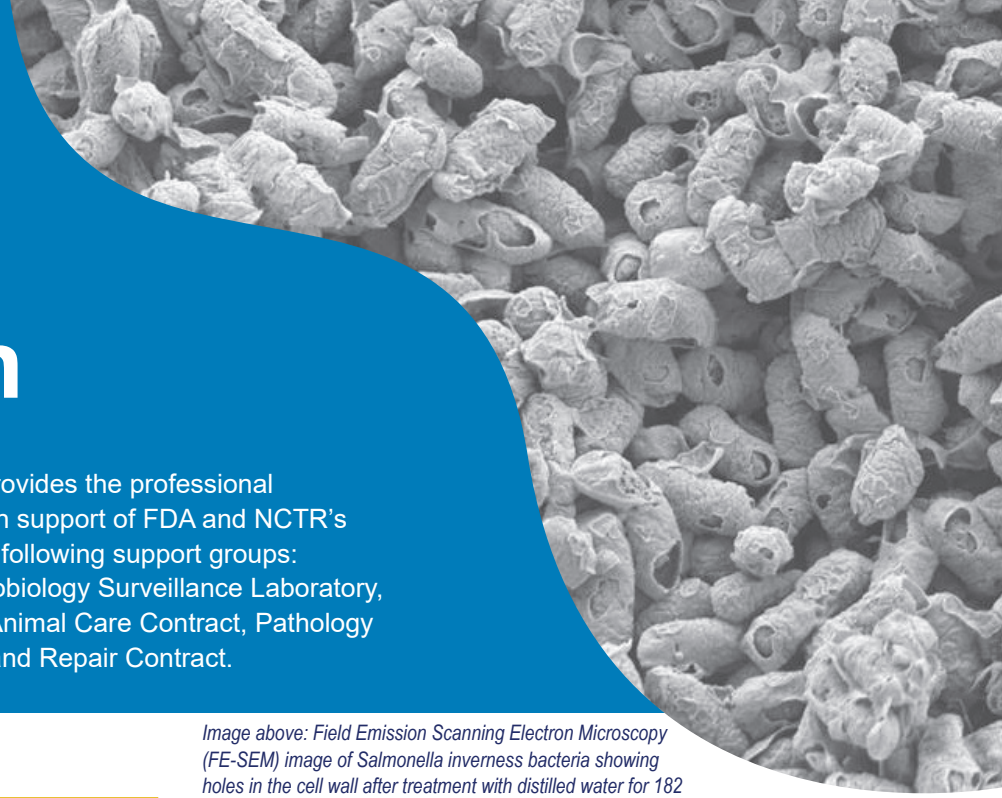
U.S. FOOD & DRUG ADMINISTRATION

National Center for Toxicological Research

Scientific Coordination



NCTR's Office of Scientific Coordination (OSC) provides the professional support necessary to conduct toxicology studies in support of FDA and NCTR's research mission. This support is provided by the following support groups: Analytical Chemistry, Experimental Support, Microbiology Surveillance Laboratory, Nanotechnology, Statistics, Veterinary Services, Animal Care Contract, Pathology Services Contract, and Equipment Maintenance and Repair Contract.

Office Capabilities

Analytical Chemistry

Analytical Chemistry research and support are conducted using trained staff and state-of-the-art instrumentation. This includes test article formulation, test article characterization and dose-certifications, and exposure assessments of test articles and metabolites in biological samples.

Experimental Support

Experimental Support staff provide computer-based support for animal studies utilizing NCTR's data collection and management system.

Microbiology Surveillance

The Microbiological Surveillance staff ensure the research animals and facilities are free from opportunistic pathogens by providing accurate and timely identification and characterization of microbes using advanced technologies including biochemical metabolism, MALDI-TOF mass spectrometry, and next-generation sequencing.

Statistics

The Statistical Support staff provide support including consultation during protocol development, statistical randomization, statistical analysis, and statistical reporting.

Veterinary Services

Veterinary Services staff ensure the welfare of all research animals. The staff participate in the review and monitoring of animal use through the Institutional Animal Care and Use Committee, advise research scientists regarding study design, perform surgery on animals, and monitor the overall health of the animal program. This facility has been continuously accredited by the Association for Assessment and Accreditation of Laboratory Animal Care since 1977.

Image above: Field Emission Scanning Electron Microscopy (FE-SEM) image of Salmonella inverness bacteria showing holes in the cell wall after treatment with distilled water for 182 days. (Courtesy: Dr. Angel Paredes with Anna Williams and Drs. Pierre Alusta and Dan Buzatu)

Nanotechnology Core Facility

The NCTR/Office of Regulatory Affairs Nanotechnology Core Facility (NanoCore) supports collaborative nanotechnology research within FDA and with other government agencies and universities. This facility is equipped with advanced analytical equipment for nanomaterial assessment, including the Electron Microscope Facility. NanoCore research provides information on nanomaterial characterization and the safety of products containing nanomaterials in FDA-regulated products.

Onsite Support Contracts

NCTR maintains on-site contracts for animal care services, veterinary pathology services, and equipment maintenance services.

Animal Care Contract

Trained and proficient staff perform the tasks necessary for in-life study support including husbandry, environmental enrichment of all animals, administration of test articles, sample collection, and data collection, ensuring the health and welfare of the animals.

Pathology Services Contract

Highly trained staff, including three veterinary pathologists, provide veterinary pathology services including clinical pathology, histopathology slide preparation, rigorous pathology examination, and complete histopathology and pathology reports.

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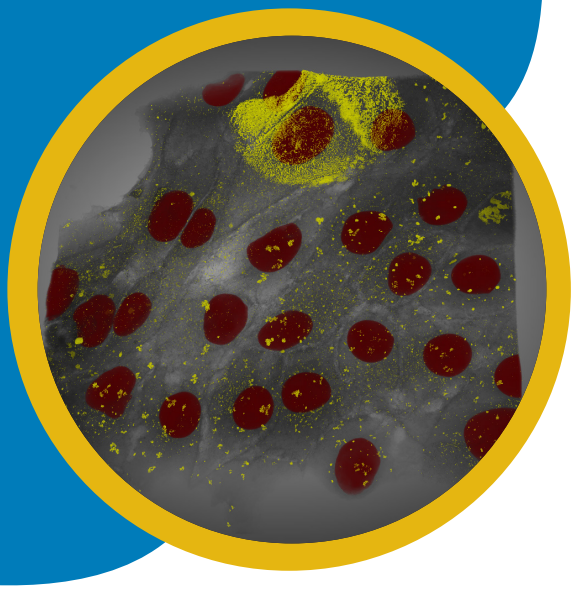


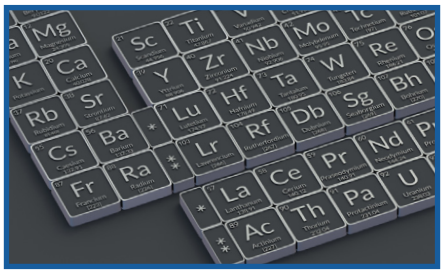
A Serial Block Face Scanning Electron Microscopy (SBF-SEM) image (left) showing cells, nuclei (red color) and nanomaterial (yellow). This 3-dimensional imaging and structural analysis is possible with SBF-SEM at the NanoCore, and is available to collaborators using computer-learning software analysis. (Courtesy: Drs. Angel Paredes and Tariq Fahmi).

Office Capabilities (Cont.)

Equipment Maintenance and Repair Contract

The contractor provides routine preventative maintenance and calibration of equipment, repair of equipment not on a service agreement, and fabrication services in support of customized research needs.

2023 Select OSC Accomplishments



- The Analytical Chemistry Lab upgraded instrumentation with two Ultra Performance Liquid Chromatography-tandem mass spectrometer systems which will be used in bioanalytical projects supporting multiple studies and FDA Centers.
- Added the preparation of dose formulations to the Analytical Chemistry support functions.
- The Microbiological Surveillance Lab developed two new diagnostic methods for use within the unit: a 16s rRNA sequence-based diagnostic method and a new endotoxin assay.
- Veterinary Services assisted in the implementation of three new animal models to answer critical questions about agents of concern to the FDA.

2023 Accomplishments (Cont.)

- Updated FDALabel to version 2.8 with new features focusing on interface and search capability enhancements to make the tool more user-friendly and resourceful. This is a collaborative effort with the Center for Drug Evaluation and Research (CDER), NCTR's DBB, and OSC.

- U.S. Environmental Protection Agency released the draft strategy "National Strategy to Prevent Plastic Pollution," which includes ambitious actions to eliminate the release of plastic and other waste from land-based sources into the environment by 2040. NCTR's NanoCore developed a baseline reference dataset of most common environmental polymers that would assist in developing a collaborative, global, comprehensive, and curated public database for the identification and quantitation of various micro/nano plastics and mixtures.

Presentations and Outreach

- FDA Grand Rounds Presentation, "Electron Microscopy, Still a Powerful Research Tool" (A. Paredes)
- NanoDay Symposium 2023: "Continuous Manufacturing of Nanomaterials," co-organized by NanoCore and CDER-Small Business and Industry Assistance.

Watch Day 1 and opening remarks by Dr. Anil Patri, NanoCore Director

- Nanotechnology Workshop at Global Summit on Regulatory Science (GSRS23), chaired by Dr. Patri.
- NanoCore staff gave three presentations at the American Society for Testing and Materials (ASTM) Meeting (Washington, DC), and two presentations at the ASTM E56 Committee Meeting (Denver, CO).