



MPTX 527: Medical Product Safety

Units: 3

Summer Term, Five full days, 9am-5pm

Instructor: France Richmond, PhD, School of Pharmacy

Office: 1540 Alcazar Street CHP
Los Angeles, CA 90033

Office Hours: TBD

Contact Info: fjr@usc.edu

Course Description

According to the 1999 Institute of Medicine (IOM) Report on “To Err is Human”, U.S. health care is a decade or more behind many other high-risk industries in its attention to ensuring basic safety. Seven years later, in July 2006, the IOM admitted that progress since then has been slow! Recently, the IOM suggested a change in focus, to enhance systems that 1) stimulate an array of stakeholders to engage in patient safety and 2) motivate health care practitioners and their supply chain stakeholder to adopt new safe practices. New national patient-safety goals for 2010 have been now set. In this course, we focus on the role of the medical product manufacturer and supplier in the management of safety. In part of this course, we define the regulatory expectations and the best-practices used to meet these expectations. Some of these practical approaches anticipate problems before they happen, at the level of manufacturing, packaging and labeling. Other approaches include corrective and preventive actions that are stimulated by field observations, complaints and other forms of pharmacovigilance.

Finally, we will study specific approaches for managing product records and archiving information and product that might be needed in case of legal challenge. Crisis management plans and recall procedures will be reviewed with a particular focus on the special challenges faced by medical product manufacturers. The course will include hands-on practice using vigilance application tools, and the MedDRA and Med Watch data bases.

Learning Objectives

Students should understand not only the regulatory expectations that govern a medical products business, but also carry with them a specific set of tools for use in managing vigilance and documentation in a business setting. They should be able to integrate the acquired knowledge and tools with scientific principles, in order to plan and manage the safety of complex medical products. They should also understand the application of MedDRA and Med Watch data bases for vigilance reporting and manage such information to satisfy regulatory expectations and meet business objectives.

Class Topics/ Discussion Items

1. Legal and Liability for Safe Product
 - a. Product and liability prevention and innovation
 - b. Documentation for legal purposes
 - c. How to write right
2. Court Cases
 - a. Case studies
 - b. Mock-up deposition
3. Designing for Medical Product Safety
 - a. System approach to total life cycle
 - b. Product and process design for safety
 - c. Case studies
4. Clinical Trials
 - a. Safety information
 - b. Benefit and risk analysis
 - c. Creation of benefit risk analysis procedure
 - d. Selecting outcomes to monitor safety
5. Clinical Trials
 - a. Safety information
 - b. Benefit and risk analysis

- c. Creation of benefit risk analysis procedure
 - d. Selecting outcomes to monitor safety
- 6. Clinical Trials
 - a. Safety information
 - b. Benefit and risk analysis
 - c. Creation of benefit risk analysis procedure
 - d. Selecting outcomes to monitor safety
- 7. Crisis Management
 - a. Risk communication
 - b. Critical incident analysis
 - c. An effective crisis management plan
- 8. Recall and Remedial Action in the Business Environment
 - a. Case studies
 - b. Voluntary and involuntary recalls
 - c. Creation of a recall procedure
- 9. Post-Market Surveillance
 - a. Reporting rules and regulations (US, EU, Japan, and others)
 - b. Challenges and solutions
 - c. Case studies
- 10. Vigilance Reporting Applications and Tools
 - a. Data bases, MedDRA, Med Watch
 - b. Software tools, e.g. Trackwise, Documentum, etc.
- 11. Advertising and Labeling
 - a. Case studies
 - b. Off label use
 - c. Label changes
- 12. Dealing with the Customer
 - a. Customer education
 - b. Safety signal analysis

Course Requirements and Grades:

Assignment #	Title	Due Date	% of Grade
I.	Ishikawa/FMEA report	TBA	15%
II.	Human Factors Independent Report	TBA	20%
III.	Test	TBA	35%
IV.	Group Presentation/Paper	TBA	25%
V.	Group/Class Engagement	TBA	5%

At the end of the course students should be able to demonstrate a competent knowledge of the subject matter by formal examination. Students will work in groups on their case study, then singly on the individual human factors report. The presentation and paper will be evaluated on the basis of the following criteria:

- Clear introduction to the issues or problem raised by the case study
- Clarity and appropriateness of the testing plan
- Use of good formatting and organization in the test reports
- Well-structured presentation and current bibliography
- Exercise of good team skills

Distance Students:

Please contact Erin Chow at 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 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. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on [Research and Scholarship Misconduct](#).

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University’s educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call

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

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

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

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086

eeotix.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

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

The Office of Student Accessibility Services (OSAS) - (213) 740-0776

osas.usc.edu

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

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

campussupport.usc.edu

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

Diversity, Equity and Inclusion - (213) 740-2101

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, 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

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323) 442-0382 (HSC)

ombuds.usc.edu

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - (323) 442-3340 or otfp@med.usc.edu

chan.usc.edu/otfp

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.