

Stevens Tech PME 535 Fall Syllabus for Spring 2007 WebCT:

Good Manufacturing Practice in Pharmaceutical Facilities Design

Text: *Good Design Practices For GMP Pharmaceutical Facilities*, (Drugs and the Pharmaceutical Sciences: a Series of Textbooks and Monographs, Andrew A. Signore, Terry Jacobs, 2005, 550 pp., ISBN: 0824754638

Additional Reference Material:

Pharmaceutical Production Facilities: Design and Applications, Graham Cole, Taylor and Francis, 2nd Ed., 1998, 344 pp., ISBN 0748404384.

Process Plant Layout and Piping Design, Ed Bausbacher and Roger Hunt, Prentice-Hall, 1993, 464 pp., ISBN 0131386298

Containment in the Pharmaceutical Industry, James Wood, Marcel Dekke, 2000, 272 pp., ISBN 0824703979

Manufacturing Plant Layout: Fundamentals and Fine Points of Optimum Facility Design, Edward Phillips, Society of Manufacturing Engineers, 1997, 259 pp., ISBN 0872634841

Sterile Manufacturing Facilities, ISPE Pharmaceutical Engineering Baseline Guides Series, 1999

Instructors Supplied Information

- Copies of Printed Documents
 - Articles
 - Reference Books
 - Web Sites
 - ISPE/PDA
 - FDA/EU
- Pharma-Online
- Articles published by Instructors

Student Responsibilities Fall 2006

- Orientation
 - Please be prepared to post a little information about yourself.
 - Who you are, why are you taking the course, what you hope to get out of it, etc.
 - If you are working please be sure to include information about your position and how you feel the course can help in your career.
- Homework
 - Assigned readings from text
 - Any reference materials that the instructor has directed you to read
 - Reading assignments can be found on the reading list supplied with the course outline.
- Weekly Quizzes
 - There will be a quiz posted each week covering the previous weeks materials
 - Weekly quizzes are worth 10 pts each, 10 best kept for grade
 - 10 % of overall grade
- Discussion Questions
 - Each week a discussion question will be posted on the bulletin board.
 - All students are expected to respond to the question and comment on other students responses.
 - 10 % of overall grade
 - Please note: answering a question does not entail copying and pasting text from the course material. No credit will be given if this is done.
- Midterm
 - Take home
 - Based on first six weeks
 - No time limit, but exam must be completed by date specified

- Exam is comprised of 40 multiple guess, 10 acronyms and 4 out of 6 essays
- 20% of overall grade
- Term Paper/Project
 - Based on the redesign of an existing pharmaceutical facility
 - Term Paper
 - Drawings and Layouts (Note: experience with computer graphics is required. All of the work can be done using the basic graphics tools supplied in Microsoft Office. Drawing files will also be supplied for Visio and AutoCAD if you prefer.)
 - A PowerPoint presentation must be developed to show your recommended results. This will be posted for everyone to see.
 - 30% of overall grade
- Final Exam
 - Timed (2.5 hours) (You may start whenever you wish but once you start you must finish in the allotted time. You cannot stop and come back to the test.)
 - Based on all course materials
 - Exam is comprised of 40 multiple guess, and 4 out of 8 essays
 - 30% of overall grade

Please note: answering any questions on exams does not entail copying and pasting text from the course material. No credit will be given if this is done.

Please Note: This course, as are all Stevens' courses, follows the Stevens Honor System for all exams and projects. Students found exchanging information will be reported and appropriate measures will be taken.