SMG 1280.63

FDA Staff Manual Guides, Volume I – Organizations and Functions

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 Intelligence II

Effective Date: October 10, 2023

1. Division of Quality Intelligence II (DCDLEC).

A. Ensures the integrity and quality of data (e.g., facility information and volume data) across relevant sources through clear and comprehensive data oversight strategies and collaboration with internal and external system owners. Optimizes the use of data within the bounds of policy and regulation to drive risk-based decisions and take surveillance actions that maximize protection of public health.

B. Uses data, and a robust analytics and informatics program, to provide supply chain oversight which informs relevant business partners and stakeholders such as Congress, the Government Accountability Office, and media. Conducts complex analyses that facilitate decision making and mitigate supply chain disruptions or drug shortages.

C. Supports the human drug surveillance program through qualitative and quantitative assessment of regulatory submissions, post-market reports (e.g., Changes Being Effected and Annual Reports), quality metrics, quality management maturity, pharmaceutical quality system effectiveness, and other related quality related data and intelligence available throughout the product lifecycle. Leads or participates in inspections as necessary.

D. Conducts research on risk-based, innovative, and modern methodologies to support surveillance actions and leverages expertise across the centers as well as external to the agency. Collaborates with business partners and stakeholders to optimize selection of data sources for integration into the

quality surveillance program. Develops, tests, validates, and maintains quantitative risk assessment methods and tools needed to monitor and determine the state of quality and achieve comprehensive drug quality surveillance.

E. Leads post-market quality-based assessments of sites and products by identifying, evaluating, trending, and visualizing quality intelligence, such as root cause analyses and corrective and preventive actions, to execute response actions that mitigate urgent quality issues and risks associated with pharmaceutical formulation and manufacturing processes.

F. Leads the strategic development and implementation of a sampling and testing program, including identification of products for sampling, development of sampling plans and experimental designs, selection of tests and methods, and integration of testing results into the broader quality surveillance program.

2. Authority and Effective Date.

The functional statements for the Division of Quality Intelligence II were approved by the Secretary of Health and Human Services on August 10, 2023, and effective on October 10, 2023.

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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 Intelligence II organization structure depicting all the organizational structures reporting to the Director:

Division of Quality Intelligence II (DCDLEC)