

**Stevens Institute of Technology
Howe School of Technology Management**

Syllabus

MGT 684

Regulation and Compliance in the Pharmaceutical Industry

Instructor name and contact information:	
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Elaine Lehecka Pratt

Elaine.Pratt@stevens.edu

Overview

This course explores the economic theory of regulation in general, and the US and international regulatory environments that govern the pharmaceutical and biotechnology industries with particular focus on the US Food and Drug Administration, the European Agency for the Evaluation of Medical Products and the Japanese Ministry of Health, Labor and Welfare. The essential components of Good Laboratory Practices, Good Clinical Practices and Good Manufacturing Practices regulations will be covered. Students will develop an understanding of the formulation and execution of regulatory strategy and key ethical issues in medical research and production. Where appropriate, case studies will be used to illustrate the challenges and issues associated with compliance as well as the consequences of noncompliance. Ethical issues and the potential consequences of ethical lapses will also be explored. Current events will be used to illustrate key ethical principles and serve as a basis for discussion.

Prerequisites: None.

Relationship of Course to Rest of Curriculum

This is an elective course in the Pharmaceutical Technology Management Program. It can be taken by students pursuing a Graduate Certificate in Pharmaceutical Technology Management or the M.S. or M.B.A. in Management.

Learning Goals

- To understand the economic theory of regulation
- To cover US and international regulatory requirements and management challenges for compliance
- To discuss the role of ethics in pharmaceutical regulation and compliance

Pedagogy

The course employs lectures, class discussions, in-class assignments, homeworks, team

projects, and an individual research term paper. Students will make several formal presentations during the class.

Required Text(s)

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, edited by Douglas Pisano and David Mantus, CRC Press, 2004, ISBN 1587160072

Research Ethics: A Reader, edited by Deni Elliot and Judy Stern, University Press of New England, 1997, ISBN 0874517974

Additional Readings

May be assigned during the course.

Course Schedule

Week	Topic Covered/Readings/Assignments
1	Introduction to the pharmaceutical regulated environment
2	The US regulatory environment
3	The US regulatory environment continued
4	Product submissions
5	Team presentations: Regulatory submissions – requirements and strategy
6	Compliance strategy for electronic technology management
7	The international regulatory environment
8	Team presentations: Consequences of noncompliance
9	Practice and components of regulatory affairs and compliance
10	Introduction to ethics in medical research
11	Introduction to ethics in pharmaceutical validation, quality assurance, production and post-marketing pharmacovigilance
12	Team presentations: Consequences of ethical lapses
13	The future of regulation and compliance, Individual presentations, term papers due
14	Final Exam