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

**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>

### Course Outline

Module	Topic	Assignments	Course Activities	Assessment
I	The Regulatory Craft	-Lecture: "Foundations of Health Regulation". -Monograph: "Regulatory Problem-Solving". -Selected Other Readings	-Discussion Board	Class Participation
II	Effective Health Regulation	-Lecture: "Theories of Health Care Regulation," -Monograph: "The Regulation/Ethics Interface." Selected Other Readings	-Discussion Board	Class Participation
III	Foundational Authority for Drug Regulation	Carpenter, Chapters 1 & 2 Harvard R&P Lectures 2&3	- Discussion Board	Class Participation
IV	Science-Based Regulatory Authority for Pharmaceuticals	Carpenter, Chapters 3 & 4 Harvard R&P Lectures 4&5	- Discussion Board	Exam I Class Participation
V	The Aggregation of Federal Power in Drug Regulation	Carpenter, Chapters 5 & 6 Harvard R&P Lectures 6&7	-Discussion Board	Class Participation
VI	Public Influence on Pre-Marketing Drug Regulatory Decisions	Carpenter, Chapters 7 & 9 Harvard R&P Lectures 8&9	-Discussion Board	Class Participation
VII	Public Influence on Post-Marketing Drug Regulatory Decisions	Carpenter, Chapters 10 & 12 Harvard R&P Lectures 10&11	-Discussion Board	Exam II Class Participation

## Discussion Board (Class) Preparation/Participation

### Grading Rubric

### (30% of Grade)

	Excellent (A)	Good (B)	Inadequate (C)
<b>Contributions</b>	Consistently initiates useful and relevant ideas when participating in the discussion board. A definite leader who contributes major effort and who makes class discussions better.	Usually provides useful ideas when participating in classroom discussion board. A strong student who tries hard but is more of a follower than a leader in discussions.	Inconsistent in providing relevant comments on discussion board. Fails to initiate new threads that stimulate participation by other students.
<b>Attitude</b>	Always respectful of others; has a positive attitude and does not rudely criticize anyone else's ideas or work. Other students feel safe responding to this student's posts.	Occasionally becomes impatient with ideas or work of others. Usually has a positive attitude toward discussions. Usually treats others and self with respect.	On more than one occasion becomes disrespectful of ideas expressed by others, using insults rather than evidence to express contrary views.
<b>Preparedness &amp; Focus</b>	Consistently stays focused on subject matter assigned for discussion board and achieves identified outcomes. Self-directed and highly motivated. Postings help with understanding of assigned materials.	Usually posts comments that are related to course materials, but occasionally rambles about subjects that are not relevant to the course.	Postings to discussion board are based on general knowledge and common sense, rather than on materials assigned for course.
<b>Quality of Work</b>	Provides work of the highest insight that motivates other students to achieve at a high level.	Provides quality work that is interesting but not consistently insightful.	Does work that reflects little understanding of the course material.