

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF PHARMACEUTICAL QUALITY

OFFICE OF PROGRAM AND REGULATORY OPERATIONS

**DIVISION OF OPERATIONAL EXCELLENCE, LEARNING AND PROFESSIONAL
DEVELOPMENT**

Effective Date: September 26, 2014

**1. DIVISION OF OPERATIONAL EXCELLENCE, LEARNING AND PROFESSIONAL
DEVELOPMENT (DKKNVGC).**

- A. Works closely with the other functional units throughout Office of Pharmaceutical Quality (OPQ) by assessing the quality of the work products, processes, or services to ensure they are fit-for-their intended use and timely.
- B. Manages the internal OPQ documentation [e.g. Internal Quality Procedures (IQP), Manual Policies and Procedures (MAPP), etc.] system to ensure procedures are defined, developed, and appropriately implemented.
- C. Conducts internal audits that will assess OPQ's process and system performance against criteria established by all stakeholders.
- D. Reports audit outcomes and working closely with the Division of Business Process Management and OPQ functional Offices in the identification, tracking, and managing of internal continual improvement opportunities.
- E. Facilitates the internal non-conformance reporting system for identifying and tracking any non-compliant work products, processes and services.
- F. Facilitates the identification and implementation of any corrective and preventive actions (CAPA) associated with the non-conformances.
- G. Manages the internal change management system in OPQ by working closely with the Division of Business Process Management to establish and maintain the

change management system that will evaluate the feasibility of all suggested changes to internal work processes.

- H. Implements, maintains, monitors, and reports all complaints and other feedback related to OPQ's internal products, processes, and services.
- I. Manages OPQ's internal management review process and developing quality metrics for OPQ work products, processes, and services.
- J. Coordinates with all OPQ Offices to identify training, development, and certification needs and requirements for all job functions.
- K. Develops internal training and development programs.
- L. Facilitates and tracks the training for all staff within OPQ relative to OPQ policy and standards.
- M. Works closely with the other Divisions in the Office of Program and Regulatory Operations, as well as the other OPQ functional Offices to identify additional training opportunities and requirements based on the professional needs of OPQ staff.
- N. Determines, develops, and implements all certification requirements within OPQ.
- O. Works closely with other Offices in OPQ in designing, developing, implementing, and monitoring staff individual development plans (IDPs).

2. LEARNING AND PROFESSIONAL DEVELOPMENT BRANCH (DKKNVGC1).

- A. Coordinates with all OPQ Offices to identify training, development, and certification needs and requirements for all job functions in OPQ.
- B. Develops internal training and development programs for OPQ.
- C. Facilitates and tracks the training for all staff within OPQ relative to OPQ policy and standards.
- D. Works closely with the other Divisions in the Office of Program and Regulatory Operations, as well as the other OPQ functional offices to identify additional training opportunities and requirements based on the professional needs of OPQ staff.
- E. Determines, develops, and implements all certification requirements within OPQ.
- F. Works closely with other Offices in OPQ in designing, developing, implementing, and monitoring staff individual development plans (IDPs).

- G. Works closely with CDER's Office of Executive Programs/Division of Division of Learning and Organizational Development (OEP/DLOD) to implement Center-wide training efforts coordinated at the Center-level by DLOD.

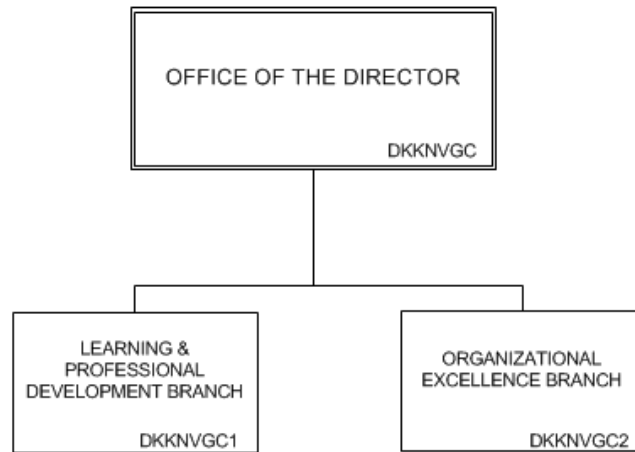
3. ORGANIZATIONAL EXCELLENCE BRANCH (DKKNVGC2).

- A. Works closely with the other functional units throughout OPQ by assessing the quality of the work products, processes, or services to ensure they are fit-for-their intended use and timely.
- B. Manages the internal documentation [e.g. Internal Quality Procedures (IQP), Manual Policies and Procedures (MAPP), etc.] system to ensure procedures are defined, developed, and appropriately implemented.
- C. Conducts internal process, product and system audits that will assess OPQ's performance against criteria established by all stakeholders.
- D. Reports audit outcomes and working closely with the Division of Business Process Management and OPQ functional Offices in the identification, tracking, and managing of internal continual improvement opportunities.
- E. Facilitates the internal non-conformance reporting system for identifying and tracking any non-compliant work products, processes and services.
- F. Facilitates the identification and implementation of any corrective and preventive actions (CAPA) associated with the non-conformances.
- G. Manages the internal change management system in OPQ by working closely with the Division of Business Process Management to establish and maintain the change management system that will evaluate the feasibility of all suggested changes to internal work processes.
- H. Implements, maintains, monitors, and reports of all complaints and other feedback related to OPQ's internal products, processes, and services.
- I. Manages OPQ's internal management review process and develops quality metrics for OPQ work products, processes, and services.
- J. Works closely with OPQ's Office of Policy/Division of Internal Policies and Programs (DIPP) to document and implement corrective and preventive actions stemming from DIPP's assessments, which are designed to ensure OPQ's existing policies, standards and programs are meeting their intended objectives.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Program and Regulatory Operations, Division of Operational Excellence, Learning and Professional Development organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVGC:

- Learning and Professional Development Branch – DKKNVGC1
- Organizational Excellence Branch – DKKNVGC2