SMG 1280.61

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administrations

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Quality Surveillance

Division of Quality Data Science

Effective Date: September 25, 2019

1. **Division of Quality Data Science (DCDLEA).**

   A. Curates data into a catalog of Center for Drug Evaluations and Research regulated sites and products by extracting data from a wide variety of Food and Drug Administration internal and external sources, including reviewing and verifying registration and listing information.

   B. Assures the integrity and quality of data used in Office of Quality Surveillance managed analytical tools, including collaboration with internal and external system owners to update and validate the data across relevant sources.

   C. Enhances data analytics by identifying data gaps and issues, promoting efficient use of resources to ensure a robust analytics and informatics program, and implementing tools (e.g., data visualization) needed to support drug quality programs.

   D. Provides analytics and informatics support to relevant business partners on site and product specific data to inform the Food and Drug Administration initiatives, including user fee programs.

   E. Responds to data inquiries regarding sites and products to inform Congress, General Accounting Office, and the media while assisting business partners with emergency response and shortages.

   F. Develops, validates, maintains, and operates risk analytic models related to monitoring and assessment of quality.

G. Provides quantitative information to stratify site and product status based on quality and product/process robustness assessments to drive planning and scheduling decisions and future surveillance activities.

H. Researches risk-based methodologies to support surveillance activities and leverage cross-center and external expertise and develops and participates in the quantitative risk assessment methods needed to monitor and determine the state of quality.

I. Supports the human drug surveillance program through quality-based assessments and activities, including regulatory evaluation of relevant information, scoring of internal or external pharmaceutical quality data, engagement with industry, and application assessment.

2. Authority and Effective Date.

The functional statements for the Division of Quality Data Science were approved by the Secretary of Health and Human Services on September 25, 2019.

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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 Pharmaceutical Quality, Office of Quality Surveillance, Division of Quality Data Science organizational structures depicting all the organizational structures reporting to the Director.

Division of Quality Data Science (DCDLEA).