

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF SCIENTIST

Effective Date: July 22, 2015

1. OFFICE OF THE CHIEF SCIENTIST (DAE).

Provides strategic leadership, coordination, and expertise to support scientific excellence, innovation and capacity to achieve the Food and Drug Administration's public health mission. Key activities include:

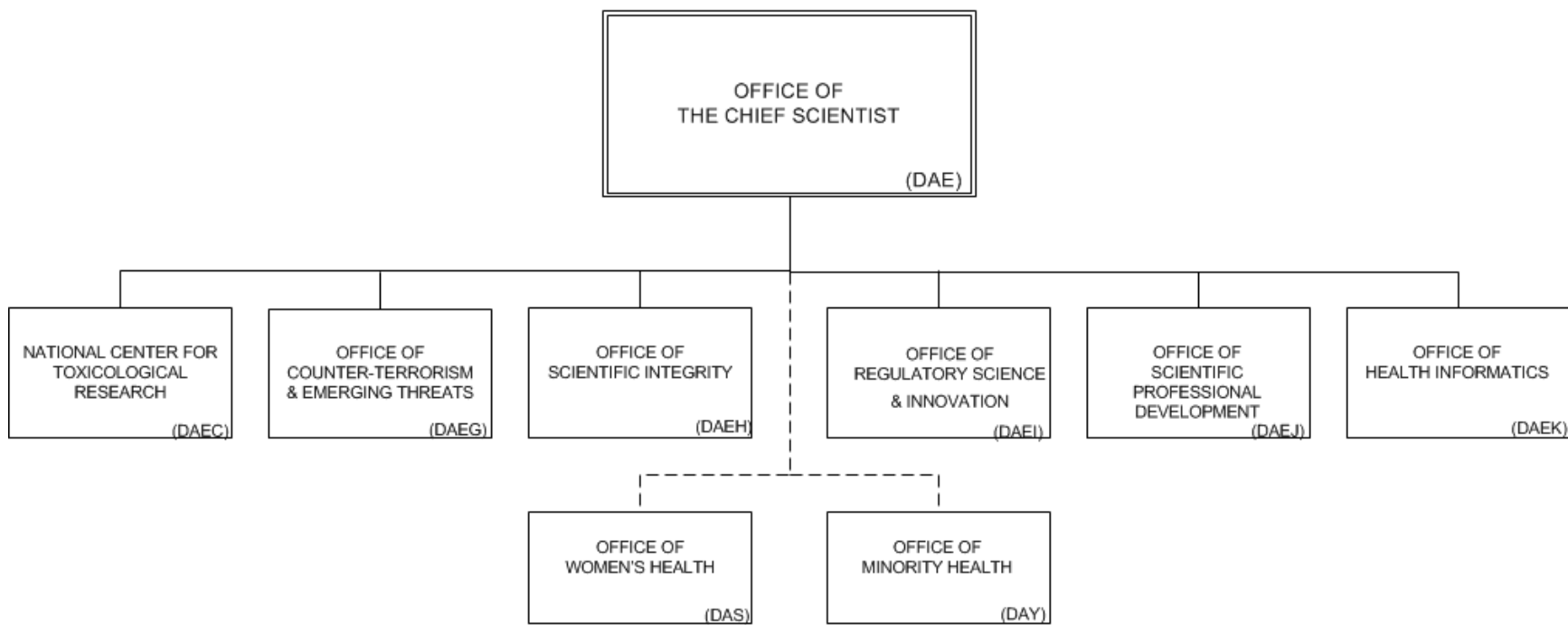
- A. Fostering development and use of innovative technologies to meet public health needs including health informatics.
- B. Supporting scientific excellence and the professional development of FDA scientists in all areas (i.e. population/statistical, review, laboratory and manufacturing sciences), including through the Commissioner's Fellowship Program, continuing education, and scientific interactions with universities and others.
- C. Providing 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.
- D. Exercising on behalf of the Commissioner direct line authority over, and providing executive leadership, management, and policy direction to, the National Center for Toxicological Research to serve as a national FDA resource for mission driven regulatory science.
- E. Assisting the Commissioner by providing general oversight of and informal direction to the Office of Women's Health and the Office of Minority Health.
- F. Providing cross-agency scientific coordination (e.g., for emerging technologies, scientific issues involving multiple agency components, standards coordination, the FDA Science Board, electronic data sources, and science communication).

- G. Supporting scientific outreach, training, and collaboration, including research, development and Critical Path activities that engage other Agencies, global regulatory partners, academia, innovators, and consumers.
- H. Supporting science and public health activities to effectively anticipate and respond to counter-terrorism and emerging deliberate and natural threats (e.g. chemical, biological, radiological and nuclear) to US and global health and security including through the Office of Counter-terrorism and Emerging Threats.
- I. Providing core scientific leadership and technical expertise, and ensuring agency capacity, for advanced bioinformatics activities needed to support FDA programs. Serve as an Agency and government resource for excellence, methods development, outreach and partnerships in advanced bioinformatics and health informatics science.
- J. Leading agency efforts to protect and enhance scientific integrity, and, where substantive scientific differences of opinion arise and require review at the FDA level, addressing them through appropriate processes intended to protect both FDA's mission and the integrity of its science.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Acting Commissioner for Food and Drugs, and effective on July 22, 2015.

FOOD AND DRUG ADMINISTRATION OFFICE OF THE COMMISSIONER OFFICE OF THE CHIEF SCIENTIST



Staff Manual Guide 1114.1
Organizations and Functions
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The following is the Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF CHIEF SCIENTIST (DAE):

- NATIONAL CENTER FOR TOXICOLOGY RESEARCH (DAEC)
- OFFICE OF COUNTER-TERRORISM & EMERGING THREATS (DAEG)
- OFFICE OF SCIENTIFIC INTEGRITY (DAEH)
- OFFICE OF REGULATORY SCIENCE & INNOVATION (DAEI)
- OFFICE OF SCIENTIFIC PROFESSIONAL DEVELOPMENT (DAEJ)
- OFFICE OF HEALTH INFORMATICS (DAEK)

Reports directly to the Commissioner and indirect report to the Chief Scientist:

- OFFICE OF WOMEN'S HEALTH (DAS)
- OFFICE OF MINORITY HEALTH (DAY)