SMG 1262.52

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 Compliance

Office of Science Investigations

Division of Good Clinical Practice Compliance

Effective Date: December 14, 2018

1. Division of Good Clinical Practice Compliance (DCDFCA).

A. Designs and operates surveillance and compliance programs in the areas of clinical drug product investigations or studies. This includes oversight of clinical investigators (CIs), sponsors, and other entities with relevant regulatory responsibilities.

B. Assigns, directs and coordinates onsite inspections in collaboration with the Food and Drug Administration (FDA) field organization in order to monitor clinical drug product studies.

C. Evaluates inspectional reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary.

D. Consults with Center for Drug Evaluation and Research review divisions to identify sites for inspection relating to clinical studies used to support investigational new drugs, abbreviated new drugs applications, or new drug application.

E. Evaluates complaints and issues for-cause/directed inspections.

2. Good Clinical Practice Enforcement Branch (DCDFCA1).

A. Evaluates complaints and incident reports received regarding CIs, sponsors, monitors, and contract research organizations (CROs), and issues related for-cause/directed inspection assignments.

B. Directs and may participate in inspections of CIs, sponsors, monitors, and CROs that are the subject of a complaint or incident report, to determine compliance with Federal regulations.

C. Reviews for-cause/directed evaluation inspection reports (EIRs) of CIs, sponsors, monitors, and CROs from FDA field staff and makes recommendations to the review divisions regarding the adequacy of the protection of rights and welfare of human subjects, and the quality, integrity, and acceptability of the data audited during onsite inspections and develops appropriate regulatory correspondence to the inspected party.

D. Reviews all EIRs classified as Official Action Indicated resulting from inspections of CIs, sponsors, monitors, and CROs, and evaluates the evidence and develops the regulatory strategy necessary to resolve the issue. This may include issuance of a Warning Letter or a Notice of Initiation of Disqualification Proceedings and the Opportunity to Explain to the inspected party.

E. Formalizes the regulatory strategy and is responsible for the coordination of regulatory actions with the Office of Chief Counsel and the Office of the Commissioner.

3. Good Clinical Practice Assessment Branch (DCDFCA2).

A. Selects for audit (in cooperation with CDER's review divisions) those clinical safety or efficacy studies that are pivotal to the Agency's evaluation of marketing applications (new drug applications and biologics license applications).

B. Directs and may participate in inspections of CIs, sponsors, monitors, and CROs when these inspections are conducted in support of marketing applications, to determine compliance with Federal regulations.

C. Reviews EIRs from FDA field staff and makes recommendations to the review divisions regarding the quality, integrity, and acceptability of the data audited during onsite inspections and the adequacy of the protection of rights and welfare of human research subjects.

D. Develops appropriate post-inspectional correspondence to the inspected entity.

4. Authority and Effective Date.

The functional statements for the Division of Good Clinical Practice Compliance were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
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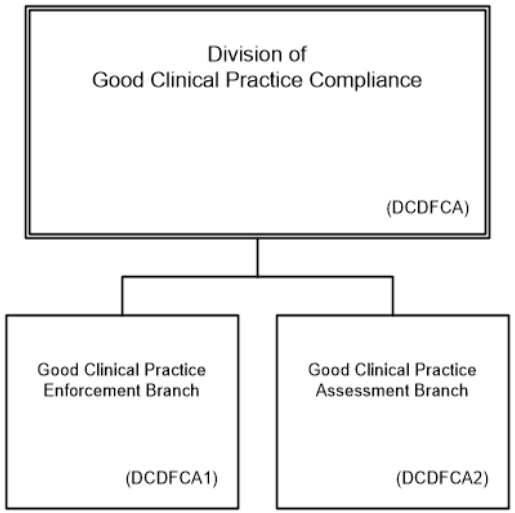

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Scientific Investigations, Division of Good Clinical Practice Compliance organization structure depicting all the organizational structures reporting to the Director.

Division of Good Clinical Practice Compliance (DCDFCA)

These organizations report to the Division of Good Clinical Practice Compliance:

Good Clinical Practice Enforcement Branch (DCDFCA1)

Good Clinical Practice Assessment Branch (DCDFCA2)

Back to Organizations and Functions, Volume I (1000-1300)