

**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 MEDICAL PRODUCTS, TOBACCO AND SPECIALTY  
LABORATORY OPERATIONS**

Effective: June 6, 2016

**1. OFFICE OF MEDICAL PRODUCTS, TOBACCO AND SPECIALTY  
LABORATORY OPERATIONS (DLLRKB).**

- A. Advises the Office of Regulatory Science (ORS) on scientific issues related to medical products, tobacco, drugs, electronic product radiation, medical devices, pharmaceuticals, radiopharmaceuticals, radionuclides in food, biological and microbiological safety of radiopharmaceuticals, and forensic chemistry.
- 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. Fosters development and use of innovative technologies to meet public health needs.
- D. Advises the Office of Regulatory Science concerning the management of the ORA's field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.

**2. MEDICAL PRODUCTS AND TOBACCO SCIENTIFIC STAFF (DLLRKB1).**

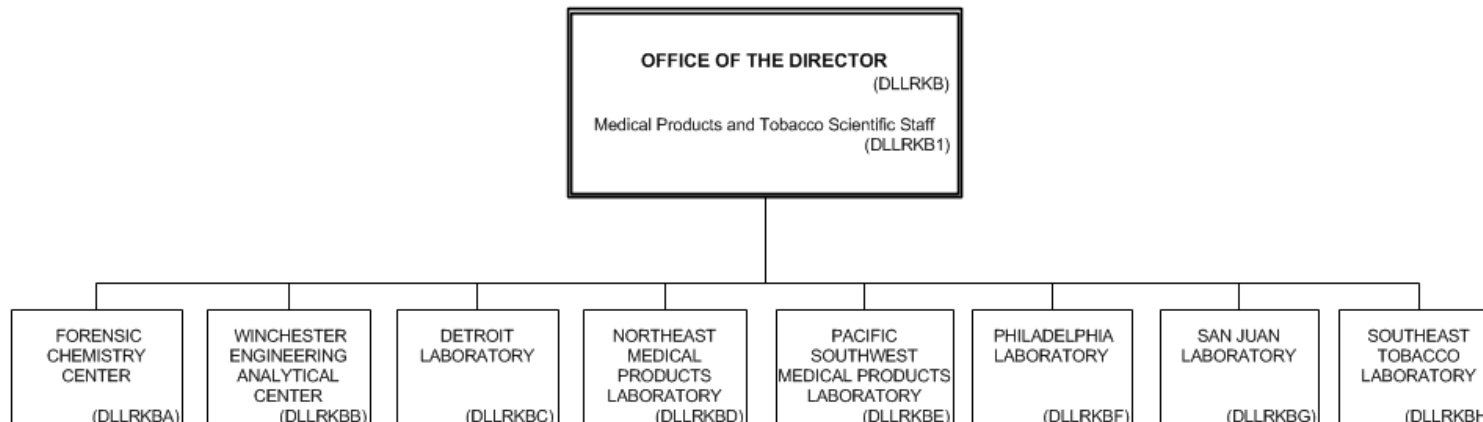
- A. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources relative to medical products, tobacco, forensic chemistry, and radiochemistry.

- B. Provides and coordinates day to day subject matter expertise and technical support and service to ORA laboratories relative to medical products and tobacco.
- C. Coordinates with ORS/Office of Research Coordination and Evaluation (ORCE) to identify and execute applied research based on data gaps, product risk, emerging public health issues.
- D. Serves as subject matter experts in the development of new or modified scientific and analytical compliance policies and regulatory procedures relevant to medical products and tobacco.
- E. Coordinates with Office of Management/Division of Human Resource Development and ORS/Office of Research Coordination and Evaluation to develop and implement training programs relative to medical products, tobacco, forensic chemistry, and radiochemistry based analytical methods.
- F. Leads in the development, implementation and maintenance of relevant laboratory accreditation standards and oversight programs.
- G. Represents ORA on internal and external working groups, committees, taskforces etc. in area of program and product responsibility.

### **3. 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.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY  
OFFICE OF REGULATORY AFFAIRS  
OFFICE OF REGULATORY SCIENCE  
OFFICE OF MEDICAL PRODUCTS,  
TOBACCO AND SPECIALITY LABORATORY OPERATIONS**



STAFF MANUAL GUIDE 1121.92  
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 Medical Products, Tobacco and Specialty Laboratory Operations organization structure depicting all the organizational structures reporting to the Office Director.

**OFFICE OF THE DIRECTOR (DLLRKB):**

- Medical Products and Tobacco Scientific Staff (DLLRKB1)
- FORENSIC CHEMISTRY CENTER (DLLRKBA)
  - Inorganic Branch (DLLRKBA1)
  - Organic Branch (DLLRKBA2)
- WINCHESTER ENGINEERING AND ANALYTICAL CENTER (DLLRKBB)
  - Analytical Branch (DLLRKBB1)
  - Engineering Branch (DLLRKBB2)
- DETROIT LABORATORY (DLLRKBC)
- NORTHEAST MEDICAL PRODUCTS LABORATORY (DLLRKBD)
- PACIFIC SOUTHWEST MEDICAL PRODUCTS LABORATORY (DLLRKBE)
- PHILADELPHIA LABORATORY (DLLRKBF)
- SAN JUAN LABORATORY (DLLRKBG)
- SOUTHEAST TOBACCO LABORATORY (DLLRKBH)