

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Medical Policy

Division of Clinical Trial Quality

Effective Date: December 14, 2018

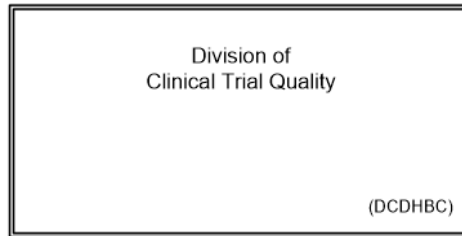
1. Division of Clinical Trial Quality (DCDHBC).

- 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 and Biologic License Applications.
- 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 the Division of Clinical Trial Quality were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy
Office of Medical Policy Initiative
Division of Clinical Trial Quality**



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The following is the Department of Health and Human Services, Food and Drug Administration, 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 Director.

Division of Clinical Trial Quality (DCDHBC).