Overview
Existing Training Programs in Regulatory Science

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NDA Partners LLC
UCSF-CDDS 2011
Acknowledgments & Apology

- **FDA (CDER)**
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- **ACDRS**
  - Ellen Feigal, Charles Grudzinskas, Fritz Buhler

- **ECPM (U. Basel):**
  - Professor Fritz Buhler, Anette Mollet, Thomas Szucs

- **Apology:** Training programs missed in my survey

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Key Findings

• Distinction between training in Regulatory Science (RS) and Regulatory Research (RR)

• Many RS training programs

• Few RR training programs

• Incentives needed to support & expand RR programs
Distinctions

• FDA: “Regulatory Science is the *science* of *developing* new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.”

• What is regulatory “Science”?
  – … concerns drug and diagnostic product regulations, standards, law and procedures
  – … a systemized body of knowledge (practiced by FDA et al) comprising public protection-oriented medical product regulations, policies and decisions using scientific in the evaluation and approval of regulated
    • “Regulatory Affairs”, “Pharmaceutical Medicine” are overlapping skillsets

• Regulatory Research – investigation and ‘development of new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.’

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“FDA University”
Regulatory Research and Training

• Research
  – 1987: CDB → CDER/CBER
  – 1989: 21 C.F.R. § 312.86 ”Focused FDA regulatory research”:
    • At the discretion of the agency, FDA may undertake focused regulatory research on critical rate-limiting aspects of the preclinical, chemical/manufacturing, and clinical phases of drug development and evaluation.
    • Early examples: …, CYP3A4 DDI’s & TdP, RCCT’s, popPKPD trial simulations
    • Recent: Critical Path Consortia, OCP PBPK @ multiple DDI’s, warfarin dosing
    • > 1000 publications 2009-11

• Training
  – 1989 CDER Staff College, Committee on Advanced Scientific Education
  – 1996 CDER Competency Program: courses, collaborations, professorships
  – 2011 CDER Federated Training Model: customized competency training and career development enterprise
    • Outreach: CDERLearn, ORA University
  – Commissioner’s Fellowship Program

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Training Programs in Regulatory “Science”

• Certificate Courses
  – PERI, RAPS, NIH Clinical Pharmacology Course
  – ECPM, UCSF ACDRS, CCDRS

• Degree Programs
  – **MS (n = 14+):** Temple U, U Maryland, USC, San Diego State U, San Jose State U, ASU College of Nursing, Johns Hopkins Center Bioscience Education, Northeastern U, GWU, U Florida FDA/CDER MS Program, U Wales, U St. Thomas Minnesota, Cranfield U, U Liverpool, …
  – **PhD (n=2):** USC Regulatory Science Doctorate, U Liverpool Centre for Drug Safety Science
• ACDRS\textsuperscript{1}, public university sponsored, non-profit, launched 2007

• Developed by UCSF, School of Pharmacy, DBS, CDDS - collaborating w/FDA, companies, ECPM Basel, US universities and societies

• **Mission:** Modernize development and regulation of medical products that integrates cutting-edge concepts and best practices in medical product development and regulatory sciences
  – through a certified, comprehensive instruction
  – Part of a global family internationally – Europe (Basel, Switzerland), US (Wash DC and SF, CA), Asia (China)

\textsuperscript{1} Director: Louis Cantilena, USUHS

UCSF-CDDS 2011
• @ UC Washington, UCSF Mission Bay SF
• Faculty: 120 experts @ industry, FDA/EMA, academia
• Participants (n=180)
  – MD, PharmD, PhD w/2-15 yr @ industry, FDA, academia
  – Current DC course: 32 FDA, 38 industry/academic
• Training method: 6 x 4-days of lectures, case studies, 3-hr Final Exam
• Content:
  – Principles, tools, practices of drug development & regulatory sciences

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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 – San Francisco
- Course begins October 25, 2010
- Mission Bay Conference Center at UCSF, San Francisco, CA
- 2-year certificate program, 6 sessions

Class of 2011-2013 – Wash DC
- Course begins Fall, 2011
- UCDC Washington Center
- 2-year certificate program, 6 sessions

Presented by:
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 concluded in June 2010.

SESSIONS

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

MORE INFORMATION

For details about the program and registration go to http://bts.ucsf.edu/acdrs/
Training for Regulatory “Research”

- **University programs**
  - University pharmaceutical science, clinical pharmacology, clinical investigator, NIH Fellowships
  - U Liverpool Centre for Drug Safety Science
  - UCSF *CDDS*

- **FDA**
  - Commissioners Fellowship
  - Collaborating Centers of Excellence in Regulatory Science and Innovation (U01)
Center for Drug Development Sciences (CDDS)

• **Launched** 1994 Georgetown University
  – Moved to UCSF, in DC & SF in 2004

• **Programs**
  – **Research**: pharmacometrics, trial simulations, regulatory pathways and evaluation, dosage optimization
  – **Training**: post-doc fellowship (20 trainees, large % worked or work at FDA)
  – **Technical Assistance**: biopharmaceutical, government development projects
  – **Policy Research**: FDAMA (section 115a), guidance commentaries

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Challenges
Advancing Academic Regulatory Research

• Missing incentives
  – Recognition, respect, academic homes,
  – Funding

• Qualifications
  – Definition
  – Experience – research, regulatory
  – Research training
Key Findings

• Distinction between training in Regulatory Science (RS) and for Regulatory Research (RR)

• Many RS training programs

• Few RR training programs

• Incentives needed to support & expand academic RR programs