

APPE Rotation Description

Pharmaceutical Industry

GENERAL INTRODUCTION

Pfizer Inc. is a major global pharmaceutical company. At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. At the La Jolla site the primary therapeutic focus is oncology where the clinical development of small and large molecules is undertaken. Numerous drugs have been developed on-site which have been approved for the treatment of varying tumor types including lung, breast, and leukemia among others.

The Pfizer La Jolla has a number of research buildings located just north of the UCSD campus on Science Center Drive and Genesee Blvd.

Michael Amantea, Pharm.D.

Senior Director, Pfizer Global Research and Development/Pharmacology/Pharmacometrics

10555 Science Center Drive, San Diego, CA 92121

Office: 858-622-3173

Email: michael.amantea@pfizer.com

INTRODUCTION TO THE ROTATION

The six-week rotation is designed to provide students an overview of the clinical development process used in assessing the potential utility of oncology drugs in the patient setting. An emphasis will be placed on the clinical pharmacology requirements necessary for regulatory drug approval. Since many specialized job functions are required to develop drugs students will have a choice in choosing those functions which best suits their area of interest. In general, student(s) will collaborate with members of the clinical pharmacology and oncology research groups at Pfizer, La Jolla. They will be introduced to basic clinical and research skills as used in an industrial setting, attend seminars in pharmacology and oncology, and meet with various colleagues, e.g. statisticians, regulatory representatives, clinical pharmacologists, etc. to understand their function. They will be introduced to study biostatistics and trial design in the clinical setting, perform basic non-compartmental analyses, review study protocols, among other activities. They will also have the opportunity to engage in interdisciplinary meetings and

develop their presentation skills via journal clubs and other venues. The following key areas will serve as guide for the students' in choosing their interest areas:

- Pharmaceutical Industry Structure: Drug Discovery thru Drug Approval
- Clinical Drug Development Paradigm
- Clinical Pharmacology Studies: Food Effect, Drug-Drug interactions, etc.
- FDA and other regulatory agencies guidelines
- Pharmacokinetic Analyses: NCA and Compartmental
- Biostatistics
- Development of oncology medications (see below)

In addition, the oncology specific pharmacology goals are listed below.

GOALS AND OBJECTIVES - ONCOLOGY SPECIFIC

1. Oncology Coursework and Training:

- Development of a basic understanding of cancer biology, biomarkers and common targets for cancer therapy
- Application of pharmacokinetic principles to pharmacology with a focus on anticancer drugs
- Identify correlations of drug exposure with toxicity and therapeutic endpoints
- Prediction of long term patient tolerability and resistance to cancer therapy efficacy

2. Clinical Oncology

- Understanding of clinical oncology principles with a focus in the therapeutic area of immune-oncology
- Engaging in discussions of study design for chemotherapeutic agents based on tumor type, drug targets and statistical requirements

3. Quantitative Pharmacology and Pharmacometrics:

- Understand the role of pharmacokinetic and pharmacodynamic models to describe clinical and pre-clinical data using non-compartmental and, population methods
- Understand the use quantitative pharmacology in the applications in populations interpreting the data for new drug development and evaluation
- Gain understanding of clinical pharmacology/oncology laboratory activities as related to drug target, biomarker or drug concentration measurements

ACTIVITIES

A typical day for the students will include interacting with colleagues with varying functions; here, students will have an opportunity to discuss the roles of clinical pharmacologists, statisticians, clinicians, etc. In some cases the colleagues may have the student conduct basic pharmacokinetic analyses, review study protocols, conduct a journal club, among other activities. Students will also be provided with a number of articles and video linkages addressing the clinical development process, pharmacokinetic/pharmacodynamic analyses, and pharmacology of drugs used in oncology. The preceptor will be available to review the latter with the student. The student will also attend clinical team meetings and other venues where strategy and other issues pertaining to specific drugs under development are discussed. One of the benefits to students who have an interest in a job in industry is the number of contacts and networking opportunities they will develop. Students while here are considered part of Pfizer and are encouraged to take advantage of their time spent with Pfizer colleagues.

EVALUATION

The student will complete three evaluations throughout this experience: 1) a Midpoint/Formative Self-Evaluation, 2) a Preceptor Evaluation and 3) a Site Evaluation. The preceptor, in addition to commenting/signing off on the student Midpoint/Formative Self-Evaluation, will complete a Summative Evaluation at the end of the rotation. Students may be evaluated at any other time at the discretion of the preceptor. Preceptors may evaluate students more frequently, so that the student is informed of areas requiring improvement early in the rotation. The primary preceptor should obtain feedback from all team members.

ORIENTATION TO THE ROTATION

1. On day 1 - Student will take a required on-line safety training course for one hour followed by issuance of a Pfizer building pass.
2. On day 1 – preceptor will review curriculum choices and discuss with student their personal goals and objectives.
3. Full time rotation- 9:00 to 5:00 M-F
4. Cafeteria on-campus
5. Business casual – student will not be meeting with patients
6. Free parking in front of CB-10 – 10555 Science Center Drive
7. Student to contact preceptor if sick or conflict with other commitments

SUPPLEMENTARY MATERIALS AND ASSIGNMENTS

Will be provided on the first day