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 2017-2018

- Course begins September 18, 2017
- Location: Washington, DC
- 10-month certificate program, 6 sessions
- Early enrollment discount deadline
  August 1, 2017

Presented by:

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

UCSF
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. Previous class cohorts completed the ACDRS in Washington DC in 2009, 2011, 2013, 2015, 2016 and 2017 (expected in May) while those in the ACDRS San Francisco CA class cohorts completed the course in 2010, 2012 and 2014. 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**"**

Interested professionals, working in drug development as part of industry, academic, government or regulatory organizations are welcome to apply for admission into the ACDRS Washington DC class of 2018. We look forward to hearing from you.

Sincerely,

The ACDRS Executive Committee

Louis R. Cantilena, MD PhD FACMT FACP, ACDRS Course Director
Carl C. Peck, MD, ACDRS Executive Board, UCSF School of Pharmacy
Charlie Gombar, PhD, Bill & Melinda Gates Foundation (Advisor)
Charles Grudzinskas, PhD, Chair - ACDRS Curriculum Committee, NDA Partners LLC
Florence Houn, MD MPH FACP, Celgene
Diane K. Jorkasky, MD FACP, Complexa Inc.

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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.
   - Incorporates online e-learning and real-world cases

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

   - In the biopharmaceutical and service industries, academic and are 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, pharmacometrics and learning-trial methodology
   - Good clinical practice and ethics
   - Pharmacovigilance and epidemiology
   - Biostatistics and exploratory/confirmatory trial design
   - Regulatory affairs and optimization
   - Health economics
   - Program and project management
   - Marketing and novel therapeutic approaches.

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

   - Regulatory sciences and policy
   - 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, PDMA and other regulatory agencies).

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SESSION THEMES

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 and Project Management
	Course Examination

DATES

Instruction begins September 18, 2017
Last day of instruction is June 22, 2018
Session 1: September 18-20, 2017
Session 2: November 7-9, 2017
Session 3: January 17-19, 2018
Session 4: February 20-22, 2018
Session 5: April 4-6, 2018
Session 6: June 19-21, 2018
Examination: June 22, 2018

VENUE

University of California, Washington Center
1608 Rhode Island Ave, NW
Washington, DC 20036

CERTIFICATE

A certificate is awarded upon completion of the course.

ACDRS has established an international network and collaboration with courses in drug development and regulatory sciences. Its partner courses at Peking University Health Science Institute (China Course on Drug Development and Regulatory Sciences, CCDRS) and the European Center of Pharmaceutical Medicine, (ECPM) at the University of Basel share the same teaching principles and quality label. This unique global collaboration offers the possibility to start training at one site and continue or successfully achieve the certificate at one of the sister courses in Basel, Beijing and Washington DC.

REGISTRATION

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

FEE

Early enrollment fee on or before August 1, 2017: $15,000
Fee after August 1, 2017: $16,500
A discounted fee for a limited number of participants from academia, government and nonprofit is available, please contact acdrs@ucsf.edu.

In case of cancellation before August 1, 2017 the fee (less $900.00 for administrative expenses) will be returned. There will be no substitute registrants or refund on cancellations made after this date.

MORE INFORMATION

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

For questions, contact: acdrs@ucsf.edu