

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 2010-2012

- Course begins October 25, 2010
- Location: Mission Bay Conference Center at UCSF, San Francisco, CA
- 2-year certificate program, 6 sessions
- Early enrollment discount deadline August 1, 2010

Presented by:

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



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. The 2007-2009 cycle of the East Coast ACDRS in Washington, DC concluded in May 2009 (new class of 2011 began September 2009) while the 2008-2010 cycle of the West Coast ACDRS in San Francisco, CA will conclude in June 2010.

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

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

American Course on Drug Development
and Regulatory Sciences

**Prepare for success in modernizing the science behind the
development and regulation
of medical products**

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, EMA, MHRA and other regulatory agencies).

ACDRS

American Course on Drug Development
and Regulatory Sciences

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 October 25, 2010
Last day of instruction is June 14, 2012
Session 1: October 25-27, 2010
Session 2: February 28-March 3, 2011
Session 3: June 13-16, 2011
Session 4: October 17-20, 2011
Session 5: February 27-March 1, 2012
Session 6: June 11-14, 2012

COMMITMENT

2-year program, 6 sessions total

VENUE

Mission Bay Conference Center at UCSF
1675 Owens Street
San Francisco, CA 94158
<http://www.acc-missionbayconferencecenter.com/>

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 August 1, 2010: \$15,000
Fee after August 1, 2010: \$16,500
A discounted fee for a limited number of participants from academia and government is available, please contact jaimе.kenyon@ucsf.edu.

MORE INFORMATION

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

For questions, contact:
Jaime Kenyon, MPH
ACDRS Program Manager
jaimе.kenyon@ucsf.edu

Dr. Ellen Feigal
ACDRS Director
ellen.feigal@ucsf.edu