SMG 1280.60

FDA Staff Manual Guides, Volume I - Organizations and Functions

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Quality Surveillance

Effective Date: September 25, 2019

1. Office of Quality Surveillance (DCDLE).

A. Assures 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 efforts to enable for programmatic enhancements, efficiencies, and data integration toward a comprehensive surveillance program that can support other Office of Pharmaceutical Quality (OPQ) data intelligence needs.

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

D. Develops innovative approaches to surveillance paradigms that complement established inspection programs, enhancing both surveillance coverage, international collaboration, and industry engagement.

E. Manages quality-related signals and risks from drug sites and products to inform future surveillance activities, resource allocation, shortages, enforcement decisions, application assessments, and communications with external stakeholders (e.g., Congress, industry, and the public).

F. Supports Food and Drug Administration’s (FDA) work toward international regulatory harmonization including regulatory FDA capability assessments and quality areas to be addressed during surveillance inspections.

G. Collaborates with 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.

H. Collaborates in drug program training development, including creating and delivering materials and standards for staff who conduct quality surveillance inspection.

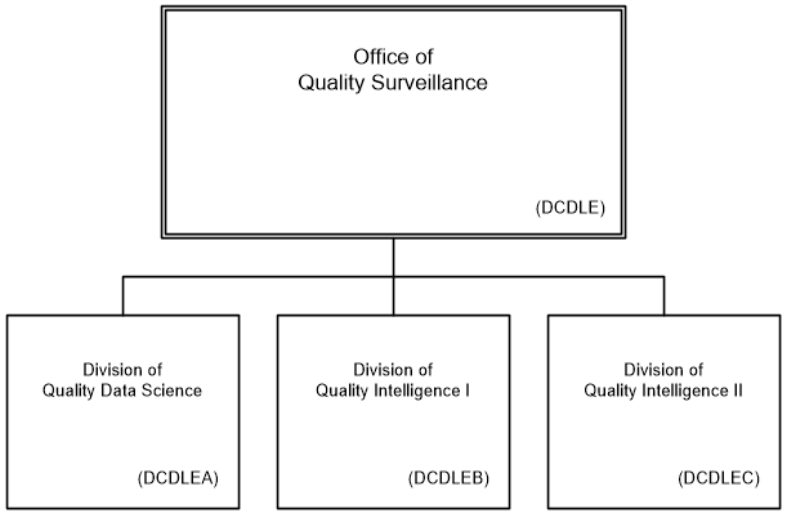
I. Develops policies and procedures governing surveillance programs in keeping with the provisions of the Food, Drug, & Cosmetic Act, as amended, and applicable provisions of the Public Health Services Act.

J. Assures alignment to OPQ's strategic objectives, and responsible stewardship of federal assets and resources, including continued professional development.

2. Authority and Effective Date.

The functional statements for the Office of Quality Surveillance was approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Quality Surveillance



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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 organizational structures depicting all the organizational structures reporting to the Director.

Office of Quality Surveillance (DCDLE).

These organizations report to the Office of Quality Surveillance:

Division of Quality Data Science (DCDLEA)

Division of Quality Intelligence I (DCDLEB)

Division of Quality Intelligence II (DCDLEC)

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