

ORA Program Areas

Under ORA's new program-based management model, there are seven key programs for operations. Each program has a unique number of program divisions for a total of 28 operational divisions.

1. Biological Products

The Office of Biological Products Operations (OBPO) conducts inspections, investigations, and compliance activities for blood and tissue products as well as vaccines and other biological products. It covers a wide range of products such as allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins.

2. Bioresearch Monitoring

The Office of Bioresearch Monitoring (BIMO) Operations is responsible for cross-center activities ensuring the protection of subjects involved in clinical research for FDA-regulated products and that non-clinical research is conducted according to Good Laboratory Practices (GLP) requirements.

3. Human and Animal Food

The Office of Human and Animal Food Operations (OHAFO) oversees all field inspection and compliance operations related to human and animal food and other products regulated by Center for Food Safety and Nutrition and the Center for Veterinary Medicine.

4. Medical Devices and Radiological Health

The Office of Medical Device and Radiological Health Operations (OMDRHO) coordinates, directs and assists with medical device and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations.

5. Pharmaceutical Quality

The Office of Pharmaceutical Quality Operations (OPQO) coordinates domestic and foreign inspectional, quality and investigational activities of pharmaceutical products, as well as providing technical assistance regarding pharmaceutical investigational operations.

6. Tobacco

Tobacco Operations, a program within the Office of Regulatory Affairs' (ORA) Office of Medical Products and Tobacco Operations (OMPTO), is a rigorous compliance and enforcement program aiming to ensure that the tobacco industry follows the law and regulations designed to reduce the health burden of tobacco use.

7. Import Program

The Office of Enforcement and Import Operations (OEIO) provides direction, assistance, management and oversight of field import operations, including investigational and compliance activities and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems.