SMG 1261.5

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Effective Date: December 14, 2018

1. Office of Surveillance and Epidemiology (DCDE)

A. Provides leadership, direction, planning, budgeting, management and supervision of divisions and staff and pre-marketing and post-marketing risk assessment program operations.

B. Coordinates regulatory efforts with international and national regulatory counterparts.

C. Develops, coordinates, and implements post-market risk assessment policies, guidance, and interpretations.

D. Initiates regulation development and enhancement.

E. Coordinates and implements policies and initiatives, including information management initiatives, across the Food and Drug Administration (FDA).

F. Creates and maintains professional and skills training programs for Office of Surveillance and Epidemiology (OSE) personnel to maintain credentials and certifications in support of surveillance and epidemiological program activities.

G. Plans and tracks goals and objectives of all OSE divisions.

H. Evaluates OSE work products and communications using quality control technology.

I. Coordinates surveillance and epidemiologic program activities with the FDA Executive Secretariat, the FDA external communications organization, and other internal and external entities.

2. Regulatory Science Staff (DCDE1).

A. Provides leadership, direction, and coordination for OSE regulatory science activities.

B. Develops and manages relationships with outside scientific groups that interface with OSE scientists on a variety of projects that relate to OSE's drug safety mission. These outside groups include academic organizations, private organizations, and other federal agencies.

C. Coordinates the access to large databases for pharmacoepidemiologic and pharmacovigilance studies, as well as to scientists external to the FDA with drug safety expertise to collaborate with OSE staff.

D. Develops and manages a regulatory science program to support OSE by including pharmacoepidemiology, risk management, pharmacovigilance, and medication error detection and prevention.

E. Ensures OSE's informatic systems (e.g., Adverse Event Reporting System, and Phonetic Orthographic Computer Analysis) serve OSE’s needs through interaction with Center and FDA information technology organizations.

F. Provides coordination, development, and assessment of policies, procedures, and best practices for OSE data and information system management.

G. Represents OSE in Center and FDA boards or workgroups that address business process improvements and information technology related to OSE’s mission.

3. Regulatory Affairs Staff (DCDE2).

A. Responsible for coordination and implementation of OSE regulatory policies.

B. Coordinates the development and upkeep of guidance, Manual of Policies and Procedures, and standard operating procedures.

C. Answers regulatory questions and manages the process for waivers of postmarket safety reporting requirements and citizen petition responses.

D. Coordinates and leads OSE involvements on Center and FDA regulatory initiatives, such as development of safety regulations.

4. Program Management and Analysis Staff (DCDE3).

A. Provides leadership, direction, and planning for OCE administrative and contract management programs.

B. Provides guidance and support services to the OSE on all aspects including administrative, budget, and facilities management and provides service and support on human resource, personnel operations services, and recruitment activities.

C. Responsible for coordination, development, and assessment of policies, procedures, and best practices related to OCE office administration and contract management.

D. Provides representation for OSE on Center and FDA best practices boards associated with staff responsibilities.

5. Project Management Staff (DCDE4).

A. Provides leadership, direction, planning, management, and supervision of programs related to drug safety reviews and personnel.

B. Provides management, tracking, and facilitation of projects related to OSE drug safety reviews.

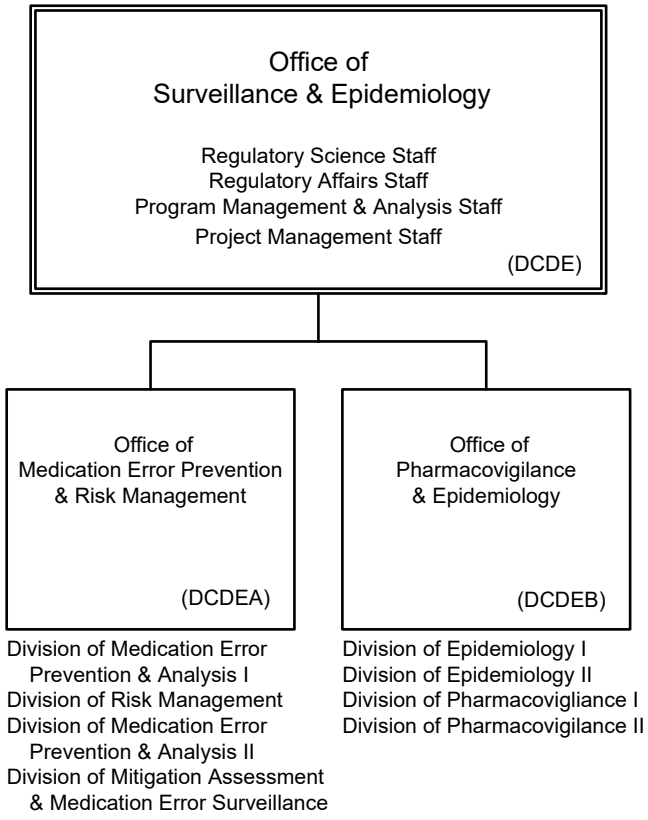
C. Provides coordination, development, and assessment of policies and procedures related to drug safety reviews, review templates, and other best practices related to OSE drug safety reviews.

D. Provides representation for OSE on Center best practices associated with staff responsibilities.

6. Authority and Effective Date.

The functional statements for the Office of Surveillance and Epidemiology were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology



Staff Manual Guide 1261.5
Organizations and Functions
Effective Date: October 9, 2020

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, organization structure depicting all the organizational structures reporting to the Director:

Office of Surveillance and Epidemiology (DCDE)
Regulatory Science Staff
Regulatory Affairs Staff
Program Management and Analysis Staff
Project Management Staff
Office of Medication Error Prevention and Risk Management (DCDEA)
Office of Pharmacovigilance and Epidemiology (DCDEB)

These organizations report to the Office of Medication Error Prevention and Risk Management (DCDEA):
Division of Medication Error Prevention and Analysis I
Division of Risk Management
Division of Medication Error Prevention and Analysis II
Division of Mitigation Assessment and Medication Error Surveillance

These organizations report to the Office of Pharmacovigilance and Epidemiology (DCDEB):
Division of Epidemiology I
Division of Epidemiology II
Division of Pharmacovigilance I
Division of Pharmacovigilance II