UCSC Extension
Clinical Trials and Regulatory Affairs Certificate Program Overviews

SARP Meeting
September 25, 2007

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About UCSC Extension

• **Who**: The continuing education arm of the University of California Santa Cruz

• **Mission**: To provide a broad range of high-quality continuing education programs for professional development

• **Student population**: Well-educated professionals from a wide range of disciplines
Bioscience Programs at UCSC Extension

Discovery and R&D

Biotechnology

Bioinformatics

Preclinical

Clinical

Clinical Trials Design & Management

Regulatory Submission

Regulatory Affairs

Bioscience Business & Marketing

To Market and Beyond
UCSC Certificate Programs of Relevance to the Bioscience Industry

- Bioinformatics
- Biotechnology (includes Devices)
- Bioscience Business and Marketing
- Clinical Trials Design and Management
- Environmental Health and Safety
- Regulatory Affairs

*Plus many other courses that can improve important skills, including leadership, project management, and communication.*
What are Certificate Programs?

• Focused, cohesive and documented study in particular subject areas
• Development guided by key academic and industry stakeholders
• Career-specific, professional and practical
• Flexible in schedule, content and structure
How Do Certificate Programs Differ from Master’s Degrees?

• M.S. programs typically require more units than the corresponding certificate programs
• M.S. programs often have formal admissions requirements; certificate programs usually only have recommended prerequisites or backgrounds
• M.S. programs in CT and RA have “soft skill” components (leadership, negotiation, communication) in addition to clinical and regulatory content
Certificate ≠ Certification

- Certificates are awarded to students upon satisfactory completion of their coursework in the certificate program; however, this doesn’t mean they are “certified”
- Certification in RA requires the passage of the RAC exam administered by (RAPS); ACRP and SoCRA administer exams for clinical research professionals
Format of Certificate Programs

- Certificate Programs consist of a series of **required courses** and a wide range of **electives**.
- Students can select electives to **customize a program** to satisfy their specific needs and interests.
- Instructors use a combination of lectures, cases studies, and hands-on exercises to convey concepts.
- Student learning is evaluated through examinations and assignments (papers, team exercises, and projects).
Clinical Trials Design and Management Certificate Program
Certificate in Clinical Trials
Design and Management

• Developed for the biotech, pharmaceutical, and device industries and clinical research study sites
  – *Yields a pool of trained applicants for understaffed positions in a growing industry*

• Designed to help professionals gain a solid understanding of the entire clinical trials process
Certificate in Clinical Trials Design and Management

- The certificate program was launched in 1999
- To date, ~300 students have successfully completed the program, 200 have applied for candidacy, and a large number of other students have taken courses but have not yet declared
- Program takes from 8 months to a maximum of three years to complete
Certificate in Clinical Trials Design and Management

- Provides professional and *practical* training
- Yields documentation of formal education in this field
- Increases job skills and knowledge for current position
- Facilitates career change
Program Benefits

- Provides a foundation in drug development
- Helps to broaden understanding of the entire clinical trial process
- Provides a solid understanding of the principles, regulations, and practices central to the conduct of clinical research
- Builds skills needed in clinical research positions
Program Benefits, continued

- Results in the development of portfolio of work
- Courses provide CEUs for recertification of clinical research professionals (CCRAs and CCRCs) and BRN-approved CE hours for nurses
- Provides important networking opportunities
Target Audience

- CRAs, CRCs
- Physicians and medical directors
- Biomedical and research scientists
- Nurses and allied health professionals
- Statisticians and database administrators, SAS Programmers
- IRB members and administrators
- Pharmacists
Program Structure

- Recommended Prerequisites:
  - Medical/Clinical Terminology (7 hours)
  - Human Physiology in Health and Disease (30 hours)
- 6 required courses (141 hours)
- 60 hours of electives (6 quarter units)
- Students must complete all of the required and elective courses with an overall GPA of 3.0
Required Courses

- Drug Development Process (30 hours)
- Medical Devices: Regulatory Strategies and Pathways to Market (15)
- Good Clinical Practices (30)
- Science of Clinical Trials Design (24)
- Clinical Trials Site Monitoring I (24)
- Clinical Statistics for Non-Statisticians (24)
Drug Development Process
(24 hours/2 units)

- The scientific processes involved in the discovery and nonclinical development of new drugs
- How drug candidates are selected for advancement into clinical studies
- The phases of clinical evaluation of new drugs
- The regulations guiding new drug development and the role of the FDA and international bodies in the process
Good Clinical Practices
(30 hours/3 units)

• The principles, guidelines, and regulations that govern clinical research in the US and abroad
• The primary resources for GCP (21 CFR and the ICH Guidelines)
• The ethical principles that underlie GCP
• Informed consent
• The responsibilities of the sponsor, investigator and IRB
Science of Clinical Trials Design
(24 hours/2 units)

• The structure and goals of each phase of a clinical trial
• The various clinical trial designs and their applications
• The ethical, regulatory, statistical, and marketing considerations in the design of a trial
• Key elements of a protocol
• Interpretation of clinical trial results
Clinical Trials Site Monitoring I
(24 hours/2 units)

• The regulatory requirements for monitoring a clinical research site
• Tools, methods, objectives, and parameters of site monitoring
• Site and investigator selection
• Preparation, conduct, and follow-through activities for key monitoring visits, including pre-study, site initiation, and close-out
Electives

• 60 hours of electives are required
• Students select electives based on their interests, backgrounds and career goals to create a program that meets their needs
• A wide range of electives are offered every term
Sample Electives

- Clinical Trials Site Monitoring II
- Case Report Form Development
- Document Preparation: Protocols, Reports, Summaries
- Preparing for FDA Inspections and Sponsor Audits
- Ethical Issues in Biotech
- Contracting with Contract Research Organizations
- Clinical Project Management
- Drug Safety and Adverse Events Reporting
- Development of Clinical Standard Operating Procedures (SOPs)
- Preclinical Development and Discovery of New Drugs
Clinical Internship Program
Why an Internship Program?

• The certificate program provides a strong theoretical foundation and some opportunity for hands-on exploration with case studies, and exercises, but…

➢ students and potential employers value the real-world experience that an internship can provide.
Internship Partnership with Stanford

• Launched in Fall 2004 as a pilot program with 4 interns who were recent UCSC Extension certificate program graduates
• Preceptors from infectious diseases (AIDS), oncology, dermatology, anesthesia, pulmonary, psychiatry and critical care departments
• Since 2004, four successful rounds of internships have been completed.
Internship Program: Eligibility and Requirements

• Students need to have completed the six required courses with a minimum GPA of 3.0 to be eligible

• To apply, students must submit:
  ► Application Form  ► A statement of purpose
  ► Current CV or resume  ► Two letters of reference

• Once selected, interns must submit medical screening, non-disclosure, liability waiver, and program responsibilities agreement and complete Stanford’s regulatory trainings
Internship Program: Structure

• The internship is **unpaid** and has some associated fees
• Interns spend **60 hours** in the clinical setting over the course of **12 weeks** (with some scheduling flexibility)
• Interns are required to enroll in an accompanying **seminar course** and attend regular sessions to discuss topics of relevance to the internship
Internship Program: Structure

- Certain restrictions are placed on internship activities
- A communication structure is set up to help insure that the goals of the program are set forth and the needs of all stakeholders are being met throughout the internship
- Intern/preceptor pair establishes detailed goals at the outset and activities are recorded throughout
- At the conclusion of the internship, interns submit an internship-related project to course instructor.
- Reciprocal evaluations are submitted by preceptors and interns
Internship Activities

Interns gained valuable exposure to:

• Protocol and IB review
• IRB process and interactions
• Study set-up
• Patient recruitment and interactions
• Informed consent
• Data entry

• QA audits of data
• CRFs and regulatory documents
• Adverse event documentation
• Safety monitoring activities
• Monitoring visits
• Drug accountability
• Study close-out activities
Intern Feedback

• Very satisfied with interactions with the preceptors and the breadth of their experiences at Stanford
• Valued seeing how coursework mapped to the realities at a clinical site and appreciated the breadth of their experience at Stanford
• Appreciated the level of detail, complexity and organization central to the activities at a clinical study site
• Gained insight into the myriad well-orchestrated interactions required in the conduct of clinical trials
• Had increased confidence in their abilities and job searches
Regulatory Affairs Certificate Program
Where do regulatory affairs professionals fit in?
What do RA Professionals Do?

• The job responsibilities of regulatory affairs professionals are **broad and varied** and span the **entire life cycle** of a biomedical product--from development until long after the product is approved for the market.

• Regulatory professionals are often thought of as the **conscience of their organizations**, combining their knowledge of the **laws and regulations** with strong ethical grounding.
What do RA Professionals Do?

- Company **liaison** with regulatory authorities
- Develop corporate **global regulatory strategy**
- Ensure **compliance** with laws and regulations throughout the development, manufacture and commercialization of biomedical products
- Gather and **analyze** regulatory information and monitor the regulatory climate
- **Educate** company personnel at all levels about regulatory requirements and strategy
What do RA Professionals Do?

• Write pre-market and marketing applications for submission to regulatory authorities
• Plan/conduct meetings with regulatory agencies
• Review and approve product labels and inserts
• Review marketing literature, publications and advertising
• Implement and audit quality systems
• Investigate, trend and report on complaints, withdrawals, recalls and field corrections
• Submit required reports to the regulatory authorities
Where do RA Professionals Get Training?

- On the job
- Individual courses offered by academic institutions, professional societies, training organizations
- Formal programs:
  - Certificate programs
  - Master’s Degree programs
The Regulatory Affairs program provides:

- An understanding of the **complex processes** involved in developing and bringing new medical products to the marketplace

- In-depth exposure to the **laws and regulations**, both US and international, that govern the testing, manufacture, and distribution of medical devices, diagnostics, pharmaceuticals and biologics
Regulatory Affairs Certificate

• **Hands-on** experience with the **documentation** required to gain new product approval and to maintain product surveillance
• An understanding of key aspects of working with regulatory agencies
• Grounding in the ethical, management and **professional competencies** needed to be effective in regulatory roles
Regulatory Affairs Certificate

Target Audience

• Entry- and mid-level regulatory affairs professionals
• Professionals interested in pursuing a career in RA, including those with the following backgrounds:
  – Clinical
  – Engineering
  – Manufacturing
  – Medical and allied medical
  – Quality
  – Law
  – Science (including bench scientists)
Regulatory Affairs Certificate

Curriculum

• **7 required courses** address regulatory fundamentals including:
  • Regulations
  • Submissions
  • Compliance
  • Professional competencies

• *All* students gain some exposure to drug, biologic, device and diagnostic regulations
Regulatory Affairs Certificate

Required Courses

Drug Development Process
Regulation of Medical Devices and Diagnostics
Regulation of Drugs and Biologics

**DRUG/BIOLOGICS TRACK**

- Regulatory Submissions: Drugs and Biologics
- Good Manufacturing Practices

**DEVICE TRACK**

- Regulatory Submissions: Devices
- Regulatory Compliance for Medical Devices

Interacting with the FDA
RA Professional’s Toolbox
Regulatory Affairs Certificate

Electives

• 4 units (40 hours) of electives must be completed for the certificate

• Electives can be selected from:
  – Remaining compliance and submission courses
  – Regulatory electives
  – Selected electives from the clinical trials and biotechnology programs
Medical Device-Related Courses

• Medical Device Design and Development
• Regulation of Medical Devices and Diagnostics
• Regulatory Submissions: Devices and Diagnostics
• Regulatory Compliance for Medical Devices
• Value-Added Quality Audits

Plus many other software and hardware courses
Thank you!
Questions? Please contact me:

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