

**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

DIVISION OF SCIENCE INNOVATION AND CRITICAL PATH

Effective Date: 07/08/2011

1. DIVISION OF SCIENCE INNOVATION AND CRITICAL PATH (DAEIA)

- A. 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
- B. Foster and support high quality, mission-targeted FDA collaborative and extramural research to enhance product evaluation tools
- C. Expand FDA efforts to provide industry clear pathways for development of novel products
- D. Advance major scientific initiatives including for example, the personalized medicine initiative through science programs directed at biomarker development and standardization; innovative strategies for clinical trial design; and scientific computing approaches for assessment of -omics data and multiple studies
- E. 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

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division 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	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, Division of Science Innovation and Critical Path organization structure depicting all the organizational structures reporting to the Office Director.

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