

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Regulatory Affairs**

**Office of Regulatory Science**

**Office of Research Coordination and Evaluation**

Effective: December 14, 2018

**1. Office of Research Coordination and Evaluation (DCIFA).**

- A. Advises the Office of Regulatory Affairs (ORA) on scientific issues related to research and evaluation.
- B. Provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning Food and Drug Administration (FDA) regulated products, including their evaluation, quality, safety and effectiveness.
- C. Coordinates with other FDA components (e.g. Office of the Chief Scientist and Center Offices' of Science) on Office of Regulatory Affairs (ORA) scientific programs to assure a cohesive approach to public health protection.
- D. Works with Centers to define research priorities for ORA labs that align with FDA's risk-informed analytical needs. . Recommends priorities for ORA applied research to joint Center/ORA Steering Committees for consideration based on product risk and potential or emerging public health issues.

**2. Scientific Research Staff (DCIFA1).**

- A. Coordinates the scientific peer review board for ORA.
- B. Reviews scientific publications and Laboratory Information Bulletins (LIBs) from ORA field scientists and researchers prior to submission.

- C. Conducts scientific reviews of Office of Regulatory Science (ORS) field laboratory processes and methods.
- D. Conducts reviews, with the administrative staff and appropriate subject matter experts, of all scientific equipment requests from the field laboratories.
- E. Participates in FDA or Center scientific meetings, scientific advisory boards, program alignments groups, and research steering committees.
- F. Coordinates and provides support for ORA's method development and validation activities.
- G. Coordinates with ORA's Human Resource Development program, Office of Management to ensure appropriate level of scientific training in various chemistry and microbiology courses.

**3. Evaluation Staff (DCIFA2).**

- A. Oversees the quality management system, including continual improvement activities, for the ORA science enterprise.
- B. Leads in the development, implementation and maintenance of laboratory accreditation standards and oversight programs.
- C. Trains field laboratory managers and staff on Quality Management Systems (QMS) principles and requirements.
- D. Coordinates and reviews field level proficiency samples.
- E. Oversees lab accreditation activities, including proficiency testing for ORA's laboratories.

**4. Authority and Effective Date.**

The functional statements for the Office of Research Coordination and Evaluation 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  
Office of Regulatory Affairs  
Office of Regulatory Science  
Office of Research Coordination and Evaluation**



Staff Manual Guide 1121.91  
Organizations and Functions  
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Research Coordination & Evaluation organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Research Coordination & Evaluation (DCIFA):

Scientific Research Staff

Evaluation Staff