

**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 Compliance**

**Office of Science Investigations**

**Division of Safety Compliance**

Effective Date: December 14, 2018

**1. Division of Safety Compliance (DCDFCB).**

- A. Designs and operates surveillance and compliance programs to protect the rights, safety and welfare of individuals participating in Center for Drug Evaluation and Research-regulated research, and to ensure the safety of the nation's drug supply by monitoring adherence to relevant regulations and statutes governing post-market adverse drug experience reporting requirements, risk evaluation and mitigation strategies, postmarketing study requirements, and safety labeling.
- B. Assigns, directs and coordinates onsite inspections in collaboration with the Agency's field organization in order to monitor post-market adverse drug experience reporting requirements and risk evaluation and mitigation strategies. Evaluates inspectional reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary.

**2. Authority and Effective Date.**

The functional statements for the Division of Safety Compliance 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 Compliance  
Office of Scientific Investigations  
Division of Safety Compliance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Scientific Investigations, Division of Safety Clinical organization structure depicting all the organizational structures reporting to the Director.

Division of Safety Compliance (DCDFCB)