CHEM 714

Pharmaceutical Analysis

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Objective: The objective of the course is to provide an overview of instrumental technique used in pharmaceutical analysis. Physically and chemically different analytes are encountered in different sample matrices. Different sample preparation techniques and analytical instrumentation are needed for analyzing these compounds. It will not be possible to cover the whole spectrum of techniques and methods. The focus of this class will be on instrumentation including chromatography and different types of spectroscopy. This course will also cover the rules governing the pharmaceutical industry in the US including current Good Manufacturing Practices (cGMP), method validation, and current industry guidance.

Required Reading

Guidance for Industry
Analytical Procedures and Methods Validation for Drugs and Biologics
www.**fda**.gov/.../**guidance**complianceregulatoryinformation/**guidance**s/ ucm386366.pdf

United States Pharmacopeia/National Formulary -I will provide copies
General Chapter <621> Chromatography
General Chapter <1010> Analytical Data – Interpretation and Treatment

ICH Guidelines
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

VALIDATION OF ANALYTICAL PROCEDURES: TEXT AND METHODOLOGY Q2(R1)

SPECIFICATIONS: TEST PROCEDURES AND ACCEPTANCE CRITERIA FOR NEW DRUG SUBSTANCES AND NEW DRUG PRODUCTS: CHEMICAL SUBSTANCES Q6A

Suggested Text Books (Not required - for your reference only)

Principles of Instrumental Analysis, 6th edition
By: Skoog
ISBN: 9780495012016

Method Validation in Pharmaceutical Analysis: A Guide to Best Practice, 2nd Edition
By:Joachim Ermer (Editor), Phil W. Nethercote (Editor)
ISBN: 978-3-527-33563-3

Weekly Time Commitment

It is estimated that students will spend an average of 9 to 12 hours per week on this course. The amount of time that will be required will vary week to week. This time commitment is consistent with the accepted standards for a three-credit, graduate-level course.

Term Paper

Students are responsible for submitting the term paper on or before the due date. Papers will be reduced by 5 points for each day that they are late. Papers submitted one week late will not be accepted and will receive a grade of zero. Extenuating circumstances due to an emergency will only be considered at the discretion of the instructors with proper documentation. The paper must be a eight to ten pages in length, double spaced, excluding references, tables, figures, etc, and must be formatted according to the 6th Ed. American Psychological Association(APA) format. 6th edition APA Style Format can be found at:

http://owl.english.purdue.edu/owl/resource/560/02/ .

All references must be sites. Any form of plagiarism will result in a failing grade on the paper and the violation will be reported to the department.

Academic Integrity

All students must observe and support high standards of honesty and integrity in all aspects of education, practice, and research. For this reason, all students in this course are expected to abide by the School's Faculty/Student Honor Code and accept responsibility to help ensure that these standards are maintained by reporting violations of the Honor Code observed in others. All academic integrity violations will be considered with gravest concern and may be punishable with sanctions as severe as suspension or dismissal.

Grading

10% Term Paper
40% Midterm Exam
40% Final Exam

Topics to be Covered (This is a plan and may be subject to change**)**

06-Sep	Introduction, Basic Concepts, Classes of Drugs (Injectable/Implanted, Orals, Topical/Transdermals, Mucosal, & Inhalation/Nasal
13-Sep	Gas Chromatography (GC)
20-Sep	High Performance Liquid Chromatography (HPLC)
27-Sep	Fundamentals of Spectroscopy
04-Oct	Mass Spectroscopy/Elemental Impurities & Dissolution/Disintegration/Drug Release
11-Oct	UV-Vis Molecular Absorption, FTIR
18-Oct	Atomic Absorption
25-Oct	Midterm
01-Nov	In depth review of Regulatory and non-Regulatory agencies and organizations, common FDA finding (483s) in drug & medical device industries
08-Nov	Pharmaceutical Packaging Requirements and Testing
15-Nov	Code of Federal Regulation Title 21 - Part 210 & 211 (Term Paper Due)
22-Nov	cGMPs for Manufacturing and Laboratory
29-Nov	Analytical Instrument Qualification –DQ, IQ, OQ, PQ, Calibration, PM
06-Dec	Method Validation
13-Dec	United States Pharmacopeia / National Formulary (USP/NF)
20-Dec	Final Exam