

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 Communication and Project Management

Division of Project Management

Effective Date: December 14, 2018

1. Division of Project Management (DCIDB).

- A. Serves as the Office of Regulatory Affairs (ORA) principal resource for managing high priority and cross-cutting projects.
- B. Provides governance support to senior leadership on how various ORA projects contribute to ORA strategic priorities.
- C. Analyzes the ORA project portfolio based on strategic alignment, risk and investment.
- D. Provides senior leadership advice on project prioritization.
- E. Provides expert project management consultative services to ORA staff on projects not directly managed by PCS.
- F. Develops, maintains and communicates project management standards and best practices.

2. Project Management Resources Branch (DCIDB1)

- A. Maintains a project management resource center including standardized processes, tools, techniques and templates for managing projects across ORA.
- B. Monitors and reports on ORA project portfolio status by tracking project resource requirements, risks and strategic alignment to ORA priorities.
- C. Supports ORA project governance process.

D. Provides project management expertise to ORA staff on best practices.

3. Project Management Branch 1 (DCIDB2)

- A. Manages high priority projects in support of the Human and Animal Food Operations, Medical Products and Tobacco Operations, Enforcement and Import Operations, and Regulatory Science programs.
- B. Serves as a partner with the above offices to provide project management support aligned to their strategic priorities and advises on project selection and prioritization.
- C. Provides status and analysis of the branch's project portfolio to enable strategic utilization of resources and maximization of ORA's return on investments.

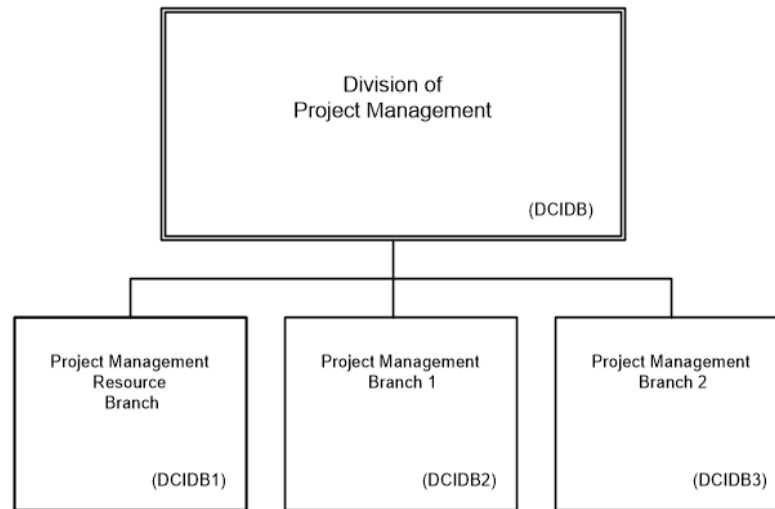
4. Project Management Branch 2 (DCIDB3)

- A. Manages high priority projects in support of the Partnerships and Operational Policy, Resource Management, Communications and Project Management, and Criminal Investigations programs.
- B. Serves as a partner with the above offices to provide project management support aligned to their strategic priorities and advises on project selection and prioritization.
- C. Provides status and analysis of the branch's project portfolio to enable strategic utilization of resources and maximization of ORA's return on investments.

5. Authority and Effective Date.

The functional statements for the Division of Project Management 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
Office of Regulatory Affairs
Office of Communications and Project Management
Division of Project Management**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Communications and Project Management, Division of Project Management organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Project Management (DCIDB):

Project Management Resource Branch (DCIDB1)

Project Management Branch 1 (DCIDB2)

Project Management Branch 2 (DCIDB3)