

# FDA EXTERNAL FACT SHEET

---

## About the Office of Biological Products Operations

*A specialized office to help protect and promote the safety and quality of biological products*

The Office of Biological Products Operations (OBPO) consists of a specialized workforce that conducts inspections, investigations, and compliance activities for blood and tissue products as well as vaccines and other biological products regulated by the Center for Biologics Evaluation and Research (CBER).

OBPO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders on field operations and emergency response activities related to products regulated by the Center for Biologics Evaluation and Research (CBER). OBPO coordinates, directs, and conducts CBER-regulated product investigative activities and supports the development of policy and guidance for investigations and compliance for biological products.

OBPO investigators and compliance officers participate as subject matter experts in the design, implementation, and presentation of biologics training programs. OBPO, with CBER, creates, reviews, and/or facilitates issuance of field assignments. OBPO coordinates emergency activities with, and provides assistance to, department components and other external stakeholders in the event of a natural disaster or other emergency.

The OBPO's subject matter experts serve on external and internal cross-agency biologics program committees, workgroups, and task forces related to field operations. OBPO also develops and maintains cooperative relationships with state, local, and other federal agencies. OBPO staff serve on interagency councils and engage with international regulatory authorities to increase competency and consistency in inspections of biological products.

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 OBPO at [engageORA@fda.hhs.gov](mailto:engageORA@fda.hhs.gov).

### For more information, visit:

- [Office of Regulatory Affairs](#)
- [Center for Biologics Evaluation and Research](#)

---

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.