

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine

Office of New Animal Product Evaluation

Division of Business Information Science and Management

Effective Date: August 23, 2024

1. Division of Business Information Science and Management (DCGCH).

- A. Oversees the development and implementation of tools and systems to support the regulatory evaluation of new animal products.
- B. Manages the compliance of new animal product developers with the financial aspects of the Animal Drug User Fee Act, prior to the review of their submissions.
- C. Oversees the quality management within the Office of New Animal Product Evaluation.
- D. Manages the Office's support of and participation in the Center's Bioresearch Monitoring Program.
- E. Oversees the management the new animal product review process from early development to marketing, liaising between animal product developers and the Office.
- F. Develops short and long-range work plans and staffing need proposals for the Division.

2. Business Informatics Branch (DCGCH1).

- A. Facilitates and coordinates the development and implementation of tools and systems to support the regulatory evaluation of new animal products.
- B. Ensures that new animal product developers are in compliance with the financial aspects of the Animal Drug User Fee Act, prior to the review of their submissions.

3. Quality Assurance Branch (DCGCH2).

- A. Serves as the quality management experts within the Office of New Animal Product Evaluation.
- B. Coordinates the Office's support of and participation in the Center's Bioresearch Monitoring Program.

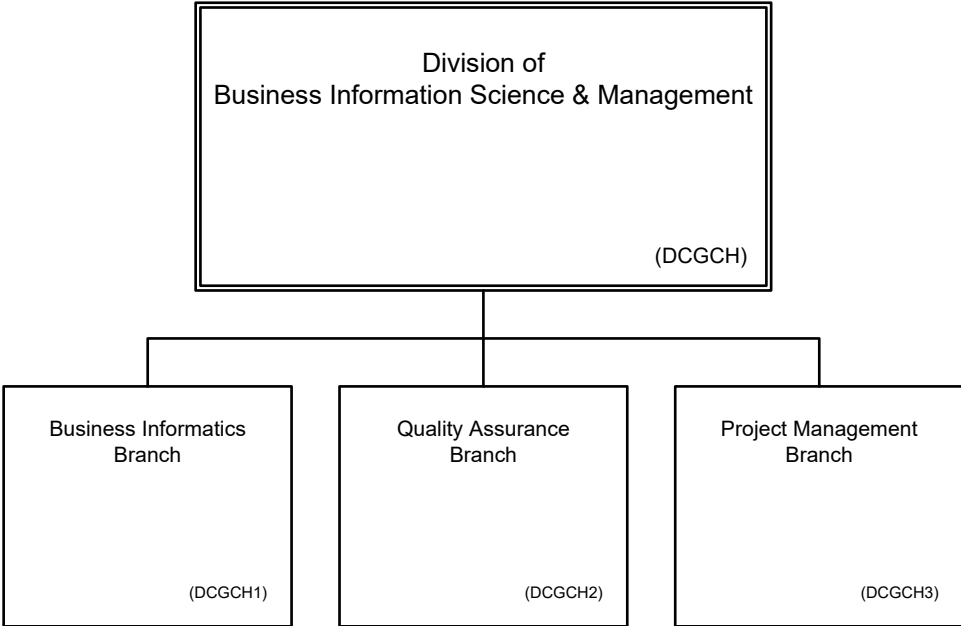
4. Project Management Branch (DCGCH3).

- A. Manages the new animal product review process from early development to marketing, liaising between animal product developers and the Office.

5. Authority and Effective Date.

The functional statements for the Division of Business Information Science and Management were approved by the Secretary of Health and Human Services on July 22, 2024, and effective on August 23, 2024.

**Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
Office of New Animal Product Evaluation
Division of Business Information Science and Management**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Product Evaluation, Division of Business Information Science and Management organization structure depicting all the organizational structures reporting to the Director:

Division of Business Information Science and Management (DCGCH)
Business Informatics Branch (DCGCH1)
Quality Assurance Branch (DCGCH2)
Project Management Branch (DCGCH3)