SMG 1280.50

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 Pharmaceutical Manufacturing Assessment

Effective Date: September 25, 2019

1. Office of Pharmaceutical Manufacturing Assessment (DCDLD).

A. Performs reviews of New Drug Applications, Abbreviated New Drug Applications, and Biologic License Applications and as appropriate, post-approval supplements, investigational drug applications, emergency use authorizations, Drug Master Files and other intra-agency applications.

B. Evaluates facilities, process design, and control strategies for certain drug substances and for all drug products to assess the capability of manufacturers to produce quality pharmaceutical and biotechnology products at commercial scale.

C. Evaluates microbial controls and assurance of sterility for sterile drug substances, excipients, and drug products and for non-sterile products, based on potential risks to quality and safety.

D. Manages and evaluates the pre-approval inspection (PAI), pre-license inspection (PLI) programs, and product specific post-approval program, including conducting, leading, or otherwise participating in PAIs, PLIs, post approval inspections and other inspections, as appropriate, and evaluating the results of the inspections.

E. Communicates with investigator, reviewer, and compliance teams, as appropriate, to collaboratively consider manufacturing process and facility related quality issues that may impact approval.

F. Partners with other Offices internal and external to Office of Pharmaceutical Quality to establish standards for Office of Process and Facilities-related review and inspectional activities, including novel and complex manufacturing technologies.

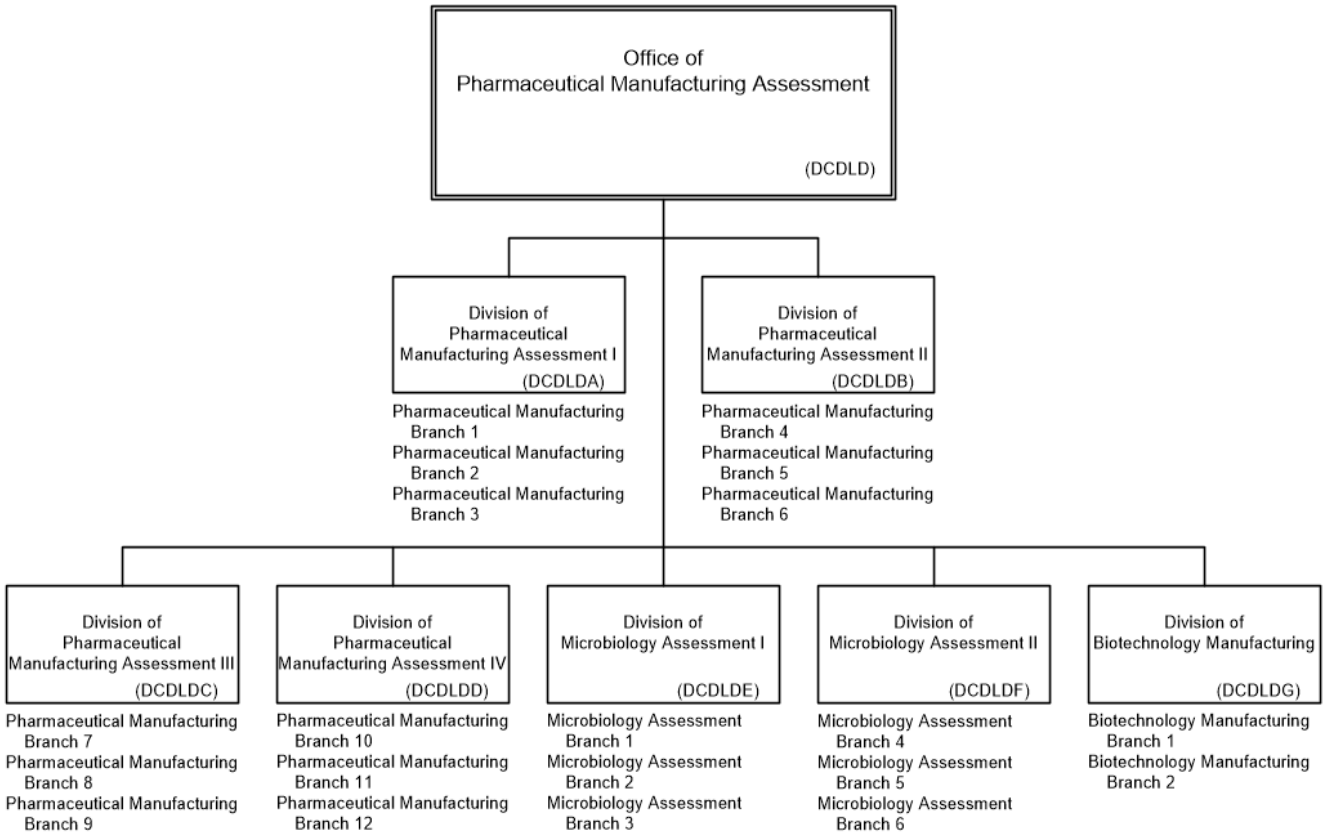
G. Provides technical expertise to other Food and Drug Administration components regarding manufacturing quality issues.

H. Communicates manufacturing quality expectations and standards to industry.

2. Authority and Effective Date.

The functional statements for the Office of Pharmaceutical Manufacturing Assessment 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 Pharmaceutical Quality
Office of Pharmaceutical Manufacturing Assessment



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

Office of Pharmaceutical Manufacturing Assessment (DCDLD).

These organizations report to the Office of Pharmaceutical Manufacturing Assessment:

Division of Pharmaceutical Manufacturing Assessment I (DCDLDA)

Division of Pharmaceutical Manufacturing Assessment II (DCDLDB)

Division of Pharmaceutical Manufacturing Assessment III (DCDLDC)

Division of Pharmaceutical Manufacturing Assessment IV (DCDLDD)

Division of Microbiology Assessment I (DCDLDE)

Division of Microbiology Assessment II (DCDLDF)

Division of Biotechnology Manufacturing (DCDLDG)

These organizations report to the Division Pharmaceutical Manufacturing Assessment I:

Pharmaceutical Manufacturing Branch 1

Pharmaceutical Manufacturing Branch 2

Pharmaceutical Manufacturing Branch 3

These organizations report to the Division of Pharmaceutical Manufacturing Assessment II:

Pharmaceutical Manufacturing Branch 4

Pharmaceutical Manufacturing Branch 5

Pharmaceutical Manufacturing Branch 6

These organizations report to the Division of Pharmaceutical Manufacturing Assessment III:

Pharmaceutical Manufacturing Branch 7

Pharmaceutical Manufacturing Branch 8

Pharmaceutical Manufacturing Branch 9

These organizations report to the Division of Pharmaceutical Manufacturing

Assessment IV:
Pharmaceutical Manufacturing Branch 10
Pharmaceutical Manufacturing Branch 11
Pharmaceutical Manufacturing Branch 12

These organizations report to the Division of Microbiology Assessment I:
Microbiology Assessment Branch 1
Microbiology Assessment Branch 2
Microbiology Assessment Branch 3

These organizations report to the Division of Microbiology Assessment II:
Microbiology Assessment Branch 4
Microbiology Assessment Branch 5
Microbiology Assessment Branch 6

These organizations report to the Division of Biotechnology Manufacturing:
Biotechnology Manufacturing Branch 1
Biotechnology Manufacturing Branch 2

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