FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA EXTERNAL FACT SHEET

About the Office of Pharmaceutical Quality Operations

A specialized office to help protect and promote the safety and quality of human and animal drug products

The Office of Pharmaceutical Quality Operations (OPQO), a program within the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding pharmaceutical products field operations and emergency response activities. OPQO collaborates with the agency's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM) on all FDA-regulated pharmaceutical and biopharmaceutical products.

OPQO coordinates, directs, and assists with pharmaceutical product investigative activities, including conducting investigations and inspections of pharmaceutical products, as well as providing technical assistance regarding pharmaceutical investigational operations. As part of FDA's implementation of the Prescription Drug User Fee Act, Medical Device User Fee and Modernization Act, and the Generic Drug User Fee Amendment, ORA, CDER, and CVM partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations.

Alonza Cruse directs OPQO's day-to-day operations and coordination with CDER and CVM. The office structure includes a Division of Pharmaceutical Quality Programs, Division of Foreign Pharmaceutical Quality Inspections, and four Divisions of Pharmaceutical Quality Operations whose staff conduct investigations and manage compliance activities, recalls, and partnerships in ORA's 20 district offices.

ORA's program division directors, formerly district directors, are the most senior FDA officials in their geographic area and continue to be the point of contact for local staff, the public, and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials continues to be managed by district state liaisons. Contact OPQO at **engageORA@fda.hhs.gov**.

For more information, visit:

- Office of Regulatory Affairs
- Center for Drug Evaluation and Research
- Center for Veterinary Products

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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