16:155:547 **Statistical Analysis and Design of Pharmaceutical Operations** (Fall 2016; 3 cr)
text: DESIGN AND ANALYSIS OF EXPERIMENTS, 8th Ed. (2013), D.C. Montgomery, John Wiley & Sons, ISBN-9781118146927; MINITAB Software is also recommended or its equivalent. Course text is available electronically from https://www.vitalsource.com/products/design-and-analysis-of-experiments-eighth-edition-douglas-c-montgomery-v9781118324264

Course Description
An introduction to statistical analysis and experimental design methods and their applications to designing and optimizing pharmaceutical processes. Classic statistical concepts and methods will be discussed using pharmaceutical examples including product/process development scenarios, routine in-process and finished product testing, and failure investigations. A clear understanding of the basis for each statistical test will be developed. Regulatory requirements for test of samples, sampling plans, tablet and capsule assays, dissolution and bioavailability tests will be highlighted. Matlab and the Minitab statistical software package (or equivalent) will be used throughout the course.

Course Timeline

Topic	Reading Assignment	HW	Start date	End date	Class unit module
Statistics, DoE overview	Ch. 1, handouts	1	09/06	09/12	1
Comparative experiments	Ch. 2, 10	2	09/13	09/19	2
Exam 1				09/23	
Single Factor ANOVA	Ch. 3	3	09/20	09/26	3
Statistical Software	Ch. 3	4	09/27	10/03	4
Blocking in Designs	Ch. 4	5	10/04	10/10	5
Examples, Ch. 3-4			10/11	10/17	6
Exam 2				10/21	
Factorial Designs	Ch. 5	5	10/18	10/24	7
2^k Factorial Designs	Ch. 6	6	10/25	10/31	8
Blocking and Confounding	Ch. 7	7	11/01	11/07	9
Examples, Ch. 5-7			11/08	11/14	10
Exam 3				11/18	
Fractional Factorial Designs	Ch. 8	8	11/15	11/21	11
Design Resolution	Ch. 8	9	11/22	11/28	12
Response Surfaces	Ch. 11	10	11/29	12/5	13
Examples, Ch. 8, 11			12/6	12/12	14
Exam 4				12/16	

HW and exam assignments are due on the end date listing.

Learning Objectives: after completing this course, students will have:

- *an ability to design and conduct experiments, as well as to analyze and interpret data*, within the context of pharmaceutical operations and beyond. Students will also have
- *an ability to use the techniques, skills, and modern tools necessary for engineering practice*, specifically targeting the analysis and design of experiments.