

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF SCIENTIST

OFFICE OF REGULATORY SCIENCE AND INNOVATION

Effective Date: 07/08/2011

1. OFFICE OF REGULATORY SCIENCE AND INNOVATION (DAEI)

Provides strategic leadership, coordination, infrastructure and support for excellence and innovation in FDA science that will advance the Agency's ability to protect and promote the health of the public. Key activities include:

1. Supporting high quality, collaborative scientific activities to address important public health and regulatory issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness
2. Supporting core scientific capacity, scientific infrastructure and bioinformatics computation
3. Fostering development and use of innovative technologies in product development and evaluation
4. Addressing scientific and public health priorities through support of high quality, peer reviewed scientific research, programs and related activities, both within and outside FDA and collaboratively, and through dissemination of new scientific information, methods and approaches
5. Providing agency-wide guidance and resources for the identification of and capturing of FDA intellectual property in order to foster an atmosphere of innovation
6. Supporting scientific outreach, training, and collaboration in research and development activities that advance FDA's mission, that engage other Agencies, global regulatory partners, academia, innovators, and consumers

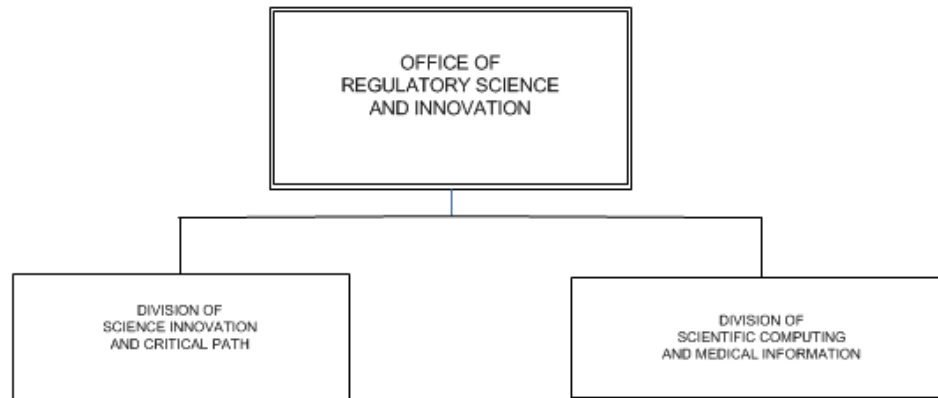
7. Seeking input from FDA programs, stakeholders and outside advisors, including the FDA Science Board, to help define, review and meet FDA scientific needs and priorities to support our public health mission
8. Serves as the nexus for cutting-edge, cross-center scientific and medical initiatives as well as policy development related to the Critical Path (CP) Initiative. Manages Critical Path-related internal and external outreach (e.g., presentations, reports, videos (DVDs), pod casts, brochures, editorials, PR, press kits, CPI website updates) across all communications platforms
9. Supports cross-center advanced scientific informatics activities, including advancing activities related to data management and analysis and safety surveillance of FDA-regulated products

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.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/07/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Secretary of the Department of Health and Human Services
Revision	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services

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Organizations and Functions
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The following is the Food and Drug Administration, Office of the Commissioner, Office of Chief Scientist, Office of Regulatory Science and Innovation organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF REGULATORY SCIENCE AND INNOVATION:

- **DIVISION OF SCIENCE INNOVATION AND CRITICAL PATH**
- **DIVISION OF SCIENTIFIC COMPUTING AND MEDICAL INFORMATION**