# Phar 652: Regulatory Science II

## PHARMACEUTICS

This course involves an in-depth analysis of domestic and international laws, regulations and guidance documents involved in the approval and maintenance of pharmaceutical products including branded and generic drug products, personal care products, over-the-counter drug products, dietary supplements and medical devices. Emphasis is placed on existing regulations and trends throughout the world. Students will learn how to assemble the most common documents for submission to regulatory agencies, and make strategic regulatory decisions based on sound science. The use of tools such as Comparability Protocols, Established Conditions, and design space will be covered. Guest lecturers with expertise in regulatory science from a variety of industry settings will provide the students with opportunity to discuss relevant problems and issues. The course will require students to critically review and present publications in small groups and/or conduct other assignments.

3 Credits

## Instruction Type(s)

- Lecture: Lecture for Phar 652

## 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