SEMINAR IN BIOTECHNOLOGY DEVELOPMENT AND REGULATION (BIOT W4201)

Advanced Topics in Research, Medical, and Commercial Biotechnology Development

Course Objectives:

This course will provide a practical definition of the current role of the Regulatory Professional in pharmaceutical development, approval and post-approval actions. This will be illustrated by exploration, and interactive discussion of regulatory history, its evolution, current standards and associated processes. The course will seek to clarify the role of Regulatory in development and lifecycle opportunities, demonstrating the value Regulatory adds by participation on research, development and commercial teams.

The course will utilize news aggregation as well as weekly case studies to provide color to current topical events related to the areas detailed below.

It is essential to note that as a Topical Seminar the class will by design focus on the most current and timely topical content

Module 1: Standards of Approval and Product Assessment

- Regulatory Affairs: A working definition
- Role of RA in the product life cycle
- Timeline of regulatory evolution
- Current base standards
- Regulatory history
- Starting your investigation : A primer
- The NDA: Getting your drug approved
- Regulatory Assessment: Mitigating issues – predicting regulatory success
- The Product Profile
- Novelty, Benefit and Risk
- The Regulatory Professional as Strategist

Module 2: Key Regulatory Meetings and Interactions

General:

- Who goes to regulatory meetings, and why?

- When to consult a regulatory agency
- Verbal or Written Communications

FDA:

- Pre-IND Meeting
- End of Phase 2 Meeting
- Pre-NDA Meeting
- Labeling Discussions
- Advisory Committees
- Special Protocol Assessments

EMEA:

- The EU Review Process
- MAA and Variations
- What/Who is CHMP?
- What/Who is the Rapporteur?
- Referrals and Assessments

Japan:

- MHLW/PMDA

Module 3: Regulatory Pitfalls in Lifecycle Management

The Lifecycle Process: Pharmaceutical's Never-Ending Story

- The lifecycle process redux
- Regulatory failure and innovation costs
- Historical basis to regulation that affects lifecycle.
    - Pre-Investigation
    - IND/CTA
    - NDA/MAA
    - Post-approval
    - Regulatory climate changes
    - New 21st Century standards
- Finding the fatal flaws, hidden risks, hidden problems
- What can increase our success

Module 5: Translating Data into Promotional Messages

The Ground Rules:

- Global Standards of Approval
- Worldwide regulations
    - Advertising and promotion
    - CME
    - Pre-approval

Perspectives:

- How can we communicate data pre-approval (drug in development or new indication for approved product)?
    - Safe harbors
- International
    - National regulator oversight
    - Considerations for data presentation outside the US
    - Relative values of an approved indication versus a publication
    - Complaints
- FDA
    - Examples of recent NOV and Warning letters
    - Enforcement (fines, sanctions, etc)
- The Advertising Agency viewpoint
    - Translating data into promotional materials

Module 6: Regulatory Rapid Response, and Compliance Actions

- Marketing Application Queries
- Product Issues
- Recalls
- Inspections
- Enforcement Actions
- Crisis Management and Communication

Module 7: Licensing and Due Diligence

- Regulatory oversight of business development activities
- Data review and assessment