

**FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY**

**OFFICE OF REGULATORY AFFAIRS**

**OFFICE OF REGULATORY SCIENCE**

**OFFICE OF MEDICAL PRODUCTS, TOBACCO AND SPECIALTY  
LABORATORY OPERATIONS**

**PACIFIC SOUTHWEST MEDICAL PRODUCTS LABORATORY**

Effective Date: June 6, 2016

**1. PACIFIC SOUTHWEST MEDICAL PRODUCTS LABORATORY  
(DLLRKBE).**

- A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates domestic and import analytical laboratory work plans and schedules with district offices being serviced.
- B. Conducts laboratory analysis of samples to:
- C. Assess each sample's compliance with applicable laws and regulations enforced by the Agency;
  - 1. Determines the extent to which findings provide evidence of violative conditions and practices; and
  - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- D. Provides evidence regarding analytical findings as requested.
- E. Conducts research to develop and refine methodology used in the analysis of samples and explore new techniques and systems of analysis.
- F. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to products regulated by the Agency.

- G. Serves as a resource in scientific knowledge and provides expert-advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.
- H. Provides assistance to districts, as requested, in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- I. Serves as national resource for analyses requiring complex electronic spectrophotometric, mass spectroscopic and other instrumental analyses.
- J. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- K. Conducts reviews of data provided from contract, state, and private laboratories in support of ORA's regulatory mission.
- L. Implements an effective internal quality assurance program.
- M. Maintains working liaison with other Federal offices-providing support services to the Agency.
- N. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

## **2. AUTHORITY AND EFFECTIVE DATE**

The functional statements for this Laboratory were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY  
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PACIFIC SOUTHWEST MEDICAL PRODUCTS LABORATORY**

OFFICE OF THE DIRECTOR

(DLLRKBE)

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STAFF MANUAL GUIDE 1121.925  
ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Laboratory Operations, Pacific Southwest Medical Products Laboratory organization structure depicting all the organizational structures reporting to the Office Director.

**OFFICE OF THE DIRECTOR (DLLRKBE)**