USC Department of Regulatory and Quality Sciences

MPTX 515: Quality Systems and Standards

Units: 3
Summer Term, Five full days, 9am-5pm
Instructor: **Susan Bain, DRSc, School of Pharmacy, USC**

The principal instructor will leverage the expertise of additional qualified speakers from this and other Schools, industry and government agencies. The instructor is available by appointment through Debbie Schroyer at 323-442-3521. The instructor also encourages spontaneous contact by phone or email for short questions or assistance at any time during the working week. "Virtual" office hours will be held at intervals decided by the class after it commences. Inquiries can be directed to Dr. Bain (bain@usc.edu).

Office: 1540 Alcazar Street CHP 140
Los Angeles, CA 90033

Contact Info: bain@usc.edu

Recommended Preparation:

Undergraduate degree in pharmacy, medical or independent health sciences, life sciences, biochemistry, biomedical engineering or equivalent mix of post-secondary training and industry experience.

Course Description and Purpose:

Over the past forty years, product quality assurance has evolved from the simple tasks of material and product inspection to the current implementation of total quality management, risk and reliability engineering. An essential tenet of regulatory oversight is the assurance of quality through guidelines, audits and inspections. In this course, the regulations and guidelines to ensure product quality will be studied to understand the basic principles important for interpretation and implementation.
Students will work in teams to develop appropriate testing plans and documentation for assigned projects in quality control. Some parts of the course will be taught through case studies presented by the students. An emphasis will be placed on relatively informal lecture formats in which students are encouraged to ask and answer questions throughout the didactic session. Students will carry out audits of a facility governed by good manufacturing practices or good laboratory practices. As part of a novel strategy to meet the needs of part-time as well as full-time students, the course will be taught in a condensed period of half days in the summer term; lecture-discussions will occupy a total of approximately 40 face-to-face hours.

Learning Objectives

To assure that students acquire a strong understanding of the regulations and guidelines regarding the design, implementation, and maintenance of a quality system for all regulated medical products.

Upon successful completion of the course. The student should be able to:

- Understand the difference between quality assurance and quality control
- Describe the requirements of ICH and ISO standards
- 2 RSCI_509
- Recognize the elements added to the FDA's Quality Systems Regulations that are not present in Good Manufacturing Practices for Drugs or in Good Manufacturing Practices for Foods
- Be able to design sampling protocols according to accepted statistical methods
- Identify the essential elements in a document control system
- Know the rules for the development of electronic document systems
- Be able to conduct a preliminary systems audit
- Understand the formal tools available to conduct a faults and hazards analysis
- Recognize the strengths and limitations of currently available methods for the product cleaning and sterilization

Course Outline

This 3-unit course will include 40 hours of lectures given as full day classes. Each 5-day period will consist of 8 contact hours of lecture (instructional time) with an additional 10 hours of one-one-discussions and faculty contact. The total number of faculty contact hours is 50.

Course topics will be organized in 3-4 hour blocks. Distance modules with content developed in an interactive on-line format will be used to supplement classroom presentations.

At the beginning of the term in which the course is taught, you will receive a detailed agenda that identifies the dates and times of the sessions and the names of any guest speakers for that session. In addition, you

will be supplied with a binder that contains all of the information about assignments and projects, reading materials that are unique to the lectures and supplement the texts, and biographical sketches of the instructors. All of this material is also posted and updated weekly on blackboard, which is our main tool for organizing materials.

You will be given information about using blackboard and other online tools at the first class. Each week, the instructor will identify the section of the textbook and supplementary readings in the binder that should be prepared for the session(s) that follow.

Course Breakdown: By Week and Hours (15 Weeks)

Week	Day	Lecture Hours	Additional Faculty Instruction Hours via Distance
1			1
2	1	8	
3			1
4			1
5	2	8	
6			1
7			1
8	3	8	
9			1
10			1
11	4	8	
12			1
13			1
14	5	8	
15			1
Total		**40**	**10**

Topics:

Unless otherwise specified, each session is 4 hours

Day 1 Morning: General Overview
8:00am-12:00pm

- Course overview
- Overview of device GMPs and QSR
- The roles of Quality Assurance and Quality Control
- Medical Device Single Audit Program (MDSAP)

Day 1 Afternoon: Introduction to Quality Systems
1:00pm-5:00pm

- Introduction to Quality Systems for Medical Devices
- The FDAs Quality Systems Requirements (QSRs)
- ISO 13485
- Use and Control of Contract Manufactures
- Writing SOPs
- SOP workshop

Day 2 Morning: Corrective Preventative Action (CAPA)
8:00am-12:00pm

- Introduction to corrective and Preventative Action
- Documentation requirements for CAPA
- Developing a CAPA plan
- Root cause analysis for CAPA and complaint files
- Human factors testing

Day 2 Afternoon: Pharmaceutical and Biologics Quality Systems
1:00pm-5:00pm

- ICH Q10-Pharamacuetical Quaility Systems
- ICH Q5-Quality Systems for Biologics
- Analytical method development and validation
- Instrument qualification and validation
- CAPA project workshop

Day 3 Morning: Combination Products
8:00am-12:00pm

- What are combination products?
- Regulatory requirements for combination products
- Quality challenges associated with combination products

Day 3 Afternoon: Product Realization and Risk Assessment
1:00pm-5:00pm

- Regulatory requirements for risk management
- Risk assessment and mitigation
- Acceptance Activities for Non-conforming product

Day 4 Morning: Adverse Events, Customer Complaint, and Recall Products
8:00am-12:00pm

- Regulatory requirements for adverse event and customer complaint reporting system
- Designing and implementing an adverse event and customer complaint reporting system
- Recall products

Day 4 Afternoon: Supplier Management and Quality Agreements
1:00pm-5:00pm

- Supplier management
- Supply chain management
- Quality agreement workshop

Day 5 Morning: Auditing and Auditing Principles
8:00am-12:00pm

- Auditing principles and checklists
- Types of audits
- Preparing for and FDA audit

Day 5 Afternoon: Biosimilar Regulation and Customer Complaint Handling
1:00pm-5:00pm

- CAPA project presentations

Course Requirements and Grades:

Assignment #	Title	Due Date	% of Grade
I.	Assignment 1: Quality Issues in the News Review and Write up	TBA	10%
II.	Midterm Exam	TBA	30%
III.	Assignment 2: SOP Creation	TBA	20%
IV.	Quizzes (2)	TBA	10%
V.	Corrective and Preventative Action (CAPA) Project	TBA	30%

Assignment 1: Quality Issues in the News Review and Write up, will require you to search current news outlets to find a news article related to a medical device or combination product with a product quality issue. The midterm examination and quizzes will be comprised of multiple choice and short-answer questions.
Assignment 2: SOP Creation, will ask you to develop a Quality System SOP template for use at a medical device manufacturing firm.
The Corrective and Preventive Action (CAPA) project is a real-life case study involving a product defect which resulted in a company having to recall a batch/batches of one of their medical devices or combination products. You will be required to list of all possible causes for the defect, develop a Corrective and Preventive Action Plan to resolve the defect and then follow up to ensure the problem has recurred. The assessment will be based on the thoroughness of the root cause analysis, the CAPA Plan and the effectiveness checks post-implementation and their compliance to the regulations.

Recommended Textbooks:

No one book will cover all aspects of this complex subject, but we strongly recommend the following textbook.

Hough, GW, Rawlings, DA and Turner, MF (1997) Pre-production Quality Assurance for Healthcare Manufacturers. Interpharm Press: Buffalo Grove IL

Distance Students:

Please contact Erin Chow at erinchow@usc.edu with any questions and for testing arrangements.

Distance students will be taking this course at the same time as site-based participants. We want these students to be well-linked with the instructor and class throughout the experience. If the student is able to participate by watching the lectures as they are streamed live, he/she can take advantage of the speakerphone that is always active in order to ask questions. If the student can only watch the archived version of the lectures, he/she will be instructed about how to contact the professor responsible for the lecture by email or telephone. In addition, we will hold internet-based office-hours which are easily accessed at a web address that will be provided. These sessions will be held in the evening, usually each week.

At each session the student will see the professor live and can talk to the group in teleconference if they have a phone near the computer or by instant messenger if they do not. Students will be reminded by email about each session a few days before each session is scheduled, and we strongly encourage participation in these sessions. A session will always be scheduled a few days before the examination dates. Students are responsible to check their USC email and the Blackboard site regularly in case of changes in schedules or other announcements. In group projects students will typically work with a site-based group. A discussion “room” on the internet will be provided, and we will use multimedia tools so that students can present

their part of the project in class. Further information about all of these tools are provided in the binder that is sent with the textbook and any other special materials, a few days before the first class begins.

We know that some of our distance students can occasionally come to the classroom. They are always welcome to join us and hope that they will take this opportunity as often as they can. However, if students are registered as a distance student, they will have to abide by the rules that govern distance students for deliverables and tests, unless we make special arrangements. Our staff will work with distance students to find a testing center and assure that they are tested at a time that is reasonably convenient to them. Please consult with us before starting this course to understand how all of these details will be managed.

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) 442-33*40 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.