

## **Division of Medication Error Prevention and Analysis (DMEPA)**

### **Pharmacy Student Experiential Program**

Food and Drug Administration (FDA)

Center for Drug Evaluation and Research (CDER)

Office of Surveillance and Epidemiology (OSE)

Office of Medication Error Prevention and Risk Management (OMEPRM)

#### **Rotation Description**

The goal of FDA's Pharmacy Student Experiential Program is to expose the student to the organization of the FDA and the tools FDA uses to protect the public health by assuring the safety, efficacy and security of medical products. Within the Center for Drug Evaluation and Research (CDER), the Division of Medication Error Prevention and Analysis (DMEPA) conducts premarket review of proposed proprietary medication names, labels/labeling, packaging, and human factor studies to reduce the potential for medication errors for CDER-regulated products. DMEPA also conducts review and analysis of post-marketing medication errors submitted to CDER to determine if regulatory actions are needed such as label /labeling revisions, product redesign, or post-marketing communications to stakeholders. Additionally, DMEPA works with external stakeholders, regulators, and researchers to better understand the causes of medication errors and the effectiveness of interventions at preventing them, and provides guidance to industry on drug development considerations from a medication errors perspective. During this rotation, the student will be exposed to DMEPA's role in premarket and postmarket regulatory activities to minimize risks of medication error and ensure safe product use.

For more information about DMEPA, see <http://www.fda.gov/drugs/drugsafety/medicationerrors/>.

#### **Learning Objectives**

Upon completion of the rotation, the student will be able to:

1. Define the FDA's mission, functions, and organizational structure, including the role of DMEPA within the FDA in premarket and postmarket regulatory activities.
2. Describe regulations and FDA guidances related to medication error prevention for drugs, biologics, and devices.
3. List examples of root causes that can contribute to medication errors and identify effective error-prevention strategies to promote safe use throughout the medication use process.
4. Describe DMEPA's principles for evaluation of proprietary names and product labels, labeling, and packaging design, and explain how the student plans to apply this knowledge in their future career as a pharmacist.
5. Articulate postmarket surveillance tools, including FDA's Adverse Event Reporting System (FAERS) and partnerships that DMEPA uses for postmarket medication error analyses.
6. Use available drug information resources that DMEPA utilizes for premarket and postmarket activities (e.g., DailyMed, Drugs@FDA, newsletters published by The Institute for Safe Medication Practices, <http://labels.fda.gov/>).

#### **Student Activities and Responsibilities** (may include, but not limited to)

1. Attend and participate in lectures offered by the FDA Pharmacy Student Experiential Program.
2. Attend drug product meetings as assigned by preceptor.
3. Create and deliver a final presentation as assigned by the preceptor.
4. Complete project(s) as assigned by preceptor.
5. Protect all confidential and privileged information.