

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Science

Office of Medical Products, Tobacco and Specialty Laboratory Operations

San Juan Laboratory

Effective Date: December 14, 2018

1. San Juan Laboratory (DCIFBG)

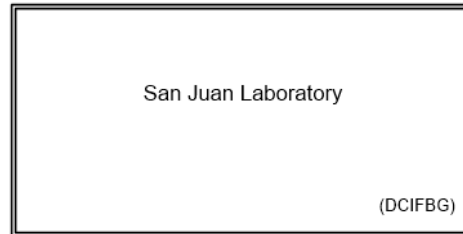
- A. Manages and evaluates program activities, measures accomplishments against annual field work-plan objectives, initiates management and program analyses, manages a quality assurance program, and advises the Office of Regulatory Science (ORS) regarding strategy changes needed to reach existing or modified objectives.
- B. Coordinates emergency activities by maintaining liaison with other Federal agencies and by providing assistance to States and localities in the event of a national disaster or other emergency.
- C. Coordinates the equal employment opportunity, internal security, safety, and emergency preparedness programs.
- D. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates analytical workplans.
- E. Performs laboratory analysis of samples to:
 - 1. Assess their compliance with laws and regulations enforced by the Food and Drug Administration (FDA).
 - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- F. Provides evidence regarding analytical findings as requested.

- G. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- H. Serves as a resource in scientific knowledge and provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, industry and academic institutions.
- I. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- J. Provides analytical support to Headquarters components as needed.
- K. Implements an effective internal quality assurance program to assure the reliability of analytical results.

2. Authority and Effective Date.

The functional statements for the San Juan Laboratory were approved by the Secretary for Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
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San Juan Laboratory**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Products, Tobacco and Specialty Laboratory Operations, San Juan Laboratory organization structure depicting all the organizational structures reporting to the Director:

San Juan Laboratory (DCIFBG)