SMG 1119A.4

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Chief Scientist

Office of Regulatory Science and Innovation

Effective Date: January 6, 2022

1. Office of Regulatory Science and Innovation (DCPC).

- A. Provides strategic leadership, coordination, infrastructure and support for excellence and innovation in Food and Drug Administration (FDA) science that will advance the FDA's ability to protect and promote the health of the public.
- B. Supports high quality, collaborative scientific activities to address important public health and regulatory issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness.
- C. Strengthening core scientific capacity and scientific infrastructure through leading and managing the Senior Science Council and topical working groups comprised of scientists from all Centers/Offices.
- D. Fosters development and use of innovative technologies in product development and evaluation.
- E. Addresses scientific and public health priorities through support of high quality, peer reviewed scientific research, programs and related activities, both within and outside FDA, through management of internal grant programs and academic Centers of Excellence in Regulatory Science and Innovation.
- F. Supports 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.
- G. Seeks 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

2. Authority and Effective Date.

The functional statements for the Office of Regulatory Science and Innovation were approved by the Deputy Secretary of Health and Human Services on October 22, 2021, and effective on January 6, 2022.

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Department of Health and Human Services Food and Drug Administration Office of the Chief Scientist Office of Regulatory Science and Innovation

Office of Regulatory Science & Innovation

(DCPC)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, Office of Regulatory Science and Innovation organization structure depicting all the organizational structures reporting to the Director.

Office of Regulatory Science and Innovation (DCPC)