

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

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY**

Effective Date: 07/08/2011

**1. OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY (DLL).**

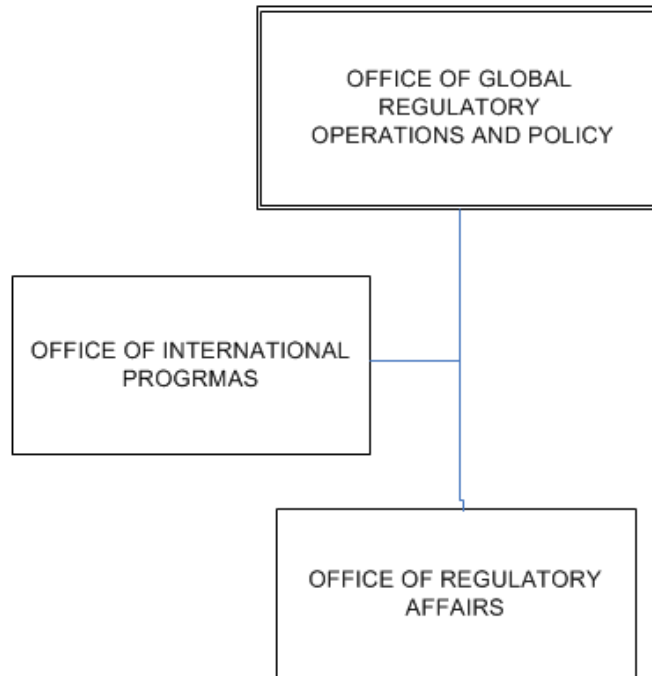
- A. Provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities
- B. Drives improvement in FDA's risk analytics and IT capability, in conjunction with the Office of Information Management, to enhance FDA's gathering and use of intelligence in directing its regulatory efforts
- C. Leverages public and private sector third parties to increase FDA's global knowledge and coverage
- D. Convenes and chairs a Global Programs Board, consisting of the Associate Commissioner for Regulatory Affairs, the Directors of all FDA Product Centers, and other agency leaders, in order to coordinate and enhance FDA's global efforts
- E. Provides executive leadership and management to all programs in the Office of Regulatory Affairs and the Office of International Programs
- F. Exercises, on behalf of the Commissioner, direct line authority over the Office of Regulatory Affairs and the Office of International Programs
- G. Exercises, on behalf of the Commissioner, all international and Office of Regulatory Affairs-related legal authorities that the Commissioner is empowered to exercise under the Federal Food, Drug, and Cosmetic Act, as amended, the Public Health Service Act, and other applicable laws
- H. Represents FDA on matters relating to domestic and international product quality and safety efforts in dealings with the executive branch, Congress, foreign governments and international organizations, and others

## 2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services effective, July 8, 2011.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	07/08/2011	N/a	OO/OM	Secretary of Health and Human Services

FOOD AND DRUG ADMINISTRATION  
OFFICE OF GLOBAL REGULATORY OPERATIONS & POLICY



Staff Manual Guide 1190.1  
Organizations and Functions  
Effective Date: July 8, 2011

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

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY:

- OFFICE OF INTERNATIONAL PROGRAMS
- OFFICE OF REGULATORY AFFAIRS