SMG 1120.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

Effective Date: 08/07/2012

1. OFFICE OF REGULATORY AFFAIRS (DLLR).

A. Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals.

B. Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner.

C. Stimulates an awareness within the Agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between voluntary and regulatory compliance and Agency responsiveness to consumer needs.

D. Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.

E. Executes direct line authority over all Agency field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the Agency through which Headquarters offices obtain field support services.

F. Provides direction and counsel to Regional Food and Drug Directors in the implementation of policies and operational guidelines that form the framework for management of Agency field activities.

G. Develops and/or recommends to the Commissioner policy, programs, and plans for activities between the Agency and State and local agencies; administers the Agency's overall Federal-State program and policy; coordinates the program aspects of Agency contracts with State and local counterpart agencies.

H. Evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.

I. Directs and coordinates the Agency's emergency response and civil defense programs.

J. Operates the Federal Medical Products Quality Assurance Program for the Agency.

K. Advises the ACRA on all matters related to ORA’s information technology needs, systems development, and budgetary issues.

L. Coordinates with staff in ORA offices, regions, districts and laboratories as well as offices and staff external to ORA to develop and evaluate business needs in relation to current and planned information technology systems, and foster relations that facilitate ORA’s IT efforts.

M. Develops long-range strategic plans for ORA’s information technology infrastructure and systems.

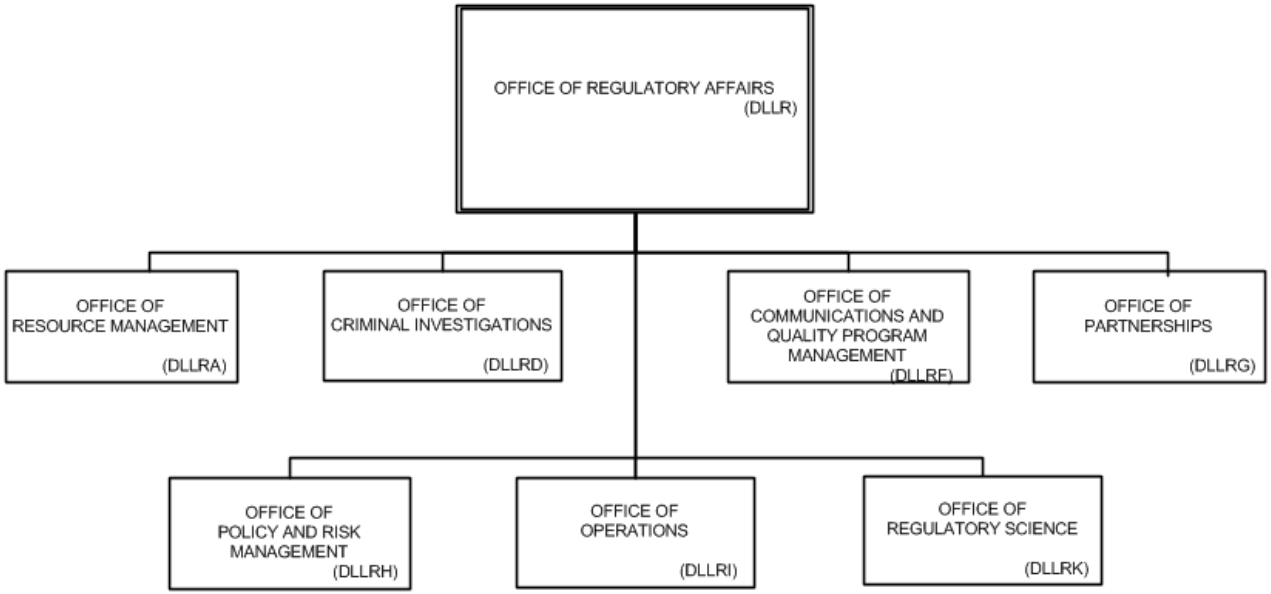
N. Coordinates programs and procedures to solicit input from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met.

O. Evaluates new policies and regulations for impacts to ORA IT systems.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Humans Services, effective on August 7, 2012.

FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
OFFICE OF REGULATORY AFFAIRS



STAFF MANUAL GUIDE 1120.1
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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLR):

- OFFICE OF RESOURCE MANAGEMENT (DLLRA)
- OFFICE OF CRIMINAL INVESTIGATIONS (DLLRD)
- OFFICE OF COMMUNICATIONS AND QUALITY PROGRAM MANAGEMENT (DLLRF)
- OFFICE OF PARTNERSHIPS (DLLRG)
- OFFICE OF POLICY AND RISK MANAGEMENT (DLLRH)
- OFFICE OF OPERATIONS (DLLRI)
- OFFICE OF REGULATORY SCIENCE (DLLRK)