

SMG 1121A.62

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Business Informatics and Solutions Management

Division of Regulatory Business Informatics and Solutions

Effective Date: May 13, 2024

- 1. Division of Regulatory Business Informatics and Solutions (DCSFC).**
 - A. Manages operational business solutions supporting the Regulatory Program operational activities of the Office of Inspections and Investigations (OII).
 - B. Works in coordination and consultation with the Office of Digital Transformation (ODT) to be consistent with enterprise-wide priorities.
 - C. Partners with the ODT to plan, implement, operate, and maintain solutions that support the Regulatory Program operational activities for OII as well as integrate such solutions with other Food and Drug Administration (FDA) Centers, Offices, and State regulatory and public health agency solutions.
 - D. Serves as a liaison to the ODT and the Department of Health and Human Services (HHS) for the business requirements and functionality, and works with ODT and contractors on design, development, application, and implementation of operational business solutions supporting the Regulatory Program operational activities; analyzes, reviews and makes recommendations for modifications to existing solutions; and proposes new business solutions to meet OII and its customers' requirements.
 - E. Provides a customer-oriented support center, technical assistance and business process re-engineering activities for OII business solutions supporting Regulatory Program operational activities.
 - F. Manages business solution projects supporting the Regulatory Program operational activities working in conjunction with business sponsors, the Office of Acquisition and Grants (OAGS) and ODT.

2. Regulatory Business Informatics Branch (DCSFC1).

- A. Provides official responses and ad hoc reports in response to data requests associated with data stored in OII Regulatory Solutions.
- B. Provides technical assistance and training to OII staff associated with the generation of data and creation of reports associated with data stored in OII Regulatory solutions.
- C. Assists business in managing data stored in OII solutions natively or received from other systems through analysis of data quality and recommending solutions to resolve or to improve data quality of data stored in systems supporting the Regulatory Program.
- D. Engages with the development and enhancement of solutions to be aware of policies that drive data collection, data exchange implementations, changes to data content, and changes to data modeling, and to advise on and have awareness of development to conduct data reporting and analysis.
- E. Facilitates implementation of best practices for data collection, data exchange, querying, and governance of data structures in OII solutions supporting the Regulatory Program.

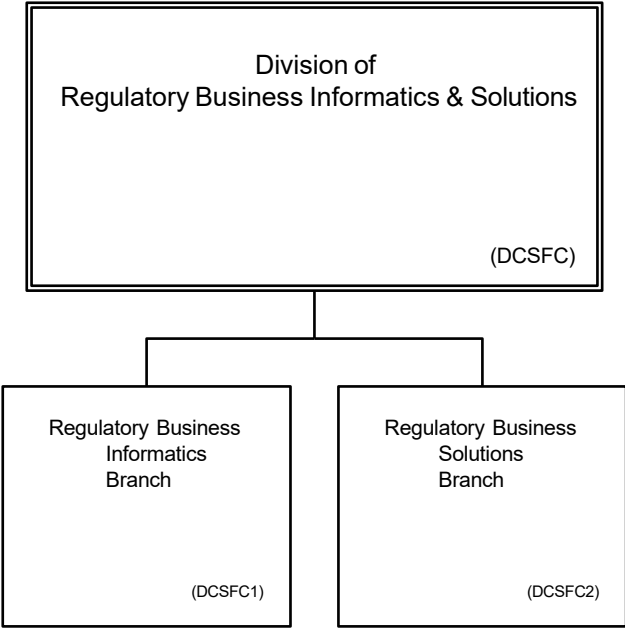
3. Regulatory Business Solutions Branch (DCSFC2).

- A. Serves as business lead and subject matter experts for OII solutions supporting Regulatory activities and processes.
- B. Conducts joint business planning with OII, Centers, and Office stakeholders to systematically assess and prioritize business needs for new functionality associated with Regulatory activities.
- C. Ensures processes and resources are in place to build, deploy, and support solutions supporting Regulatory activities.
- D. Supports adherence to policies and procedures for Regulatory program operations through business process analysis and solutions development activities.

4. Authority and Effective Date.

The functional statements for the Division of Regulatory Business Informatics and Solutions were approved by the Secretary for Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Business Informatics' and Solutions Management
Division of Regulatory Business Informatics and Solutions**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Business Informatics' and Solutions Management, Division of Regulatory Business Informatics and Solutions organization structure depicting all the organizational structures reporting to the Director:

Regulatory Business Informatics Branch (DCSFC1)

Regulatory Business Solutions Branch (DCSFC2)