

SMG 1266.123

FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF MEDICAL POLICY

OFFICE OF MEDICAL POLICY INITIATIVES

DIVISION OF CLINICAL TRIAL QUALITY

Effective Date: March 23, 2015

1. DIVISION OF CLINICAL TRIAL QUALITY (DKKNFBC).

- A. Fosters efficient oversight of clinical trial conduct through policy initiatives that build quality upfront to ensure data integrity and human subject protection.
- B. Collaborates with the Office of New Drugs (OND) to assess clinical trial protocols to integrate risk-based monitoring, quality by design, and quality risk management paradigms in Investigational New Drug Applications (IND), New Drug Applications (NDA) and Biologic License Applications (BLA).
- C. Manages and coordinates surveillance activities and science-based inspectional approaches for clinical trials in collaboration with the Office of Scientific Investigations (OSI) and OND including site selection and evaluation of inspectional findings from a trial quality perspective.
- D. Promotes quality initiatives through policy development, outreach, and Public-Private Partnerships, in coordination with other Agency components.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by Commissioner for Food and Drug, and effective on March 23, 2015.

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OFFICE OF THE DIRECTOR

(DKKNFBC)

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiative, Division of Clinical Trial Quality organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKNFBC)