

Syllabus

**US Food and Drug Administration, Drug Development, Science and Health Policy
PH 290.11*CCN 76363*2 Units
UC Berkeley, School of Public Health
Thursday 6:30 – 8:30 PM Room; 106 Stanley Hall
January 23 – May 1, 2014**

Course Description: This interdisciplinary course reviews the history, authorizing statute and regulatory authority of US FDA and the influence and impact of FDA on science and health policy. Using the Forum for Collaborative HIV Research's experience in HIV/AIDS and HCV, we demonstrate the interdisciplinary nature of the agency's mandate (basic sciences, statistics, clinical medicine, ethics, toxicology, pharmacology, policy, law, political science, economic, foreign policy) and its impact on public health policy. Real-time examples such as maintaining quality of generic drug products distributed through PEPFAR, development of regulatory policy on the use of next generation sequencing platforms in the HIV and HCV space, and HIV cure research serve as case studies to illustrate both the ability of public entities to affect FDA policy and FDA's impact on society. Biotech and pharmaceutical industry experts will participate as guest lecturers to illustrate the ongoing need for interaction between the agency, academia, industry and public health community. The course will be of interest to students in public health, law, medicine, business or policy interested in biotech and the pharmaceutical industry.

Instructor: Veronica Miller, PhD; Jur Strobos, MD, JD, FACEP

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GSI: N/A

Attendance: Students are expected to attend 14 classes each of two hour duration. Class time will be divided between lectures and assigned readings discussions. Students will participate in assigned reading discussions based on materials assigned in the syllabus.

Grading: Grade or Satisfactory/Unsatisfactory
Students are required to complete 3 mini-tests, each consisting of one essay style answer (choose 1 question from 3 questions provided for each mini-test). Students will participate in one group project culminating in a class presentation. The 3 mini-tests will account for 45/100 points; the group project 30/100. Class participation (active discussion of assigned readings) will contribute 25/100 points for a total of 100 points. The grading will follow the University of California at Berkeley policies (<http://berkeley.edu/catalog/policies/grades.html>). Cheating or plagiarism on exams is against the University regulations.

Textbooks: A textbook is not required for this course. Course materials will be distributed electronically and will include selected excerpts from a variety of books and published articles; policy and regulatory documents of the US Food and Drug Administration; reports from the Forum for Collaborative HIV Research (www.hivforum.org); and excerpts from other publications, such as judicial opinions and FDA slide presentations. Reading assignments are listed in the full course syllabus.

Course Objectives:

This course will provide an in-depth consideration of the major issues in drug development, focusing on the US Food and Drug Administration laws, regulations and guidance. Knowledge fundamental to drug development will be acquired in preparation for a possible career in the pharmaceutical or other related industries. Drug development science is taught in the context of the HIV/AIDS and HCV epidemics and the influence of these on FDA and international policy.

Course Learning Objectives

- 1) Describe and discuss the historical and public policies underlying current drug regulation and the impact on areas of international science outside drug development such as clinical trial design and statistics, manufacturing, drug safety and toxicology, medical ethics, basic sciences, and foreign policy, with a focus on HIV/AIDS and HCV.
- 2) Describe and discuss the major issues in first-in-man exposure to a new drug product including accelerated access, parallel track/treatment IND, ethical standards for medical research and their enforcement mechanisms.
- 3) Understand the role of the private sector including public private partnerships, industry, community activists, and academic medicine in the evolving development of federal health policy and research with a focus on HIV/AIDS.
- 4) Understand the process for developing a drug including the economic and financial impact to enable preparation of a draft drug development plan.
- 5) Acquire knowledge critical to a career in the pharmaceutical or related industry.
- 6) Critically read and discuss drug regulatory literature.

Course outline:

Session	Date	Instructor	Session details
Pre-1	1-23		Course Opening Reception (5:45-6:30)
1	1-23	VM+JS	Introduction to the PubH290.11; FDA; Forum for Collaborative HIV Research <i>Guest(s):</i> <i>Required readings:</i> (FDA Form 356h , Young 1972, ICH Expert Working Group (M4) 2004, Miller 2009) <i>Optional readings:</i> (Hamburg and Sharfstein 2009, Anderson M and Manganiello M 2011, Sebelius 2011)
2	1-30	JS	Standards for Efficacy <i>Guest(s):</i> <i>Required reading:</i> (21 CFR 201.128 , 21 CFR 314.126 , Exh 300 Council on Pharmacology and Chemistry 1944, Exh 39 Starr I 1961) (Federal Food Drug and Cosmetics Act 1938) (Goodman Testimony , Kordel v United States 1948) <i>Optional readings:</i> (Fisher 1960, Whitaker v Thompson 2003)
3	2-6	JS	Ethics and Informed Consent <i>Guest(s):</i> <i>Required readings:</i> (Sugarman 2013) (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 'Belmont Report' 1978, FDA 'IRB Rev' 2006, DHHS Fed Reg 'Holland' 2010) (FDA CBER 'Irvine Warning' 2002) <i>Optional readings:</i> (FDA Fed Reg 'HSRP' 2011)
4	2-13	JS	Toxicology, and GLP (Good Laboratory Practice) <i>Guest(s):</i> <i>Required readings:</i> (DHHS Fed Reg 'Concepcion' 2012) (Schneider 1983) (Expert

			Scientific Group 'Northwick Park' 2006) (ICH M3 R2 2009) <i>Optional readings:</i> (21 CFR58 'GLP' 1978)
5	2-20	JS	Pharmacology <i>Guest(s):</i> <i>Required readings:</i> (FDA 'Simeprevir' 2013) (Simeprevir Package Insert 2013) (Sofosbuvir Package Insert 2013) <i>Optional readings:</i>
6	2-27	VM	HIV and HCV Biology; Surrogate Markers <i>Guest(s):</i> <i>Required readings:</i> (Mani, Murray et al. 2012, Lontok, Mani et al. 2013) <i>Optional readings:</i> (Struble, Murray et al. 2005, Chan-Tack, Struble et al. 2008, Kwong, Najera et al. 2011, Moir, Chun et al. 2011, Kwong 2014, Schinazi, Halfon et al. 2014)
7	3-6	VM	New Technologies & Diagnostics; Companion Diagnostics <i>Guest(s):</i> Chris Petropoulos, PhD (Monogram Biosciences); Gabrielle Heilek, PhD (Roche Molecular Systems) <i>Required readings:</i> (Archer, Weber et al. 2012, Beerenwinkel, Gunthard et al. 2012, Kramer, Xu et al. 2012, Collins and Hamburg 2013, Eriksson, Graf et al. 2013, Henrich, Hu et al. 2013, Paquet, Solberg et al. 2014) <i>Optional readings:</i> (Haas, Kuritzkes et al. 2011, Ciuffi and Telenti 2013, Wagner, Pacold et al. 2013, McElroy, Thomas et al. 2014)
8	3-13	VM	New Indications/Formulations: Regulatory Challenges in ARV based Prevention Research <i>Guest(s):</i> Jim Rooney, MD (Gilead); Robert Grant, MD (UCSF) <i>Required readings:</i> (Strobos J, Hauschild B et al. 2011, Baeten, Donnell et al. 2012, European Medicines Agency 2012, FDA 2012, FDA Approval Letter 2012, FDA Fact Sheet 2012, FDA Truvada Label 2012, Van Damme, Corneli et al. 2012) (Grant, Lama et al. 2010, Cohen 2014) <i>Optional readings:</i> (White, Chileshe et al. 2011, Donnell, Hughes et al. 2013, Koblin, Andrasik et al. 2013, Sugarman and Mayer 2013, Thompson, Cohen et al. 2013, Kirby and Thornber-Dunwell 2014)
9	3-20	VM	Regulatory Challenges in HIV Cure (Eradication) Research <i>Guest(s):</i> Romas Geleziunas, PhD (Gilead); Matt Scharp (Patient Advocate) <i>Required readings:</i> (Eyal and Kuritzkes 2013, Lo and Grady 2013, Miller and Kraus 2013, Saez-Cirion, Bacchus et al. 2013, Spire and Suzan-Monti 2013, Sugarman 2013, Yukl, Boritz et al. 2013, Cohen 2014, Forum 2014, Jessen, Allen et al. 2014, Tebas, Stein et al. 2014, The Editorial Board 2014) <i>Optional readings:</i> (King, Henderson et al. 2005, Dresser 2009, Richman, Margolis et al. 2009, Cory, Schacker et al. 2013, Tebas, Stein et al. 2013)
10	4-3	VM	Safety and Pharmacovigilance; REMS <i>Guest(s):</i> Tobias Peschel (Gilead) <i>Required readings:</i> (Bisson, Gross et al. 2003, Miller, Nwokike et al. 2012, Triant, Josephson et al. 2012, Bate, Jensen et al. 2013, FDA 2013, Psaty, Goodman et al. 2013) <i>Optional readings:</i> (Fry J 2007, Strengthening Pharmaceuticals Systems (SPS) Program 2011, Bollyky and Stergachis 2014)

11	4-10	JS	Chemistry, Manufacturing and Controls
			<i>Guest(s):</i> Chris Plaford (Pharma Advisory LLC)
			<i>Required readings:</i> (69 2004, FDA Inspection Compliance Enforcement Criminal Investigation 2010, Whitmire, Bryan et al. 2010, Gilead 2013)
			<i>Optional readings:</i>
12	4-17	VM	Global Epidemics & Response (Open to the Public)
			<i>Guest(s):</i> Gregg Alton (Gilead); Stef Bertozzi (SPH); Eric Goosby (UCSF)
			<i>Required readings:</i> (Cheng, Landay et al. 2008, Holmes, Coggin et al. 2010, Miller, Nwokike et al. 2012, Abrams and Myer 2013, El-Shabrawi and Kamal 2013, Quinones-Rivera 2013, Grebely and Dore 2014)
			<i>Optional readings:</i> (Pepin 2013)
13	4-24	VM	Student Project Presentations
14	5-1	VM+JS	Student Project Presentations & End-of-Course Reception

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