Phar 651: Regulatory Science I

Pharmaceutics & Drug Delivery

This course involves practical and theoretical principles involved in regulatory approvals of pharmaceutical products, and compliance requirements related to the development and manufacturing of pharmaceutical products. Emphasis is placed on Chemistry Manufacturing and Control (CMC) documents contained in regulatory submission packages and major FDA and ICH guidance documents applicable to product development, manufacturing, post-approval changes, and quality assurance. Guest lecturers with expertise in regulatory science will provide the students with the opportunity to discuss problems relevant to the industry. The course will require students to critically review and present publications in small groups and conduct other assignments.

3 Credits

Instruction Type(s)

- Lecture: Lecture for Phar 651

Subject Areas

- Pharmaceutical Sciences

Related Areas

- Clinical and Industrial Drug Development (MS, PhD)
- Industrial and Physical Pharmacy and Cosmetic Sciences (MS, PhD)
- Medicinal and Pharmaceutical Chemistry
- Natural Products Chemistry and Pharmacognosy (MS, PhD)
- Pharmaceutical Marketing and Management
- Pharmaceutics and Drug Design (MS, PhD)
- Pharmacoeconomics/Pharmaceutical Economics (MS, PhD)
- Pharmacy (PharmD - USA - PharmD, BS/BPharm - Canada)
- Pharmacy Administration and Pharmacy Policy and Regulatory Affairs (MS, PhD)
- Pharmacy, Pharmaceutical Sciences, and Administration, Other