RUTGERS IJOBS WORKSHOP REGULATORY WRITING

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Rutgers School of Health Professions

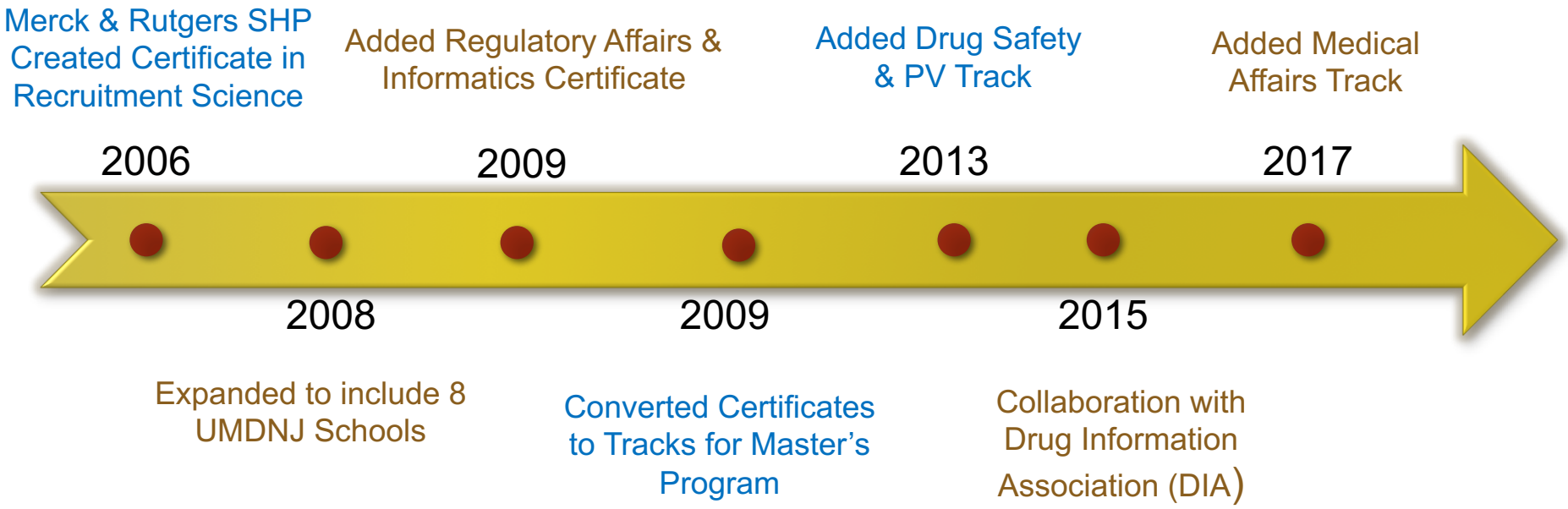
WORKSHOP AGENDA

- 5:30 Welcome
  - Introduction to Biopharma Educational Initiative
  - What is regulatory writing?
- 5:45 Panel Discussion Regulatory Writing Professionals
- 6:30 Dinner
  - AMWA Introduction
  - Lecture on “Writing an Investigator Brochure”
- 7:15 Hands-On Activity: Build an Investigator Brochure

Rutgers Biopharma Educational Initiative

is an Industry-University collaboration that provides online web-based education to those individuals who are either working in, or desire to join, the biopharmaceutical workforce

Industry-University Collaboration Timeline



Rutgers School of Health Professions

Master's Degree in Clinical Trial Sciences

On-line Web-based Program

Total of 36 credits

Core Content (9 credits):

- Clinical Trial Overview: Methods and Practice
- Regulatory and Ethical Requirements
- Capstone Course or Evidenced Based Literature Review

4 Specialization Tracks (27 credits):

- Management and Recruitment
- Regulatory Affairs
- Drug Safety and Pharmacovigilance
- Medical Affairs

Courses in each Specialization Track

Clinical Trial Management and Recruitment

- Biomedical Informatics for Clinical Trials
- Multiple Analyses in Clinical Trials
- Overview of Disease Process and Treatment
- Applied Clinical Trials & Good Clinical Practices
- Principles of Subject Recruitment and Retention
- Clinical Operations
- Project Management

Medical Affairs

- Practice of Medical Affairs
- Strategy, Insight Generation and Patient Strategy
- International Regulatory Affairs
- Overview of Disease Process and Treatment
- Applied Clinical Trials & Good Clinical Practices
- Special Topics in Clinical Trial Science
- Scientific Writing for Translation of Medicine

Drug Safety and Pharmacovigilance

- Overview Disease Process and Pharmacology
- Principles of Pharmacovigilance
- Adverse Events Reporting and Post marketing
- Analyzing Adverse Events in Clinical Trials
- Risk Management Tools
- Pharmacoepidemiology
- Signal Detection and Quantitative Benefit-Risk

Regulatory Affairs

- Multiple Analyses in Clinical Trials
- Concepts of GxPs and Quality Assurance
- Regulatory Writing for Submissions and Publications
- International Regulatory Affairs
- Advertising and Labeling of Pharmaceuticals
- Regulatory Requirements for Medical Device
- Adverse Events Reporting and Post marketing

Rutgers School of Health Professions

Biopharma Certificate

On-line Web-based Program

Total of 15 credits

Recruitment Sciences Core (9)

- Regulatory and Ethical Requirements
- Overview of Disease Process/Treatment
- Subject Recruitment and Retention

Regulatory Affairs Core (9)

- Regulatory and Ethical Requirements
- Clinical Trial Overview
- Adverse Event Reporting/Post-Marketing

Drug Safety and PV Core (9)

- Regulatory and Ethical Requirements
- Adverse Event Reporting/Post-Marketing
- PV Regulations and Reporting

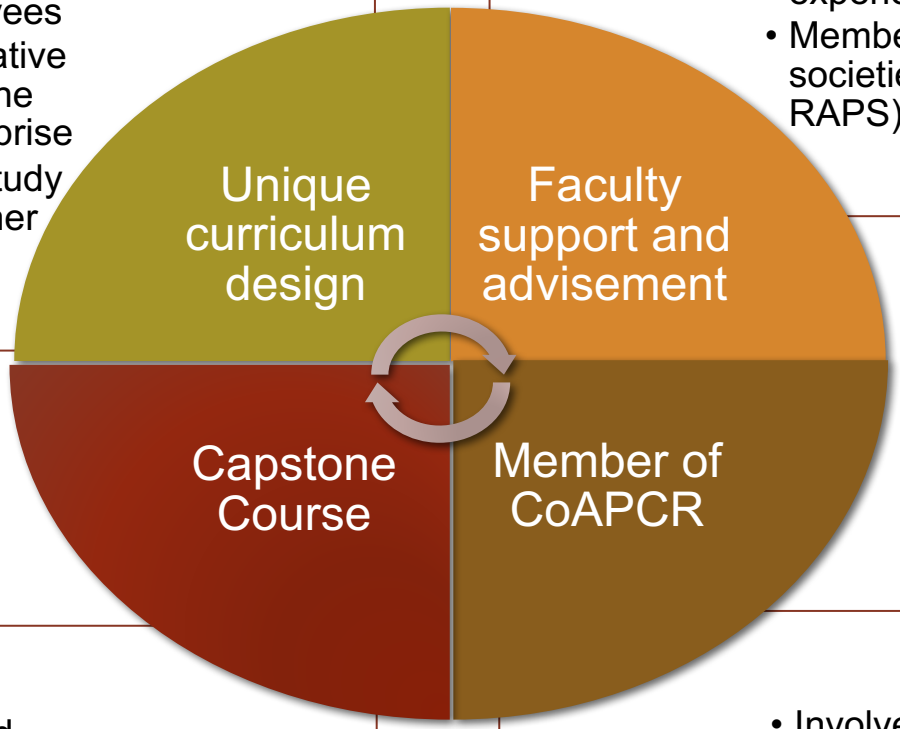
PLUS 2 approved electives of your certificate specialty

Non-matriculated and Certificate students

Why is this Program Unique?

- Program goals vary depending on track
- Flexible for full-time employees
- Electives taken from alternative tracks so fully understand the breath & depth of the enterprise
- Mode of study is directed study (emphasizes what the learner does vs. stressing what the professor teaches)

- Come from pharmaceutical companies and bring real-life experience
- Members of professional societies (ACRP, DIA, SOCRA, RAPS)



- Face to Face or remote field mentorship experience

- Involved in writing accreditation standards for academic programs

WHAT IS REGULATORY WRITING?

Regulatory Writing

Preparation of a wide variety of clinical documents throughout the life-cycle of a (potential) treatment

Describe and report data from clinical trials through preparing regulatory submissions documents

After treatment is approved by a regulatory authority post-approval reports on the use of the treatment in patients.

Examples of clinical documents

- Investigator Brochures (IBs)
- Clinical Study Protocols
- Clinical Study Reports (CSRs)
- Integarted Summaries of Safety(ISS) and Efficacy (ISE)
- Common Technical Document (CTD), The audience for these documents are usually regularity authorities and ethics committees.

What do Regulatory Writers do?

- Add value in the production of clinical study documentation required by national regulatory agencies when assessing the safety and efficacy of drugs
- Act as a pool of knowledge at every step, from protocol development to the drug submission process.
- Skilled indivduals of global regulatory requirements and adhering to guidance's such as International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines, while still fulfilling the needs, preferences and styles of sponsors/study teams.
- Understand, interpret, and summarize complex scientific and statistical data while providing effective guidance to clinical study teams, which usually include experts from other fields such as clinical/medical, statistics, regulatory affairs, pharmacovigilance and pharmacology.
- Experts in a particular therapeutic area or disease and can provide invaluable insights to the sponsors/study teams.
- Proof read and provide editorial support on documents produced by sponsors/study teams.

Do you have the Skills ?