



Syllabus

PME 540 Validation and Regulatory Affairs in Pharmaceutical Manufacturing

Objectives:

Validation of a pharmaceutical manufacturing process is an essential requirement with respect to compliance with Good Manufacturing Practices (GMP) contained within the Code of Federal Regulations (21 CFR).

Course covers validation concepts for plant, process, cleaning, sterilization, filtration, analytical methods, and computer systems; GAMP (Good Automated Manufacturing Practice), IEEE SQAP and new electronic requirements – 21 CFR Part 11. Master validation plan, IQ, OQ, and PQ protocols, and relationships to GMP. National (FDA) and international (EU) regulatory affairs for cGMP (current Good Manufacturing Practice) and cGLP (current Good Laboratory Practice) requirements in development, manufacturing, and marketing. Handling the FDA inspection.

Also offered as ME 540 and ChE 540. Prerequisite: PME 530.

Course Outline:

Week	Discussion Topics	Text Reading
0	Orientation	
1	An Introduction to FDA Operations & Industry Compliance Regulations	Introduction
2	The Fundamentals of Regulatory Compliance with respect to Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) & Good Laboratory Practice (GLP)	Ch. 1
3	An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (IQ, OQ & PQ) Procedures	Ch. 21, 23
4	A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC) Techniques	Ch. 2, 3, 18
5	ISO 9000 Series & International Harmonization & their effect upon GMP's	Ch. 24
6	Planning & Managing a Validation Program including Change Control, Scale-Up and Post-Approval Changes (SUPAC), PAI & Technology Transfer Issues Term Paper Topic Midterm Exam on Weeks 1-6	Ch.20
7	Validation of Water & Thermal Systems, including HVAC, Facilities & Cleaning Validation	Ch 12, 13, 14

Week	Discussion Topics	Text Reading
8	Validation of Active Pharmaceutical Ingredients (APIs) & Aseptic Processes Term Paper Top Level Outline	Ch. 4, 11
9	Validation of Non-Sterile Processes (used in the manufacture of Solids, Liquids, & Semisolid Dosage Forms)	Ch. 5, 19
10	Medical Device, In-Vitro Diagnostics & Packaging Validation Issues Term Paper 2 nd Level Outline Due by April 11	Ch. 6, 17
11	Validation of Analytical Methods, Computerized & Automated Systems under 21 CFR Part 11 & the Influence of Good Automated Manufacturing Practice (GAMP); IEEE SQAP	Ch. 15, 16
12	The FDA's Approach to GMP Inspections of Pharmaceutical Companies Term Paper & Slide Presentation	Ch.7 or Ch. 8 or Ch. 9 or Ch. 10
13	View and Comment on Student Slide Presentations Final Exam on Weeks 7-12	

Course Material:

Text book(s)

Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker, 2003, 860 pp., ISBN 0-8247-0838-5.

The text can be ordered from the Stevens Bookstore: <http://www.stevenscampusstore.com>

It can also be ordered directly from the Marcel Dekker website:

<http://www.dekker.com/servlet/product/productid/0838-5>

Marcel Dekker also sells an electronic version of this text book:

<http://www.ebooks.dekker.com/eBookCover.asp?eBookID=0824748344&type=ISBN>

References

Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control From Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed., 2000, 723 pp., ISBN 0824704258.

Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed., 1998, ISBN 0824793846.

Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider, Saint Lucie Press, 2002, 496 pp., ISBN 1574443313.

Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press, 1998, ISBN 1574910795.

Commissioning and Qualification, ISPE Pharmaceutical Engineering Baseline Guides Series, 2001.

Grades:

Available Points

- √ **Term Paper & PowerPoint-style presentation:** Assigned in middle of term. A list of term paper topics will be provided for students to choose from; an alternative topic of the student's choice may be used with permission of the instructor.
- √ **Exams:** There will be midterm and final exams. The midterm exam will cover weeks 1-6 and the final exam will cover weeks 7-12. Makeups will be given only for medical reasons (with doctor's note) or prior arrangement with instructor. Exams are open-note and open-book.
- √ **Weekly Participation:** All discussion postings for the week are due by 11PM Monday of the following week (e.g. postings for Week 1 starting January 31 must be completed by 11 PM Monday, February 7). The same policy applies for weekly quizzes or assignments. Note that weekly participation (discussions/quizzes/assignments) totals 20% of the finale grade. If you are not participating in this course on a weekly basis you will not do well in it. A word to the wise is sufficient.
- √ **Assignments:** Details of the term paper assignment will be posted shortly after the start of the term; major milestones for the term paper are included in the class schedule.
- √ **Final Course Grade:**
 - a. **Weekly Quizzes/Assignments: 10%.** There will be at least 11 weekly quizzes or assignments; overall quiz/assignment grade will be based on the best 10. Grades for late submissions will be reduced by 10 percent per week. All quizzes are open-note & open-book
 - b. **Weekly participation in online discussions: 10%.** 10 points available each week; up to 9 will be awarded for response to weekly discussion topic; 1 additional point is available for responding to at least one other student's posting. Grades for late participation will be reduced by 10 percent per week.
 - c. **Midterm Exam (covering weeks 1-6): 25%.**
 - d. **Final Exam (covering weeks 7-12): 25%.**
 - e. **Term Paper and PowerPoint-style Presentation: 30%.**