

**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

Effective: June 6, 2016

1. OFFICE OF REGULATORY SCIENCE (DLLRK).

- A. Provides strategic leadership, coordination, and expertise to the Associate Commissioner for Regulatory Affairs (ACRA), Assistant Commissioner for Operations (ACO), and other Office of Regulatory Affairs (ORA) senior leaders on scientific issues related to policy and regulations.
- B. Advises ACO concerning the management of the ORA's field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.
- C. Provides scientific support in the review of regulatory documents, the development of regulatory decisions, and the analysis of postmarket surveillance issues.
- D. Leads the planning, development, and implementation of ORA's scientific programs including the development, modification, and validation of test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance public health protection and respond to emergencies.
- E. Fosters development and use of innovative technologies to meet public health needs.
- F. Provides strategic leadership and support for high quality, collaborative, scientific activities and research 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.

- G. Coordinates with other Agency components (e.g. Office of the Chief Scientist and Center Offices' of Science) on ORA scientific programs to assure a cohesive approach to public health protection.

2. AUTOMATED LABORATORY MANAGEMENT STAFF (DLLRK1).

- A. Coordinates the maintenance of ORA's Laboratory Procedures Manual and the analytical and scientific review of publications relevant to the work of ORA laboratories, such as field assignments and compliance programs.
- B. Liaises with appropriate FDA Information Technology (IT) staff to implement and oversee all ORA scientific computing and knowledge management needs. In addition, serves as business subject matter experts in the development of information technology systems relevant to ORA laboratory operations.
- C. Ensures that work plan obligations and performance metrics are met.
- D. Provides outreach and technical support for laboratory training related to business Program Management (PM) and system training.
- E. Tracks and provides PM support for ORA's method development and validation activities.
- F. Assists ORA Office of Policy and Risk Management in sampling/analytical program evaluation including data aggregation and trending.

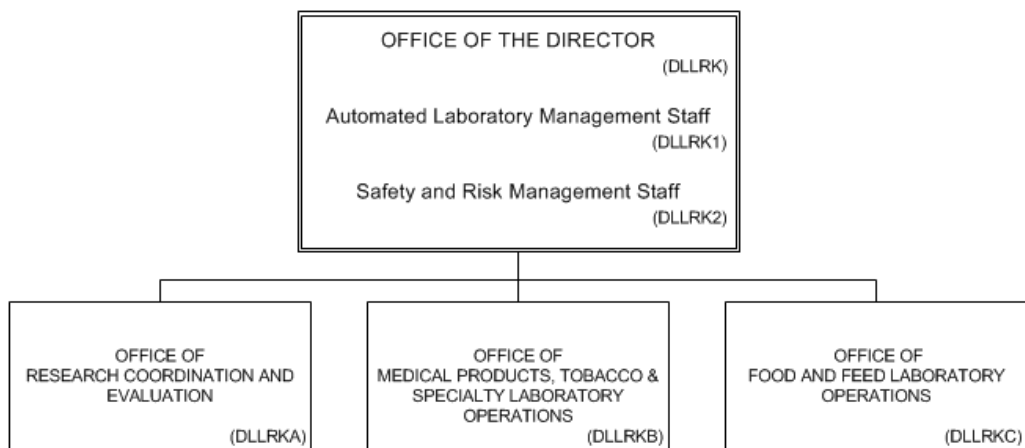
3. SAFETY AND RISK MANAGEMENT STAFF (DLLRK2).

- A. Oversees personal safety in laboratories, biosafety, and radiation safety programs throughout ORS.
- B. Liaises with the FDA ESEM group (FDA OO).
- C. Oversees waste stream management and shipping of hazardous materials.
- D. Coordinates with field laboratories to ensure compliance with state and federal OSHA and environmental standards.
- E. Ensures that safety training is being conducted at field laboratories.
- F. Conducts assessments of safety programs at field laboratories.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

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STAFF MANUAL GUIDE 1121.90
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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRK):

- Automated Laboratory Management Staff (DLLRK1)
- Safety and Risk Management Staff (DLLRK2)
- OFFICE OF RESEARCH COORDINATION AND EVALUATION (DLLRKA)
- OFFICE OF MEDICAL PRODUCTS, TOBACCO AND SPECIALTY LABORATORY OPERATIONS (DLLRKB)
- OFFICE OF FOOD AND FEED LABORATORY OPERATIONS (DLLRKC)