What makes the Office of Translational Sciences a special place to work at FDA? We are a Super Office composed of the Office of Biostatistics, Office of Clinical Pharmacology, the Office of Computational Science and the Office of Study Integrity and Surveillance. We also house the Program Management and Analysis Staff who support budget, contracts, hiring, and on-boarding for a growing staff of nearly 600. In our Immediate Office, we support translational medicine efforts for CDER and lead the areas of technology transfer, data mining, science and research oversight, and knowledge management. Together, our staff makes a difference by leveraging innovation and technology integration to help streamline and advance the Center’s work.”

– ShaAvhrée Buckman-Garner, M.D, Ph.D., F.A.A.P.
Director, Office of Translational Sciences

OTS promotes and protects public health and ensures that safe and effective drugs are available to Americans.

OTS occupies a unique position in CDER’s organization to:
• Promote scientific collaboration and innovation in drug regulatory review across CDER
• Assure the validity of clinical trial design and analysis in regulatory decision making
• Develop and apply quantitative and statistical approaches to decision making in the regulatory review process
• Ensure alignment of CDER research with CDER goals
• Serve the CDER scientific community in establishing technology transfer agreements that are vital to collaboration with the broader scientific community
• Maintain knowledge management databases that can be the basis of improvements in the regulatory review process
• Oversee bioequivalence inspections to ensure the availability of safe and effective generic equivalents of investigational drugs

Our talented professionals include:
• Clinical pharmacologists, statisticians, and medical officers who review drug applications
• Scientists who conduct and direct bioavailability/bioequivalence inspections of facilities
• Laboratory researchers who address critical regulatory science questions
• Computer scientists who review and analyze vast amounts of data
• Administrative staff who support the critical day-to-day functions of the office
• Project managers, who manage internal and external partnerships and operational, scientific, and technical programs

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