

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 Testing & Research

Division of Product Quality Research

Effective Date: September 25,2019

1. Division of Product Quality Research (DCDLFA).

- A. Conducts research to evaluate the product and process design and assess their impact on product quality, pharmaceutical equivalence and bioequivalence.
- B. Develops *in vitro* test systems and quantitative analysis procedures for product quality assessment and prediction, as well as bioavailability/bioequivalence determinations.
- C. Evaluates emerging manufacturing technologies to inform a regulatory risk-based framework for quality assessment, as well as quality standard and policy development.
- D. Provides subject matter experts and hands-on laboratory training to relevant the Food and Drug Administration's (FDA) staff to support review, inspection, and policy functions.

2. Product Quality Research Branch 1 (DCDLFA1).

- A. Develops analytical methodology to support the research efforts of the division, assessing product quality and the influence of environmental conditions on product stability.
- B. Evaluates emerging technologies in advanced analytics that can improve efficiency, accuracy and specificity of drug product and bioanalytical methods.

- C. Provides analytical support to critical FDA research areas related to human and animal pharmacokinetic studies, shelf life extension and medical countermeasures.
- D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection, and policy functions.

3. Product Quality Research Branch 2 (DCDLFA2).

- A. Assesses product quality attributes and performance via formulation and physiochemical characterization to support pre-market and post-market decisions for new and generic drugs.
- B. Conducts research to understand critical quality attributes of complex dosage forms to establish scientific basis for quality, pharmaceutical equivalence, or bioequivalence standards.
- C. Identify the risks to quality from materials, formulation, and processing through experimentation in support of review, inspection and policy functions.
- D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection and policy functions.

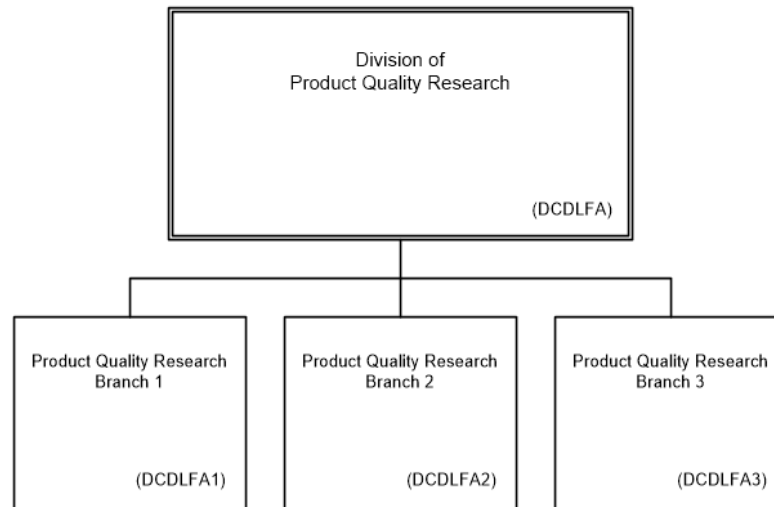
4. Product Quality Research Branch 3 (DCDLFA3).

- A. Develops and maintains state of the art research scale pharmaceutical manufacturing, computational, and modeling capabilities to support the research efforts of the division.
- B. Conducts research to understand sources of variability and material-process interactions in pharmaceutical unit operations through risk identification, quality by design experimentation, computational modeling and simulation.
- C. Evaluates and disseminates emerging manufacturing technologies including novel process designs, process analytical technology, process modeling, process controls, statistical product quality monitoring platforms, and data analytics.
- D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection, and policy functions.

5. Authority and Effective Date.

The functional statements for the Division of Product Quality Research 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
Office of Pharmaceutical Quality
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Division of Product Quality Research**



Staff Manual Guide 1280.71
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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 Testing and Research, Division of Product Quality Research organizational structures depicting all the organizational structures reporting to the Director.

Division of Product Quality Research (DCDLFA).

These organizations report to the Division of Product Quality Research:

Product Quality Research Branch 1 (DCDLFA1)

Product Quality Research Branch 2 (DCDLFA2)

Product Quality Research Branch 3 (DCDLFA3)