SMG 1280.62

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 Intelligence I

Effective Date: September 25, 2019

1. Division of Quality Intelligence I (DCDLEB).

A. Detects, analyzes, and trends product quality signals to identify strategies and lead the mitigation of urgent quality issues and prevention of risks associated with pharmaceutical formulation and manufacturing processes.

B. Leads the strategic development and implementation of the Drug Quality Sampling and Testing program, including identification of products, development of sampling plans and experimental design, analytical testing, laboratory data management, and trending of chemical and microbial results as they relate to formulation science and manufacturing.

C. Leads post-market quality-based assessments of drug products, through evaluation of post-market product quality reports, including assessment of root cause analysis, corrective and preventive actions, and impact to patient health.

D. Collaborates with business partners to determine data to be collected from firms or sites through inspections or other innovative approaches in support of the assessment of the state of quality and Quality Management System performance and develop internal strategies for follow-up of identified critical risks or other relevant quality-related information in support of application review and the surveillance program.

E. Informs Congressional inquiries and other data calls, future Good Manufacturing Practices inspections, enforcement decisions, and application assessment.

F. Leads the collection and evaluation of data related to pharmaceutical quality and availability through the Food and Drug Administration’s quality metrics program

to identify the most useful qualitative and quantitative measures for informing drug quality programs.

G. Mines internal and external data sources and supports the assessment of quality intelligence throughout the product lifecycle to engage business partners and stakeholders about the state of pharmaceutical quality, outreach initiatives, and regulatory policy needs.

H. Develops and maintains dashboards; visualization support; risk-based analyses; supply chain assessments; models; and statistical, analytical and informatics tools to extract qualitative and quantitative factors that correlate with quality-related outcomes.

I. Leads or participates in inspections as necessary.

2. Authority and Effective Date.

The functional statements for the Division of Quality Intelligence I were 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
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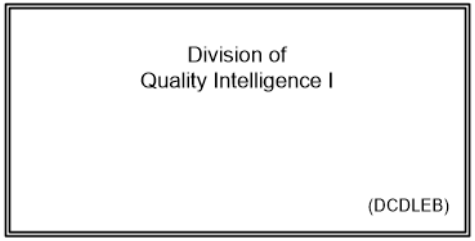
Division of Quality Intelligence I



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

Division of Quality Intelligence I (DCDLEB).

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