

# **INTRODUCTION TO PHARMACOVIGILANCE AND REGULATORY AFFAIRS SPRING 2012**

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## **Course Description:**

Pharmacovigilance is the science and activities that relate to the detection, monitoring, assessment, understanding and prevention of adverse effects of medicines including vaccines and biological products. This survey course is designed to expose students to the practice of pharmacovigilance in the rapidly changing and highly regulated pharmaceutical industry. Students who intend or have an interest in working in the industry will gain a broad perspective on how pharmacovigilance and epidemiology play a role in drug development and post-marketing surveillance. Students will develop a better understanding of the legal and regulatory framework for drug safety. This course will focus heavily on the analysis of current industry and regulatory activities to provide students the opportunity to apply the principles of pharmacovigilance.

**Time and Location:** TBD

## **Instructor:**

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Office Hours: By appointment

## **Course Objectives:**

1. Discuss the basic definitions of terms used in pharmacovigilance
2. Identify the critical role of pharmacovigilance and epidemiology in the industry
3. Understand the importance of pharmacovigilance, epidemiology, and regulatory affairs in drug development, marketing and post-marketing
4. Identify the principles and regulatory framework for clinical safety or pharmacovigilance
5. Explain and apply the basic concepts and principles of signal detection in the safety surveillance of drug products
6. Understand data mining techniques to analyze adverse event report data
7. Gain a broad understanding of the industry, major health authorities, and other relevant parties

8. Gain working knowledge of US, EU and international guidance, and legal and regulatory principles applicable to safety surveillance regulatory requirements
9. Be able to analyze case studies and current events to appreciate the pending issues and apply applicable laws, regulations, and guidelines to recommend possible solutions
10. Describe the criteria and elements of expedited and periodic reporting of drug safety from pre-clinical to post-marketing phase of drug development
11. Demonstrate an awareness of risk management/mitigation and communication in drug labeling and promotion
12. Discuss key messages from health authorities on pharmacovigilance and regulatory affairs
13. Understand relevant regulations and guidelines for drug labeling and promotion for effective risk communication and mitigation
14. Evaluate safety issues in new and emerging technologies and future trends in pharmacovigilance

**Textbook:**

Recommended text: An Introduction to Pharmacovigilance by Patrick Waller (2010)

References: Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics by Linda Fossatti Wood and MaryAnn Foote

Course will be supplemented with additional reading materials (*e.g.*, industry news, journal articles, etc.) that reflect current pharmacovigilance and/or regulatory events. These will be emailed to students 3 to 4 working days before class.

**Student Evaluation** - Grading will be determined as follows:

Class attendance and participation (30%)

Midterm exam (20%)

Project on an important pharmacovigilance and/or regulatory issue (30%)

Final exam (20%)

Each student is expected to choose a topic of her/his interest on pharmacovigilance or regulatory affairs by the fourth week of class (February 15, 2012). Students should obtain instructor's approval on their project.

The student will conduct research on the selected topic and is expected to write a report of no more than 20-double-spaced pages providing an in-depth analysis of the current issues, trends, and recommendations on the topic.

Each student will make a 10-minute presentation of his or her final project and submit a final report at the same time.

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**UMDNJ-SCHOOL OF PUBLIC HEALTH**

**HONOR CODE**

Each student bears a fundamental responsibility for maintaining academic integrity and intellectual honesty in his or her graduate work. For example, all students are expected to observe the generally accepted principles of scholarly work, to submit their own rather than another's work, to refrain from falsifying data, and to refrain from receiving and / or giving aid on examinations or other assigned work requiring independent effort. In submitting written material, the writer takes full responsibility for the work as a whole and implies that, except as properly noted by use of quotation marks, footnotes, etc., both the ideas and the words used are his or her own. In addition to maintaining personal academic integrity, each student is expected to contribute to the academic integrity of the school community by not facilitating inappropriate use of her/his own work by others and by reporting acts of academic dishonesty by others to an appropriate school authority. It should be clearly understood that plagiarism, cheating, or other forms of academic dishonesty will not be tolerated and can lead to sanctions up to and including separation from the UMDNJ-School of Public Health.

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Acknowledge (Print Name)

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Signature

Approved by Executive Council, UMDNJ – School of Public Health: February 11, 2008

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## **January 25** *Basic concepts and practice of pharmacovigilance (Part I)*

- Legal and regulatory basis for pharmacovigilance, including a historical perspective
- Basic definitions (*e.g.*, adverse drug reactions/events, causation)
- Safety databases
- Roles of health authorities in pharmacovigilance, WHO, and CIOMS Working Group
- Ethical and societal considerations

## **February 1** *Basic concepts and practice of pharmacovigilance (Part II)*

- Assessments for clinical and causality (causal relationship between drug and adverse event)
- Signal detection
- Data mining
- Adverse event reporting
- Medical dictionary for regulatory activities (MedDRA)

## **February 8** *Pharmacovigilance and its role in other departments*

- Pharmacovigilance – where does it fit in the company ?
- Role of epidemiology in pharmacovigilance
- Regulatory
- Medical information
- Clinical
- Marketing/business development/commercial
- Other potential functions

## **February 15** *Laws, regulations, and guidelines on pharmacovigilance*

- ICH guidelines
- FDA regulations and guidelines
- EU regulations and guidelines
- Laws, legal cases, and legislations on drug safety

## **February 22** *Pre-clinical (Part I)*

- Role of preclinical safety studies in drug development
- Non-clinical safety evaluation and adverse events in Phase I trials
- Safety reporting requirements in pre-marketing phase

**February 29 *Pre-clinical (Part II)***

- Investigator's brochure (IB)
- Guidelines and regulations for animal and *in vitro* studies
- Toxicity, genotoxicity, mutagenicity and carcinogenicity studies

**March 7 *Clinical drug safety (Part I)***

- Risk assessment in clinical trials
- Orphan drug designation
- Fast track application
- Pediatric studies
- Periodic Safety Update Reports (PSUR)
- Protocols
- Independent data monitoring boards

**March 14 *Clinical drug safety (Part II)***

- Basic principles – key features for capturing drug safety data
- Case record form design and data capture
- Data management and drug safety
- Clinical versus safety databases
- Assessment of individual serious adverse event reports

**March 21 *Spring Break (No class)***

**March 28 *Post-marketing drug safety (Part I)***

- Differences in clinical and post-marketing drug safety
- Post-marketing safety in the US and EU
- Post-marketing clinical trials

**April 4 *Post marketing drug safety (Part II)***

- Postmarketing surveillance
- Postmarketing adverse events
- Drug recalls/withdrawals (based on epidemiological data)

**April 11 *Drug labeling and risk mitigation***

- Risk Evaluation Mitigation Strategies (REMS)
- Company core data sheet (CCDS)
- Company core safety information (CCSI) and CIOMS III
- US package insert, patient package insert, and Medication Guide

- Drug interactions and clinical significance
- System organ classes

**April 18**     *Promotion and risk mitigation & communication*

- Social media and drug safety
- Direct-to-consumer advertising and promotion
- Risk communication and minimization strategies

**April 25**     *Drug safety and at risk groups*

- Regulations and guidelines in connection with at risk groups
- Pregnancy labeling
- Drugs and the elderly
- Oncology and cardiovascular adverse drug reactions
- Renal and hepatic adverse drug reactions
- Pharmacovigilance in pediatrics

**May 2**     *Safety risks in new technologies and products*

- FDA's Sentinel initiative
- Biosimilars
- Nanotechnology
- Combination products

**May 9**     *Safety risks in new technologies and trends in pharmacovigilance*

- Biomarkers
- Personalized medicine
- Pharmacogenomics
- New trends in pharmacovigilance

**May 16**     *Student Presentations*