

FOURTH YEAR ELECTIVE TITLE Introduction to Drug Safety within the Pharmaceutical Industry		COURSE NUMBER PHAR 9010	LOCATION Pfizer, Inc. Collegetown, PA, New York, NY, or Groton, CT
ELECTIVE DIRECTOR DANIEL S. PILCH, PHD (RWJMS – DEPT. OF PHARMACOLOGY)	ELECTIVE FACULTY George N. Pajovich, R.Ph. (PFIZER) DANIEL S. PILCH, PHD (RWJMS – DEPT. OF PHARMACOLOGY)	ELECTIVE CONTACT George N. Pajovich, R.Ph. (PFIZER) DANIEL S. PILCH, PHD (RWJMS – DEPT. OF PHARMACOLOGY)	CONTACT INFO DR. PAJOVICH: 484-865-3492 (TEL) 484-323-7633 (FAX) geo.pajovich@pfizer.com DR. PILCH: 732-235-3352 (TEL) 732-235-4073 (FAX) pilchds@rwjms.rutgers.edu
BLOCKS AVAILABLE ALL	DURATION/WEEKS MIN: 4 MAX: 4	HOURS PER WEEK 40	STUDENTS MAX: 1
LECTURES/SEMINARS YES	OUTPATIENT NO	INPATIENT NO	HOUSESTAFF NO
NIGHT CALL NO	WEEKENDS NO	LAB NO	EXAM REQUIRED NO EXAM. PRESENTATION REQUIRED

NOTE: 1) A Criminal Background Check and/or a Drug Test may be required – at the discretion & cost of Pfizer.
2) A Confidentiality Agreement is required to be signed by all students taking the Elective.
3) Please allow four (4) weeks to process the tests, CBC and Agreements when scheduling the Block in which you wish to take the elective.

OVERALL EDUCATIONAL GOAL OF ELECTIVE

OBJECTIVES:

I. Patient Care – Pfizer is committed to the provision of clear direction of the benefit-risk profile of its products. This is accomplished by the timely evaluation and determination of medical position regarding emerging information (safety and risk, efficacy/effectiveness and benefit) through Pfizer’s Worldwide Safety department. The Safety organization is comprised of approximately 1400 colleagues including healthcare professionals (physicians, pharmacists, veterinarians, nurses, etc.) who monitor Pfizer’s portfolio of products independently, using scientific and medical data to drive decision-making with patient safety as our priority. The student will be exposed to processes and activities and understand pharmacovigilance’s impact on public health for prescription and over-the-counter products including medical devices.

II. Medical knowledge – Following completion of the rotation, the student will have an understanding of the scientific basis for therapies, drug-induced diseases and how that relates to drug safety. He/She will also have an understanding of the drug development process.

III. Practice-based learning and improvement – Following completion of the rotation, the candidate will understand the basic principles of drug safety data review, safety data assessment, clinical safety signal identification, risk identification and risk management; from a medical perspective, the student will develop an understanding of how to evaluate drug safety data, identify and analyze safety signals and how pharmacovigilance has an impact on patient care as well as public health. The candidate will also have a basic understanding of Pharmacovigilance regulations worldwide.

IV. Interpersonal and communication skills – The candidate will have the opportunity to display effective interpersonal and communication skills, collaborating with safety colleagues as well as other departments within the company. At the end of the rotation, the candidate will be expected to provide a brief presentation on a relevant topic determined at the start of the elective.

V. Professionalism – Candidates will be exposed to and be expected to display high levels of professionalism that include, but are not limited to, integrity, objective point of view, collegiality, follow-through, and transparency based on medical and scientific decision-making.

VI. Systems-based Practice –Candidates will be exposed to pharmacovigilance processes including processes for assuring quality.

BRIEF DESCRIPTION OF ACTIVITIES – The candidate will be exposed to the principles of pharmacovigilance and drug safety including regulations and guidances that govern the processes. The candidate will participate in/observe proactive holistic safety review for products and medical devices which include safety signal detection, risk identification, and risk management.

METHOD OF STUDENT EVALUATION – day to day participation with team, applied learning, final presentation at end of elective

Are there any prerequisites for this elective? No Yes ___

Is this elective available to third year medical students as well? No Yes ___