SMG 1280.60

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

Effective Date: October 10, 2023

1. Office of Quality Surveillance (DCDLE).

A. Ensures that quality medicines are available through signal detection, data analysis, review of the state of quality, and proactive stakeholder engagement.

B. Coordinates Office of Quality Surveillance analytics, informatics, and research and development efforts to enable programmatic enhancements, efficiencies, and data integration toward a comprehensive quality surveillance program that can support other Center for Drug Evaluation and Research (CDER) and Office of Pharmaceutical Quality (OPQ) supply chain oversight needs.

C. Directs analytic and predictive programs to assess and report on the state of quality of regulated industry at manufacturing site and drug product levels using informative, innovative, and impactful data sources.

D. Develops innovative approaches to quality surveillance and supply chain oversight that complement established inspection programs and enhance surveillance coverage, international collaboration, and industry engagement.

E. Manages quality-related intelligence and risks about manufacturing sites and drug products to inform future quality surveillance resource planning, response actions and communications (e.g., mitigation of supply chain disruptions and drug shortages, enforcement decisions, and inspectional strategies).

F. Collaborates with Food and Drug Administration (FDA) business partners to recommend and develop regulations, guidance, and policy that improve regulatory reporting, mitigate risks, and address recurring or acute manufacturing quality issues and product quality defects.

2. Authority and Effective Date.

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

Department of Health and Human Services
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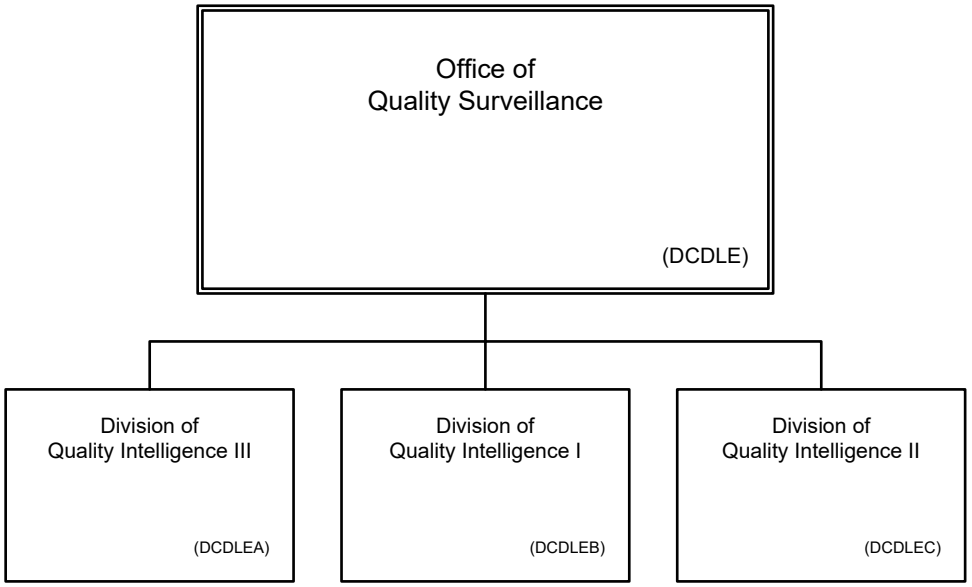

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Quality Surveillance organization structure depicting all the organizational structures reporting to the Director:

Office of Quality Surveillance (DCDLE)
Division of Quality Intelligence III (DCDLEA)
Division of Quality Intelligence I (DCDLEB)
Division of Quality Intelligence II (DCDLEC)