

# ACDRS

American Course on Drug Development  
and Regulatory Sciences

**An invitation to  
prepare for success in modernizing the science behind the  
development and regulation  
of medical products**

## Class of 2009-2011

- Course begins September 30, 2009
- Location University of California, Washington Center, Washington, DC
- 2-year certificate program, 6 sessions
- Enrollment open through August 15, 2009
- Early enrollment discount  
March 1, 2009 – June 1, 2009

### Presented by:

Department of Bioengineering and  
Therapeutic Sciences  
School of Pharmacy  
University of California, San Francisco



## COLLEAGUES IN INDUSTRY, ACADEMIA AND GOVERNMENT

We invite you to join your peers as a participant in the nonprofit American Course on Drug Development and Regulatory Sciences (ACDRS), which supports the FDA's Critical Path Initiative to modernize the science required to deliver medical products to market.

The course is presented by the University of California, San Francisco, working with the FDA, a network of universities, biopharmaceutical companies and the European Center for Pharmaceutical Medicine in Basel, Switzerland.

Former participants rate the program as a tremendous success and benefit to their work and workplace goals:

“It is the one Course that I have found personally to provide the greatest learning experience – and very much unparalleled”

“...The nice thing about the breakout sessions is the fact that you are working on solving problems or proposing a strategy with colleagues who come from across the map in drug development – preclinical, clinical, legal, FDA, small cap companies or Big Pharma. Everyone comes together and there are really no boundaries”

We look forward to hearing from you.

Sincerely,

The ACDRS Executive Committee

Four handwritten signatures in black ink, corresponding to the names listed below: Ellen G. Feigal, Carl P. Peck, Fritz Bühler, and Charles Grudzinskas.

Ellen G. Feigal, MD  
Director, ACDRS  
UCSF School of  
Pharmacy

Carl P. Peck, MD  
ACDRS Executive  
Board  
UCSF School of  
Pharmacy

Fritz Bühler, MD  
ACDRS Executive  
Board  
European Center for  
Pharmaceutical  
Medicine  
University of Basel

Charles Grudzinskas, PhD  
Chair, ACDRS Curriculum  
Committee  
NDA Partners

# ACDRS

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## **FIVE REASONS TO PARTICIPATE IN ACDRS**

### **1. ACDRS is needed now by medical product scientists and regulators. Course content:**

- Meets today's training gap in medical product discovery and development
- Aims to advance integrated product development that is science-based, efficient, high quality and rapid
- Emphasizes requirements and best practices for the rational and rapid development of new products for the global marketplace.

### **2. ACDRS participants leverage their current expertise. They are all:**

- In the biopharmaceutical and service industries, academic and government scientists and decision- and policy-makers who already have a good grounding in the basics
- Looking for a rigorous, in-depth, comprehensive and systematic immersion into modern medical product development, regulation and market introduction.

### **3. ACDRS builds knowledge and new networks. Participants:**

- Integrate workplace goals with the education needed to better accomplish those goals
- Gain in-depth knowledge on timely topics important to the successful development of medical products into the future
- Actively engage in lectures, workshops, panel discussions, and team-oriented case studies
- Build an international network of colleagues.

### **4. ACDRS content is comprehensive and interconnected. Program content includes:**

- Discovery and development of new medicines
- Biopharmaceutical sciences
- Clinical pharmacology and trial methodology
- Good clinical practice and ethics
- Pharmacovigilance and epidemiology
- Biostatistics
- Regulatory affairs
- Health economics
- Project management
- Marketing and new therapeutic approaches.

### **5. ACDRS faculty members are recognized international experts. Their backgrounds include:**

- Regulatory sciences
- Medical product discovery and development
- Product evaluation and business practices from US and European universities, pharmaceutical, biotechnology and device companies and regulatory authorities (including the FDA, EMEA, MHRA and other regulatory agencies).

## SESSIONS

Session 1	The Pharmaceutical Enterprise: Current and Future Perspectives
Session 2	Learning Trials: From Discovery to First in Humans
Session 3	Learning and Confirming Trials: Finding and Confirming the Right Dose
Session 4	Confirmatory Trials: Methodology and Biostatistics
Session 5	The Global Registration and Approval Process
Session 6	Integrated Product Development Strategy, Execution and Program Management
	Course Examination

## DATES

Instruction begins September 30, 2009  
Last day of instruction is May 5, 2011  
Session 1: September 30-October 2, 2009  
Session 2: February 1-4, 2010  
Session 3: May 3-6, 2010  
Session 4: September 20-23, 2010  
Session 5: January 24-27, 2011  
Session 6: May 2-5, 2011

## COMMITMENT

2-year program, 6 sessions total

## VENUE

University of California, Washington Center  
1608 Rhode Island Avenue, NW  
Washington, DC 20036  
See [www.ucdc.edu/aboutus/location.cfm](http://www.ucdc.edu/aboutus/location.cfm)

## CERTIFICATE

A certificate is awarded upon completion of the course.

## REGISTRATION

Seating is limited and will be guaranteed on a first-come first-serve basis. Online registration will be available at <http://bts.ucsf.edu/acdrs/>.

## FEE

Early Enrollment Fee through June 1, 2009: \$15,000

Fee after June 1, 2009: \$16,500

A discounted fee for a limited number of participants from academia and government is available, please contact [jaime.kenyon@ucsf.edu](mailto:jaime.kenyon@ucsf.edu).

## MORE INFORMATION

For details about the program and registration go to <http://bts.ucsf.edu/acdrs/>

For questions, contact:  
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