



ACDRS

American Course on Drug Development
and Regulatory Sciences



October 2008 - June 2010
Mission Bay Conference Center at UCSF
San Francisco, CA

University Sponsor

Department of Biopharmaceutical Sciences
Center for Drug Development Science
School of Pharmacy



University of California
San Francisco

An East-coast Parallel ACDRS 2007-2009 was launched at
University of California, Washington Center, Washington, DC

<http://bts.ucsf.edu/acdrs>



**Invitation to participate
in the American Course on Drug Development and Regulatory Sciences (ACDRS)**

Dear Colleague,

In the spirit of the FDA Critical Path Initiative, the University of California San Francisco (UCSF) is working with academia, industry and FDA to launch a postgraduate comprehensive education program especially designed for professionals working within the pharmaceutical, biotechnology and device industries, regulatory authorities and universities. The ACDRS program provides education and training in the field of medical product development at an advanced level. The ACDRS is targeted for the biopharmaceutical industry and its 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.

The ACDRS emphasizes integrated product development which is science-based, efficient, high quality and rapid. Emphasis is placed on requirements for rational and rapid development of a new product for the global marketplace. The Founders of the ACDRS envision the course to contribute to the modernization of development and regulation of medical products through the certified, comprehensive instruction for integrating cutting-edge concepts and best practices in medical product development and regulatory sciences.

The ACDRS is a nonprofit educational course established in 2006 by the Department of Biopharmaceutical Sciences, School of Pharmacy, UCSF and the Center for Drug Development Science, UCSF working with the FDA, professional societies, a network of universities, a network of pharmaceutical, biotechnology and device companies, and with the European Course in Pharmaceutical Medicine (ECPM), University of Basel, Switzerland. ACDRS is managed by an Executive Office and collaborates with a highly experienced international faculty with a network of experts in pharmaceutical medicine and medical product development science. ACDRS-Washington, DC was launched in September 2007.

The syllabus of the ACDRS program covers all aspects of pharmaceutical medicine and medical product development sciences. This includes the 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. Participants will be involved in lectures, workshops, panel discussions, team-oriented case studies and interactive learning. A faculty network of experts from US and European universities, pharmaceutical, biotechnology and device companies and regulatory authorities (including the FDA, EMEA, MHRA and other regulatory agencies) carry the teaching responsibility.

Participation in the ACDRS provides you with the opportunity to integrate work and education, to discuss with experts face-to-face, to gain in-depth knowledge while building an international network, and to put this into perspective with your own career plan. Finally you have the opportunity to obtain an ACDRS Certificate.

We enthusiastically invite you to participate in the ACDRS.



Kathy M. Giacomini, PhD
Professor and Chair
Department of Biopharmaceutical
Sciences
UC San Francisco



Carl C. Peck, MD
Adjunct Professor and Founder
Center for Drug Development
Sciences
UC San Francisco



Ellen G. Feigal, MD
Adjunct Professor
Director, ACDRS
UC San Francisco

Vision and Mission

The Founders of the ACDRS envision a modernization of development and regulation of medical products through the certified, comprehensive instruction for integrating cutting-edge concepts and best practices in medical product development and regulatory sciences.

The Goals of the ACDRS are to:

- Present a foundation of integrated knowledge in science-based medical product development and regulation
- Enable application of innovative methods, tools and strategies that best utilize recent scientific advances and technologies to medical product design, development and regulatory review
- Address real world challenges encountered during the development, manufacture, review and commercialization of FDA regulated medical products
- Cover the entire medical product lifecycle – from molecule or device concept to marketplace
- Train the leaders and integrators for medical product development
- Understand future directions in global pharmaceutical and health economics and business environments, and implications for product development and evaluation
- Provide an understanding of the consumer protection culture and changing approaches taken by regulatory bodies

What is the Course Program?

The ACDRS consists of 24 teaching days divided into six sessions over a period of two years (eight hours per day, each lesson 45 minutes), including “team” involvement in mentored, case-oriented breakout sessions. In addition, approximately eight hours of preparation per session is required in order to prepare for the case studies. Distance learning formats are in development.

- 6 Sessions
- 13 Case Studies
- 5 State-of-the-Art Workshops as part of the Frontiers in Drug Development and Regulatory Sciences Series
- 1 Certificate Course Examination

Session 1	October 20-23, 2008	The Pharmaceutical Enterprise: Current and Future Perspectives	4 days
Session 2	February 23-26, 2009	Learning Trials: From Discovery to First in Humans	4 days
Session 3	June 15-18, 2009	Learning and Confirming Trials: Finding and Confirming the Right Dose	4 days
Session 4	October 19-22, 2009	Confirming Trials: Methodology and Biostatistics	4 days
Session 5	February 22-25, 2010	Global Registration and Approval Process	4 days
Session 6	June 14-16, 2010	Integrated Product Development Strategy, Execution and Project Management	3 days
	June 17, 2010	Course Examination	0.5 day

Teaching Faculty

The ACDRS teaching faculty comprises international experts in regulatory sciences, medical product discovery and development, product evaluation and business practices. Lecturers and mentors will be drawn from academia, regulatory agencies (such as FDA, EMEA, MHRA and other regulatory agencies), pharmaceutical, device, diagnostic and biotechnology industry, coverage and reimbursement organizations and professional societies and the National Institutes of Health.

Who Should Attend this Course?

This Course is targeted for the biopharmaceutical industry (including medical device manufacturers) and its service industries, academic and government scientists and decision- and policy-makers who 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.

This Course emphasizes integrated product development which is science-based, efficient, economical, high quality and rapid - leading to better and safer medical products for patients.

This Course targets the following professionals:

- Drug Discovery and Non-Clinical Development Team Leaders
- Drug Discovery and Translational Scientists from Academia and Industry
- Drug and Medical Device Product/Clinical Development Team Leader and Members
- Clinical Pharmacology and Development Team Leaders and Clinical Scientists
- Therapeutic Area and Technology Platform Managers
- Regulatory Scientists from Industry, Academia and Government
- Portfolio, Program and Project Managers
- Knowledge Transfer, Partnering, Licensing and Legal Experts
- Heads of Research and/or Product Development and Business Executives
- Investors from Venture Funds and Financial Institutions

Eligibility Criteria

To be eligible for enrollment in the ACDRS, applicants must have a higher university degree, such as MD, PharmD, PhD, Master's, or JD and a primary interest in medical product discovery, development, regulation or related activity. ACDRS is a postgraduate level education program, and is particularly aimed at professionals who are involved in the medical product development process and have at least one to two years of working experience. Participants must be qualified via standards and nominations. A one-page curriculum vitae must be submitted to jaimie.kenyon@ucsf.edu immediately following registration.

What Will You Gain from Attending this Course?

Participants of this Course will be able to understand how to incorporate the latest innovative biopharmaceutical development strategies, methodologies and tools to:

- Be prepared for future developments and changes of the global pharmaceutical, health economics and business environments, as it impacts product selection, product development, regulatory and business evaluations
- Design, evaluate and manage integrated product development programs and the resulting pharmaceutical R&D portfolio
- Devise timely Go/No Go decision-making criteria and procedures based upon critical analyses of non-clinical and clinical data sets leading to improved success rates for new drug candidates and devices
- Incorporate into milestone decisions, including early-on, the potential commercial value of development candidates/products and their return on investment
- Address real world challenges encountered during the development, manufacturing, review and commercialization of FDA regulated medical products
- Prepare and critique an integrated product development plan
- Optimize and critique clinical and non-clinical protocols
- Incorporate integrated product safety management programs
- Design a global NDA/MAA registration strategy for rapid market approvals
- Incorporate present and future regulatory policies, guidances, and opportunities into FDA meetings with sponsors and NDA reviews
- Effectively understand and network a given corporation's structure and functions
- Understand legal basis of regulatory authorities and current developments
- Prepare for the next career step

The Pharmaceutical Development Enterprise: Current and Future Perspectives

Session Chairpersons: Fritz Bühler, MD, University of Basel and Thaddeus Grasela, PhD, Cognigen Corporation

Principles and organization of global pharmaceutical research and label-driven product development. Future directions of global pharmaceutical and health economics and business environments, and their implications for drug selection, drug development, regulatory and business evaluations. Innovation in discovery and development as a response to medical and market needs. Health economics and disease management and their application in the changing health care environment. Patenting of new chemical and biological compounds.

Lectures

- Introduction to the Principles of Contemporary Drug Development and Regulatory Science
- Development Time Lines Today and Tomorrow
- The Drug Development Deficits
- The IOM Report on ‘Drug Safety’ and FDA Science Board Subcommittee on Science and Technology Report ‘FDA Science and Mission at Risk’: Where are We Now?
- The Value of Target Product Profiles in Discovery and Development
- Overview of the Major Decision Points in Drug Discovery, Development and Regulatory Process
- What Will 2013 Look Like?
- Introduction to Model-based Development
- A Systems Biology View of Drug Development
- The Economics of New Drug Development
- Forward Perspective of Global Drug Development and the Pharma Enterprise
- Trends in Venture Capital
- What Will it Take to be a Pharma Enterprise CEO of the Future?
- The Needs of Healthcare Delivery Systems in the Future
- Comparative Effectiveness Research as the Basis for Drug Plan
- Impact of Health Technology Assessment on Drug Development and Commercialization
- How are Drugs and Biologics Paid for by Public and Private Payors in the US?
- Third-Generation Portfolio Management
- Management Science: Portfolio, Program and Project Teams

Case Studies

Target Product Profile Identification
Value Driven Pricing and Reimbursement

Teaching Faculty

Christopher Adams, PhD
Federal Trade Commission
Steve Arlington, PhD
PricewaterhouseCoopers

Teaching Faculty *(continued)*

Anthony Barrueta, JD
Kaiser Foundation Health Plan
Leslie Z. Benet, PhD
University of California, San Francisco
Fritz Bühler, MD
University of Basel
D. Bruce Burlington, MD
Independent Consultant
Patricia Evans, PhD
Independent Consultant
Ellen Feigal, MD
University of California, San Francisco
Rodney Ferguson, PhD
Panorama Capital
Mikhail Gishizky, PhD
Entelos
Thaddeus Grasela, PhD
Cognigen Corporation
Julian Gray, MD, PhD, MBA
Neuroglobe, LLC
Charles Grudzinskas, PhD
NDA Partners LLC
Fred Hom, MD
Kaiser Permanente
Kenneth Kaitin, PhD
Tufts University
Kevin Kirby, JD
The Moran Company
Teresa Musser
Rigel
Eleanor Perfetto, PhD
Pfizer
Carl C. Peck, MD
University of California, San Francisco
P. Roy Vagelos, MD
Retired Chairman and CEO, Merck & Co., Inc.

Learning Trials: From Discovery to First in Humans

Session Chairpersons: David Jacobson-Kram, PhD, DABT, Food and Drug Administration; Malcolm Rowland, PhD, DSc, DPh, MSc, FRPharmS, University of Manchester; and John Wagner, MD, PhD, Merck

Prioritizing areas of therapeutic interest and target product profile. Principles for target identification, understanding of combinatorial chemistry and drugability of new compounds. Exploring possible new drugs by means of preclinical safety and efficacy testing. The choice and the predictive value of animal testing for toxicity data as well as the principles of ADME, the possibilities and opportunities of computer assisted modeling on the way to proof of concept. The procedures and databases for pharmacovigilance and pharmacoepidemiology surveillance. Pharmaceutical engineering and choice of formulation.

Lectures

- Drug Discovery and Early Development: A Strategic Overview with a Focus on the Learning and Confirming Paradigm
- From Idea to Drug Candidate—Identifying and Validating Unprecedented Targets
- Discovery Chemistry: Building the Right Drugable Properties into the Molecule
- CMC Considerations for Selection of a Successful Drug Candidate (Drug Substance and Drug Product)
- Introduction to Drug Metabolism, Pharmacokinetics (PK) and ADME Principles
- Non-Clinical Toxicology
- Introduction to Pharmacodynamic Principles
- Planning for Successful Learn Phase
- Intellectual Property in Drug Discovery and Development
- The Regulatory Framework: Focus on the Safety Drivers for IND and CTA Submission Strategies
- The Role of Modeling and Simulation in Candidate Selection
- Strategies for Predicting Human PK
- Selection Criteria for Successful Biologics
- Preclinical Drug Development Strategies for Small Molecules
- Preclinical Drug Development Strategies for Large Molecules
- Overcoming Roadblocks to IND Initiation and Nontraditional INDs
- Determinants of Human PK Variability with Impact on Candidate Selection and Drug Development
- Pharmacogenomics and Pharmacogenetics in Drug Discovery and Development
- Experimental Models and Imaging
- The Use of Devices to Support Early Drug Development

Case Studies

Dipeptidyl Peptidase-4 (DPP-4)
Antibody X (Part I)

Teaching Faculty

Thorir Bjornsson, MD, PhD
Wyeth

Terrence Blaschke MD
Stanford University

Mary Ellen Cosenza, PhD, DABT
Amgen

David W. Feigal Jr., MD, MPH
Amgen

David Flockhart, MD, PhD
University of Indiana

Robert L. Garnick, PhD
Lone Mountain Biotechnology and Medical Devices

Michael Hale, MD
Amgen

David Jacobson-Kram, PhD, DABT
Food and Drug Administration

Diane K. Jorkasky, MD, FACP
Independent Consultant

William Kluwe, PhD
Novartis

Ismail Kola, PhD
Schering-Plough Research Institute

Christopher Lipinski, PhD
Melior Discovery

James MacDonald, PhD
Schering-Plough

Malcolm Rowland, PhD, DSc, DPh, MSc, FRPharmS, FIMA

University of California, San Francisco

David Savello, PhD
Xenoport

Nancy Sambol, PharmD
University of California, San Francisco

Nancy A. Thornberry, PhD
Merck

John Wagner, MD, PhD
Merck

Nan Wu, MD, PhD, JD
Cooley Godward and Kronish, LLP

Learning and Confirming Trials: Finding and Confirming the Right Dose

Session Chairpersons: Diane K. Jorkasky, MD, FACP, Independent Consultant and Robert Powell, PharmD, Food and Drug Administration

Strategy for taking drugs into humans and through proof of principle in patients will be detailed including preclinical prediction of humans, trial design and decisions. This phase of development emphasizes measuring change in disease, drug efficacy and safety. Generally, efficacy and safety are modulated by dose-response. Strategies for determining dose-response prospectively as well as finding individual dose-response by exploratory analysis will be described. Case studies will be presented for participants to learn these principles.

Lectures

- The Art and Science of Choosing Doses for First in Human Studies
- Developing Drugs from First in Human Dosing to Understanding Dose-response in Patients
- Proof of Concept Trials
- Learn-Apply Paradigm to Drug Development
- Adaptive Trial Designs for Dose Response, Safety and Proof of Concept
- Dose-response Evaluation Based on Pharmacokinetic and Pharmacodynamic Principles
- Considerations for the Development of Vaccines
- Fast Data, Fast Results, Fast Decisions
- Measuring Tumor Response and Predicting Outcome
- Measurement of Efficacy and Safety in Clinical Trials: An Overview of Issues
- The Business of Biomarkers: From Clinical Trials to Clinical Practice
- Implications of Pharmacogenomics and Personalized Medicine on Dose-response
- Bioinformatics Development at FDA/CDER and Beyond
- Dose-response from an FDA Perspective
- Dose-ranging in Patients in Phase 2 and 3
- Leveraging Prior Knowledge to Drive Drug Development Decisions: FDA
- Regulatory NDA Analysis for Effectiveness and Safety
- Individualizing the Dose: Right Dose, Right Patient, Right Time

Case Studies

Antibody X (Part II)
Developing an Efficacy Biomarker

Teaching Faculty

Sandra RB Allerheiligen, PhD
Eli Lilly

Donald Berry, PhD, MD
MD Anderson Cancer Center

Jogarao Gobburu, PhD
Food and Drug Administration

Marc Hovde, MBA
Pharsight

Pravin Jadhav, PhD
Food and Drug Administration

Kathrin U. Jansen, PhD
Wyeth

Diane K. Jorkasky, MD
Pfizer

Richard L. Lalonde, PharmD
Pfizer

George Mills, MD, MBA
Perceptive Informatics

Jeffrey Murray, MD, MPH
Food and Drug Administration

Robert Powell, PharmD
Food and Drug Administration

Aidan C. Power, MB BCh MRCPsych
Pfizer

Brian Smith, PhD
Amgen

Dominic G. Spinella, PhD
Pfizer

Gervais Tougas, MD
Novartis

Yaning Wang, PhD
Food and Drug Administration

Stephen Williams, MD, PhD
Decisionability, LLC

Confirmatory Trials: Methodology and Biostatistics

Session Chairpersons: Christy Chuang-Stein, PhD, Pfizer; and Robert O'Neill, PhD, Food and Drug Administration

The rationale and applications of different tests and methods of biostatistics are discussed. Various clinical trial designs, including adaptive designs will be presented and simulated, as well as considerations for within-trial decisions, data management, extraction, manipulation and storage of data.

Lectures

- Biostatistical Concepts and Principles for Confirmatory Clinical Trials
- Choice of Endpoints
- Sample Size Analysis
- Study Initiation, Trial Conduct, Investigator Interface, Data Management, Data Standards (CDISC) and Data Acquisition and Verification
- Non-inferiority Trials
- Choosing a Clinical Trial Design
- The Role of the Statistical Analysis Plan in Confirmatory Clinical Trials
- Attrition in Randomized Controlled Clinical Trials
- Exploratory vs. Confirmatory Trials
- Multiple Comparisons/Endpoints
- Statistical Issues in the Use of Imaging Technology in Clinical Studies
- Sequential Design and Analysis
- Adaptive Designs: An Overview
- Adaptive Designs: Regulatory Perspective
- Data Safety Monitoring Boards
- Safety Analysis: Points to Consider
- Meta Analysis: How to Get It Right?

Case Studies

LIFE Study
Surrogate Endpoints
Seamless Phase II/III Design

Teaching Faculty

Keaven Anderson, PhD
Merck

Alex C. Bajamonde, PhD
Independent Consultant

Scott Emerson, MD, PhD
University of Washington

Paul Flyer, PhD
Pacific Northwest Statistical Consulting

Joseph Heyse, PhD, MBA
Merck

Andrew G. Lee, MA
Genzyme

Ying Lu, PhD
Stanford University

Jeff Maca, PhD
Novartis

Ralph O'Brien, PhD
Case Western Reserve University

Robert O'Neill, PhD
Food and Drug Administration

Steven M. Snapinn, PhD
Amgen

Roy Tamura, PhD
Eli Lilly

Lu Tian, PhD
Stanford University

Joachim Vollmar, MSc
International Clinical Development Consultants

Global Registration and Approval Process

Session Chairpersons: Charles Grudzinskas, PhD, NDA Partners LLC; Murray Lumpkin, MD, Food and Drug Administration; and Frank Sasinowski, JD, Hyman, Phelps, & McNamara, PC

Overview on regulatory agencies and procedures in Europe, the US and Asia. Requirements for a regulatory application, documentation and collaboration between developers and regulators. Special regulatory pathways, strategies and crisis management.

Lectures

- The History of the Regulation of Drugs and Biologics: US, UK, Germany, and Japan
- FDA Regulatory Pathways: INDs, e-INDs, NDAs/BLA, 505(b)(1), 505(b)(2), and ANDAs
- EMEA and EU Registration Procedures: Centralized Procedure, Mutual Recognition Procedure and Decentralized Procedure
- FDA Meetings: What, Why and When?
- The Opportunity and Value of Scientific Advice in Europe
- Recent FDA Center for Drug Evaluation and Research Initiatives
- The Role of Industry Regulatory Affairs
- New Drug Review: 2009 Update and a Look Forward
- International Regulatory Cooperation
- Orphans at FDA: The Fundamentals
- Preparing Focused and Effective Regulatory Communications
- NDA/BLA Review Outcomes, Appeal Process, and Case Studies
- Mini-case Study: Oncolox
- Referrals and Appeals in the EU
- Heads of Medicines Agencies: An Overview
- EU Clinical Trial Directive
- Global Registration of Biologicals and Biosimilar Biologicals
- Medical Device Registration in US, EU, and Asia
- Developing an Integrated and Optimized Global Drug Development and Regulatory Strategic Plan

Case Studies

How to Prepare for a FDA-Sponsor Guidance Meeting
Success Factors Associated with First Cycle Approvals of NDAs/BLAs

Teaching Faculty

D. Bruce Burlington, MD
Independent Consultant

Frank Carillo
ECG, Inc.

Timothy Cote, MD, MPH
Food and Drug Administration

David W. Feigal Jr., MD, MPH
Amgen

Bruno Flamion, MD, PhD
Committee for Medicinal Products for Human Use

Charles Grudzinskas, PhD
NDA Partners LLC

Ian Hudson, MD
Medicines and Healthcare products Regulatory Agency

Sandra Kweder, MD
Food and Drug Administration

Malcolm Lloyd-Smith, MSc
Cadence

Murray Lumpkin, MD
Food and Drug Administration

Xavier Luria, MD
European Medicines Agency

Frank Sasinowski, JD
Hyman, Phelps, & McNamara, PC

Integrated Product Development Strategy, Execution and Project Management

Session Chairpersons: Charles Gombar, PhD, Wyeth; William Hewitt, PhD, Centocor and Patricia Evans, PhD, Covalence Capital

Principles of project and portfolio management, including aspects of planning, project evaluation and decision making. Management structures and organization of clinical development. Team work and performance assessment. Interaction between project teams and business. How to place a new drug successfully into the market.

Lectures

- Basic Principles of Portfolio Management
- Decision Analytics Tools and Techniques
- Decision Making
- Capacity Planning and Implications for Portfolio Management
- Setting the Goals: The Target Product Profile
- Strategic Marketing Role in Research, Early and Late Development
- The Target Product Profile: FDA View
- Turning Strategy into Plans and Tactics
- Team Dynamics
- Working Globally (How to Make 24/7 Work)
- Life Cycle Strategy
- How Will Pharmaceutical Product Life Cycles be Changing?
- How Do We Launch a Product?
- Role of Licensing in Portfolio Management

Case Studies

- Risk Management
- How to Build an Economic Value Case in Development

Teaching Faculty

D. Bruce Burlington, MD
Independent Consultant

John Celona, PhD
Independent Consultant

Charles Gombar, PhD
Wyeth

Patricia Evans, PhD
Covalence Capital

Others to be confirmed

State-of-the-Art Lectures

Principles of patho-physiology and clinical pharmacology of important diseases, state-of-the-art information on pharmacotherapy and new therapeutic approaches. These topics are intimately interwoven with pharmaceutical medicine and are distributed over the six course sessions.

Frontiers in Drug Development and Regulatory Science Series – 4th day of each session 1-5

On Day Four of each ACDRS session 1 through 5, one-day workshops on new trends and developments in medical development science is offered. These workshops are a mandatory part of our Course and in addition, are also open to other interested professionals. These workshops provide flexibility for introducing contemporary topics into the curriculum.

Session 1 – “Meeting the Regulators”, Chairperson: D. Bruce Burlington, MD, Independent Consultant

Lectures

- FDA’s Critical Path Initiative
- EMEA 2010 Roadmap Initiative
- Impact of the Institute of Medicine Report, 2007 FDAAA Legislation, and Emerging Safety Tools
- A Current Comparison of US, Europe, and Asia Regulatory Systems for New Drug Approvals
- Stumbling Blocks in European Regulation
- How We Need to Understand Drug Benefits and Balance Risks
- US Good Review Management Practices, Regulatory Interactions, and Submissions over the Next Five Years
- Industry View on Today’s Regulation

Teaching Faculty

Alasdair Breckenridge, FRSE, FMedSci
Medicines and Healthcare products
Regulatory Agency

D. Bruce Burlington, MD
Independent Consultant

Hans-Georg Eichler, MD
European Medicines Agency

David W. Feigal Jr, MD, MPH
Amgen

Judith Jones, MD, PhD
The Degge Group, Ltd

Malcolm Lloyd-Smith, MSc
Cadence Pharmaceuticals

Jeffrey N. Siegel, MD
Food and Drug Administration

Raymond L. Woosley, MD, PhD
Critical Path Institute

Session 2 – “New Therapeutics: Beyond Small Molecules”, Chairpersons: David W. Feigal, Jr., MD, MPH, Amgen and D. Bruce Burlington, MD, Independent Consultant

Lectures

- Update on Hot FDA Issues in 2009
- Controversies in In Vitro Diagnostics
- Case Studies in Combination Products
- Follow-on Biologics
- Vaccine Safety: An FDA Perspective
- Perspectives on the Development of Medical Devices
- Challenges in Medical Device Development and Approval

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Session 2 (continued)

Teaching Faculty

D. Bruce Burlington, MD
Independent Consultant

James Casella, PhD
Alexza

Andrew Farb, MD
Food and Drug Administration

David W. Feigal Jr., MD, MPH
Amgen

Thomas Fogarty, MD
Fogarty Institute for Innovation

Alberto Gutierrez, PhD
Food and Drug Administration

Henry Klyce
Spartek

Alan Kugler, PhD
Coastal Pharma Group

Bruce F. Mackler, PhD, JD
Independent Consultant

Andrea Sutherland, MD, MSc, MPH
Food and Drug Administration

Session 3 – “Special Populations, New Challenges and the Future”, Chairpersons: Diane K. Jorkasky, MD, FACP, Independent Consultant; and Robert Powell, PharmD, Food and Drug Administration

Lectures

- Overview of Special Populations: Issues to Consider and a Case Example
- Special Populations: Age from 0-120 Years
- End Organ Dysfunction: Focus on Renal Impairment
- Understanding the Impact of Potential Drug - Drug Interactions: Not Just a Bioequivalence Exercise
- Nanostructured Interfaces for Therapeutic Delivery
- BioMEMS/Lab on a Chip and Biosensors
- Panel Discussion on Developing New Technologies Safely and Effectively

Teaching Faculty

Andrew T. Chow, PhD
Amgen

Tejal Desai, PhD
University of California, San Francisco

Carl C. Peck, MD
University of California, San Francisco

Marc Pfister, MD, FCP
Bristol-Myers Squibb

Robert Powell, PharmD
Food and Drug Administration

Shuvo Roy, PhD
University of California, San Francisco

Kellie Schoolar Reynolds, PharmD
Food and Drug Administration

Session 4 – “The Risk-Benefit-Value Equation”, Chairperson: James Cross, PhD, University of Washington

Lectures

- Risk Evaluation and Mitigation Strategies (REMS): FDA, Industry and Patient Perspectives
- Quantifying Pharmaceutical Benefit-Risk: Promises and Perils of Proposed New Methods
- Patient-Benefit Risk Preferences for New Pharmaceuticals: A Case Study of Maximum Acceptable Risk and Minimum Acceptable Benefit
- Epidemiological Approach to Benefit/Risk Assessment (including post marketing and registrational trials)
- Valuing Drug Benefits and Risks from a CMS Perspective: Future Trends in Medicare Coverage and Reimbursement
- Insights on US Payer Process for Product Valuation
- A European Perspective on Product Value and Coverage Decisions
- Panel Discussion

Teaching Faculty

H. Michael Arrighi, PhD, MSPH
JANSSEN Alzheimer Immunotherapy

Wade M. Aubry, MD
Center for Medical Technology Policy

Jane A. Axelrad, JD
Food and Drug Administration

John FP Bridges, PhD
Johns Hopkins Bloomberg School of Public Health

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Session 4 (continued)

James Cross, PhD
University of Washington

Robert Erwin, MS
Marti Nelson Cancer Foundation

Rekha Garg, MD, MS
Amgen

Thomas Szucs, MD, MBA, MPH, LLM
University of Basel

John B. Watkins, RPh, MPH, BCPS
Premera Blue Cross

Session 5 – “Adherence in Drug Development and Regulation and Physiologically Based Pharmacokinetics”, Chairperson: Carl C. Peck, MD, University of California, San Francisco

Lectures

- Introduction to Adherence - Definitions, Methods, Patterns in Clinical Trials
- Consequences of Variable Adherence in Clinical Trials and Clinical Medicine
- Implications of Variable Adherence in Drug Development and Regulation and in Comparative Effectiveness Research
- Principles of Physiologically Based Pharmacokinetics (PBPK), Illustrated by Use in Risk and Safety Assessment
- PBPK Applications in Drug Development
- PBPK Applications in New and Generic Drug Regulation

Teaching Faculty

Terrence F. Blaschke, MD
Stanford University

Harvey J. Clewell III, PhD, DABT
The Hamner Institute for Health Sciences

Robert Lionberger, PhD
Food and Drug Administration

Carl C. Peck, MD
University of California, San Francisco

Geoffrey T. Tucker, BPharm, FRCPE, FRCA, FFPM, FBPharmacolSoc, FBToxicolSoc
University of Sheffield and Simcyp Ltd.

John Urquhart, MD
University of California San Francisco and AARDEX Group

Bernard Vrijens, PhD
AARDEX Group

Ping Zhao, PhD
Food and Drug Administration

Session 6 – Examination for Certification

Course Documents

On the first day of each course session participants will receive a course notebook at the registration desk containing the final program, and documents for each lecture and case study. In general, the documents include a summary, a reference list, and slides of each lecture. Students are personally responsible for preparing for the final examination. Student evaluation forms are also provided for the course, faculty, and assessment of facilities.

Learning Methods

The learning process of the course includes didactic teaching and places a great emphasis on interactive participation. Each session includes the following activities:

Lectures

State-of-the-art lectures and updates on important drug, device, diagnostic and therapeutic areas and issues. These will be followed by in-depth discussions.

Case Studies

Participants work in small interdisciplinary teams on “real-life cases.” Problems are analyzed and discussed together with faculty members. Participants try to reach a common strategy, which is then presented and defended in a round-table discussion. Prior to each course session participants will receive the pertinent case studies and background literature. We expect participants to read the material in advance, in order to be able to spend the time discussing the problem.

Examination and Certification

The University of California, San Francisco will award a Course Certificate to participants who successfully complete a two-year course cycle and pass the final (multiple-choice) examination.

Continuing Education Credit

The University of California, San Francisco (UCSF) School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians .

This course is eligible for ACPE credit. Please see final announcement for specific details.

Venue

The ACDRS 2008-2010 is to be held at the Mission Bay Conference Center at UCSF (1675 Owens Street, San Francisco, CA 94158). The Mission Bay Conference Center at UCSF is located on UCSF's new 43-acre life sciences campus for teaching and research, located just south of downtown San Francisco and convenient to the Bay Area. A parallel ACDRS 2007-2009 is held at the University of California, Washington Center in Washington, DC.

Tuition Fee

The early bird tuition fee is \$15,000 (\$625–per day, \$2500 per session with six sessions over two years). A discounted fee for a limited number of participants from academia and government is available, please contact jaimе.kenyon@ucsf.edu. The fee for this nonprofit, academically based course is inclusive of course material, lunches, coffee breaks and final examination. It does not include other meals or accommodations.

The entire tuition fee is payable at time of registration [The payment may be made in two installments, first payment at time of registration and second payment by July 30, 2009.]

In case of cancellation before August 1, 2008 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.

A block of hotel rooms has been reserved, and participants will be responsible for booking and transportation.

Registration

Registration can be done via the internet at <http://bts.ucsf.edu/acdrs>. As enrollment is limited, prospective participants are encouraged to register well in advance.

Contact

Please contact Dr. Ellen Feigal, ACDRS Director, ellen.feigal@ucsf.edu for questions about the ACDRS content and curriculum or contact Jaime Kenyon, ACDRS Program Manager, jaimе.kenyon@ucsf.edu for questions about ACDRS logistics.

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