



## **MPTX 519: International Approaches to Medical Product Regulation**

**Units: 3**

**Spring Term, Five full days, 9am-5pm**

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## Course Description

The marketplace for medical products is global. Increasingly, companies recognize the importance of global sales to ensure the financial success of the company. In addition development, clinical testing and manufacturing of products is increasingly conducted overseas. This advanced course in Regulatory Science is designed to compare the laws, regulations and institutions governing medical products in North America with those of several other countries and groups of countries, including the major trading blocks of the European Community and Asia. Particular attention will be paid to regulations that shape the developmental path and marketing applications for drugs, biologics, and medical devices in the EU but other constituencies will be considered in comparison. The students should understand the history that has led to the different regulatory approaches used by other countries. Students will also become familiar with the regulations shaping the structure and conduct of preclinical and clinical trials in other countries, including developing countries in which ethical considerations are often very important to understand.

## Learning Objectives

Below are listed some of the capabilities and knowledge expected of students who graduate from this course. Students should be able to:

1. Explain the evolution of the integrated EU system for drug and device regulations, and be able to relate these developments to economic imperatives in Europe
2. Chart the process by which drugs are approved by the centralized procedure through the European Medicines Evaluation Agency
3. Explain the rationale for selecting either the Centralized procedure, Mutual Recognition procedure or National procedure for the approval of a specific type of drug
4. Explain the considerations that go into selecting a lead country when the Mutual Recognition procedure is used
5. Draw a flow chart to explain the drug development and approval process in Japan
6. Be able to identify if a drug or device would qualify for orphan product status in different countries
7. Describe the differences in the application process for the approval to market a generic vs an innovative drug product in Europe, Canada and Japan
8. Describe the role and recent accomplishments of the International Council for Harmonization
9. Be able to report an adverse reaction worldwide and how they interface with the US system.
10. Classify devices according to risk according to the Canadian and European systems and identify the approach that would need to be used to commercialize each type of product
11. Explain how compliance is assessed in at least three constituencies globally
12. Identify three current issues of concern when clinical trials are conducted in underdeveloped countries, and how these concerns can be addressed successfully

## Class Topics/ Discussion Items

1. World-wide overview
  - a. Commercialization pressures
  - b. Harmonization efforts
  - c. Reimbursement considerations
  - d. Distribution channel requirements
2. History of regulation in Europe; current organization of EU regulatory bodies overseeing drug development and marketing
  - a. Development of pharmaceutical legislation
  - b. Overview of National Health Authorities

- c. Review of the mutual recognition procedure and national procedure
  - d. Review of the Centralized Procedure
  - e. Case studies to identify when different procedures are used
  - f. OTC vs prescription drugs
- 3. European Approaches to New Device Marketing
  - a. The “new” approach to product approvals
  - b. Classification of medical devices
  - c. Path to securing a CE mark
  - d. Choosing a notified body
  - e. Labelling and special rules that govern entry into specific countries
  - f. Risk assessment
- 4. The Canadian Regulatory System
  - a. Steps to drug commercialization
  - b. Device classification and regulatory submissions
  - c. Import-Export rules and concerns
  - d. Postmarket reporting requirements
- 5. The Japanese Regulatory System
  - a. The organizational structure of relevant bodies for drug approvals
  - b. Device approval systems compared to the US and EU
  - c. Import-export concerns
- 6. Clinical trials for drugs and devices in the EU
  - a. Good clinical Practices
  - b. Identifying subjects, informed consent
  - c. Ethics Boards
  - d. The role of the Competent Authority in different countries
- 7. Clinical Trials for drugs and devices in other constituencies
  - a. The Japanese system under change
  - b. Rules for clinical trials in selected constituencies
  - c. Dealing with the coercive elements of trials in developing countries
  - d. Auditing and distributing clinical supplies to other constituencies
  - e. What does the US FDA need to know?
  - f. Clinical Trials directives
  - g. Bridging studies
- 8. Quality Systems and Conformity Assessment
  - a. Directives, guidances and standards
  - b. Legal requirements and implementation of GMPs
  - c. Differences between drug and device oversight in Europe
  - d. Assessment of quality in Asian constituencies
- 9. Regulation of foods, dietary supplements and cosmetics
  - a. Defining boundaries between products in different constituencies
  - b. Regulations concerning genetically engineered products
  - c. Rules governing labelling and claims
  - d. Dietary supplements vs over-the counter drugs: rules in different constituencies
- 10. Post-marketing Assessments and Concerns
  - a. Country by country comparison of reporting requirements

- b. Adverse events reporting-when where and how?
- c. Managing recalls internationally
- d. Counterfeit drugs and smuggling
- e. Pricing products in different constituencies
- f. The internet and cross-border product procurement

### **Course Requirements and Grades:**

Assignment #	Title	Due Date	% of Grade
I.	Workshop Deliverable #1 (BB)	TBA	10%
II.	In-Class Exam	TBA	25%
IV.	Take-Home Exam	TBA	25%
V.	Workshop Deliverable #2 (BB)	TBA	10%
V.	Group Research Presentation	TBA	15%
VI.	Group Research Project Paper	TBA	15%

### **Distance Students:**

Please contact Erin Chow at [erinchow@usc.edu](mailto:erinchow@usc.edu) with any questions and for testing arrangements.

### **ALL STUDENTS:**

All submissions are to be entered in to <http://blackboard.usc.edu> and emailed to Erin Chow at [erinchow@usc.edu](mailto:erinchow@usc.edu) to ensure confirmation of receipt. Be sure to see the accompanying Getting Started sheet for directions.

Please format MS Word file titles with your last name, initial, course number and assignment number, for example: Brown\_C\_516\_A1.doc. Be sure to include your name, the course number and title at the beginning of the text itself.

If applicable, provide details of accessing course if not in a traditional classroom setting.

## Statement on Academic Conduct and Support Systems

### Academic Conduct:

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, “Behavior Violating University Standards” [policy.usc.edu/scampus-part-b](https://policy.usc.edu/scampus-part-b). Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on scientific misconduct, [policy.usc.edu/scientific-misconduct](https://policy.usc.edu/scientific-misconduct).

### Support Systems:

*Counseling and Mental Health - (213) 740-9355 – 24/7 on call*  
[studenthealth.usc.edu/counseling](https://studenthealth.usc.edu/counseling)

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

*National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call*  
[suicidepreventionlifeline.org](https://suicidepreventionlifeline.org)

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

*Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press “0” after hours – 24/7 on call*  
[studenthealth.usc.edu/sexual-assault](https://studenthealth.usc.edu/sexual-assault)

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

*Office of Equity and Diversity (OED) - (213) 740-5086 | Title IX – (213) 821-8298*  
[equity.usc.edu](https://equity.usc.edu), [titleix.usc.edu](https://titleix.usc.edu)

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

*Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298*  
[usc-advocate.symplicity.com/care\\_report](https://usc-advocate.symplicity.com/care_report)

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office of Equity and Diversity | Title IX for appropriate investigation, supportive measures, and response.

*The Office of Disability Services and Programs - (213) 740-0776*  
[dsp.usc.edu](https://dsp.usc.edu)

Support and accommodations for students with disabilities. Services include assistance in providing readers/notetakers/interpreters, special accommodations for test taking needs, assistance with architectural barriers, assistive technology, and support for individual needs.

*USC Campus Support and Intervention - (213) 821-4710*

[campussupport.usc.edu](http://campussupport.usc.edu)

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

*Diversity at USC - (213) 740-2101*

[diversity.usc.edu](http://diversity.usc.edu)

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

*USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call*

[dps.usc.edu](http://dps.usc.edu), [emergency.usc.edu](http://emergency.usc.edu)

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

*USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-120 – 24/7 on call*

[dps.usc.edu](http://dps.usc.edu)

Non-emergency assistance or information.