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 2021 (Cycle 13)

- Course begins March 1, 2021
- Location: online & Washington, DC
- 10-month certificate program, 6 sessions
- Early enrollment discount deadline January 31, 2021

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, GOVERNMENT AND ACADEMIA

We invite you to join your peers as a participant in the nonprofit American Course on Drug Development and Regulatory Sciences (ACDRS) presented by the University of California, San Francisco in collaboration with the University of Basel in Switzerland and Peking University Clinical Research Institute in China. The course is targeted for the biopharmaceutical industry and their service industries, academic and government scientists and decision and policy-makers who already have a good grounding in the basics and will benefit from a more in-depth, comprehensive and systematic immersion into modern medical product development, regulation and market introduction. Former participants rate the program as a tremendous success and benefit to their work and career:

> "Attending ACDRS was one of the most rewarding experiences of my educational journey. It has helped me tremendously in my career. I felt so strongly about the value of this program that I joined the ACDRS family as a guest lecturer. It's not just what you gain in the time you spend at the sessions or the exceptional content, it's also the connections you make and the lifelong value you derive from it."
> *–Mike Dyszel, Senior Director, Global Portfolio & Program Management, Mallinckrodt Pharmaceuticals*

Interested professionals, working in medical product development as part of industry, academic, government or regulatory organizations are welcome to apply for admission into the ACDRS class of 2021.

Sincerely,

The ACDRS Executive Committee

Charlie Gombar, PhD, ACDRS Course Director
Daniela Drago, PhD, Biogen
Joshua Galanter, MD, Genentech
Charles Grudzinskas, PhD, NDA Partners LLC
Diane K. Jorkasky, MD FACP, Consultant
Carl C. Peck, MD, UCSF School of Pharmacy
Stephen Ruberg, PhD, Analytix Thinking LLC
Advisor: Christine Garnett, PharmD, US Food & Drug Administration

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FIVE REASONS TO PARTICIPATE IN ACDRS

1. **ACDRS is needed now by everyone involved in medical product development. 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, project and portfolio 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, PMDA and other regulatory agencies).

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SESSION THEMES

Session 1	The Medical Product Development Enterprise: Past, Present 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	Statistics: Design, Analysis and Interpretation of Clinical Trials
Session 5	The Global Registration and Approval Process
Session 6	Integrated Product Development: Project and Portfolio Management; Preparing for Transition to the Market
	Course Examination

DATES

Instruction begins March 1, 2021
Last day of instruction* is December 9, 2021
Session 1 *online*: March 1-5, 2021
Session 2 *online*: April 19-23. 2021
Session 3 *online*: June 14-18, 2021
Session 4*: September 27-29, 2021
Session 5*: October 26-28, 2021
Session 6*: December 7-9, 2021
Examination*: December 10, 2021
* *in-person attendance if possible*

VENUE

Online & 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 Clinical Research Institute (China Course on Drug Development and Regulatory Sciences) and the European Center of Pharmaceutical Medicine at the University of Basel (ECPM Course in Pharmaceutical Medicine) 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 or Washington DC.

REGISTRATION

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

FEE

Registration fee: $13,500
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 January 31, 2021 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 https://pharm.ucsf.edu/acdrs/course

For questions, contact acdrs@ucsf.edu