

**FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

OFFICE OF RESEARCH COORDINATION AND EVALUATION

Effective: June 6, 2016

1. OFFICE OF RESEARCH COORDINATION AND EVALUATION (DLLRKA).

- A. Advises the Deputy ACRA 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 FDA regulated products, including their evaluation, quality, safety and effectiveness.
- C. Coordinates with other Agency 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 agency'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 (DLLRKA1).

- 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 Agency 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 Division of Human Resource Development, Office of Resource Management to ensure appropriate level of scientific training in various chemistry and microbiology courses.

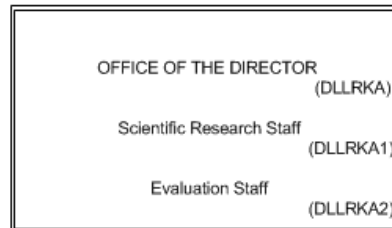
3. EVALUATION STAFF (DLLRKA2).

- 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 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 this Office were approved by the Secretary of Health and Human Services and effective on June 6, 2016.

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STAFF MANUAL GUIDE 1121.91
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Regulatory Science, Office of Research Coordination and Evaluation organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKA):

- Scientific Research Staff (DLLRKA1)
- Evaluation Staff (DLLRKA2)