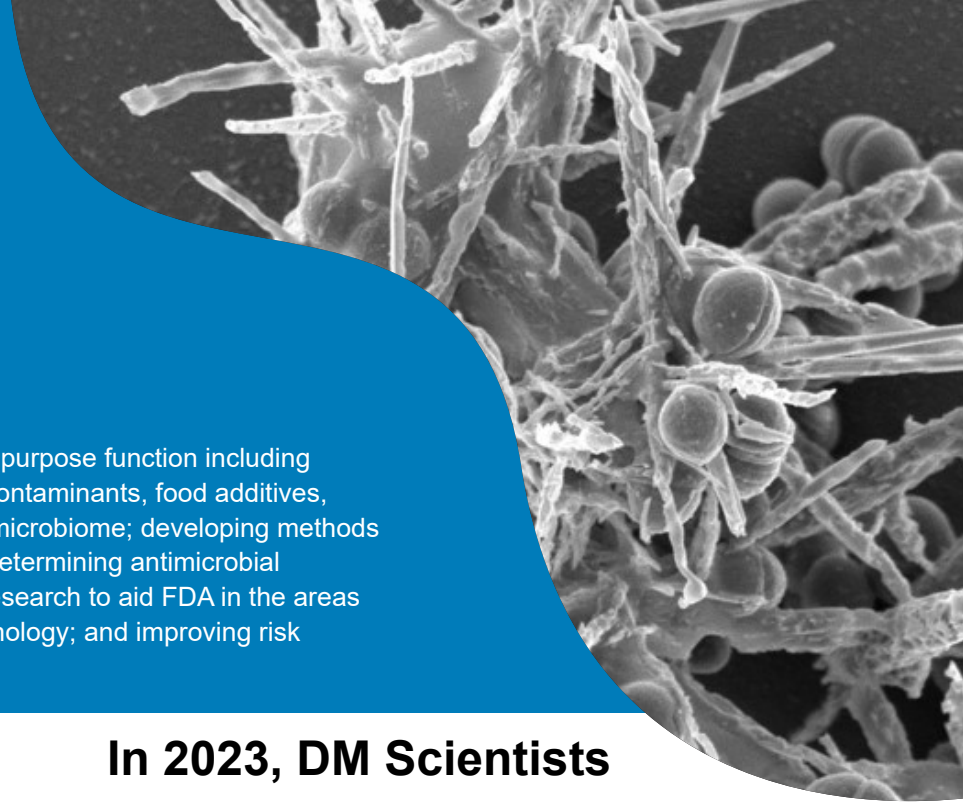
U.S. FOOD & DRUG ADMINISTRATION

National Center for Toxicological Research



Microbiology

NCTR's Division of Microbiology (DM) serves a multipurpose function including evaluating the impact of antimicrobial agents, food contaminants, food additives, nanomaterials, and FDA-regulated products on the microbiome; developing methods to detect and characterize microbial contaminants; determining antimicrobial resistance and virulence mechanisms; conducting research to aid FDA in the areas of women's health, tobacco products, and nanotechnology; and improving risk assessments.

By the Numbers

DM staff were engaged in the following accomplishments and activities in 2023:

30	posters presented
20	platform presentations delivered
20	papers published
14	scientific conferences attended
6	projects completed/closed
5	concept papers submitted

Collaborations

- 11 collaborations with other NCTR divisions
- 15 collaborations with other FDA centers
- 5 collaborations with outside entities (non-FDA)

In 2023, DM Scientists

- Received **NCTR Director's Award** for outstanding research efforts in support of the Center for Drug Evaluation and Research's (CDER) compounded drug safety efforts.
- Received **NCTR Outstanding Service Award** for initiative and perseverance to bring new approaches and techniques to support Division multidisciplinary and technology-driven research projects.
- Presented at **FDA Grand Rounds**, "The Plasmid Puzzle: Finding Solutions in *Salmonella*."
- Served on planning committees for **Arkansas Bioinformatics Consortium** conference, **FDA Science Forum**, **FDA Microbiome Day**, and **FDA Omics Day** series.
- Organized a monthly seminar speaker series to feature prominent microbiologists who present virtually to groups ranging from 30-45 attendees.
- Collaborated with **National Toxicology Program** to assess the role that microbiome may play in the toxicity of xenobotiocs.
- Collaborated with **Center for Food Safety and Applied Nutrition** to generate significant data on the microbial contamination of tattoo inks.These results have led to multiple publications and aided in understanding the potential risks of tattoo inks.
- Collaborated with **CDER** to address data gaps in the safety of compounded pharmaceuticals.
- Collaborated with **Center for Veterinary Medicine (CVM)** to characterize antimicrobial resistance and pathogenicity in foodborne and zoonotic pathogens.

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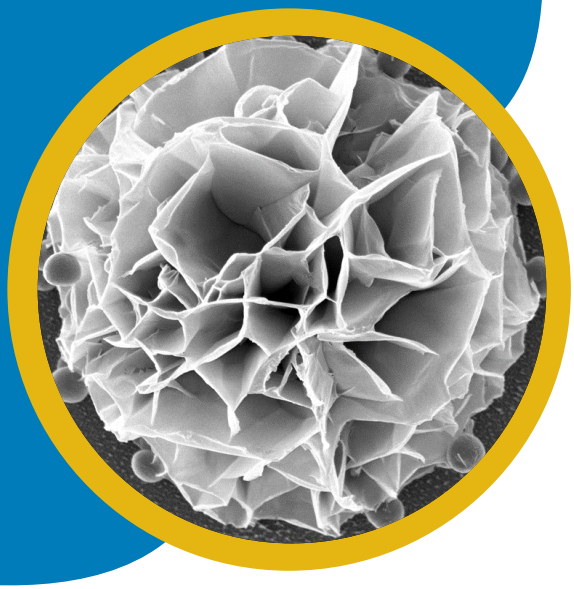


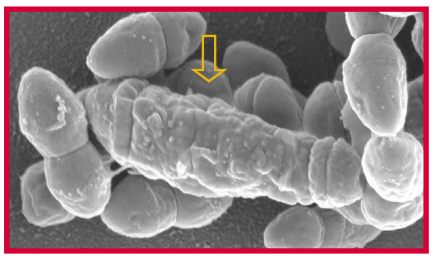
Electron Microscopy Image: Following a 10-minute exposure of Staphylococcus aureus *HAR12 to a nanostructured copper surface, a distinctive flower-like structure formed, and the cells adhered to this unique configuration.*

Completed Projects

- An assessment of the interactions of nanoscale (TiO_2 and ZnO) materials used in sunscreens on the skin microbiome
- Studies on the intrinsic structural multidrug efflux pump mechanisms in antimicrobial resistant *Salmonella enterica* and their role in antimicrobial resistance
- Anaerobic bacterial detection in tattoo inks and other related products

Ongoing Projects

- Standardized methods for sporicidal efficacy assessment and building up an efficacy database of sporicidal products
- Safety assessment of nanocrystal drug to determine effects on the gastrointestinal tract microbiome and functions
- Recombinant coronavirus spike proteins to generate reagents, study cell interactions, and antibody-dependent enhancement
- Evaluation of antimicrobial, antibiofilm and cytotoxicity activity of nanoparticles, and nanostructured surfaces

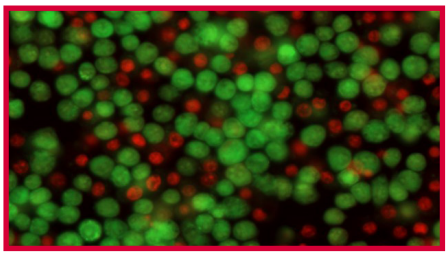


This SEM image illustrates the significant contribution of the unusually enlarged cells of Enterococcus faecalis *ATCC 29212 in the process of biofilm formation.*

2023 Select DM Accomplishments

Developing a Plasmid Analyses Toolbox

NCTR collaborated with CVM scientists to develop tools and approaches to cure bacterial plasmids—genetic structures outside of the bacteria's chromosome that often carry genes encoding for antimicrobial resistance (AMR) and/or virulence traits—and specifically remove plasmid genes to identify their functions related to virulence and AMR.



In this image, the green cells are live macrophages (immune cells) and the red cells are macrophage that have been killed by virulent Salmonella strains *(Courtesy: Dr. Kuppan Gokulan)*

These efforts will help researchers better understand the factors that increase the ability of resistance plasmids to be shared among bacteria spreading AMR. Recent publications describing this work are available in the journals, *BMC Genomics*, *Frontiers in Microbiology*, and *Microbiology Spectrum*.

Using Biofilm Models to Study AMR

Biofilm-associated infections associated with implanted medical devices is a major challenge and public health concern. During treatment, bacterial cells in biofilms may be exposed to sublethal concentrations of the antimicrobial agents which can drive antimicrobial resistance development. These studies demonstrate that global protein expression differences within biofilms following antibiotic pressure may improve our understanding of the mechanisms of antibiotic resistance in biofilms. A recent publication describing this work is available in the journal, *Pathogens*.

Surveying Microbial Contaminants in Commercial Tattoo Inks and Other Related Products

Tattooing and the use of permanent makeup inks have dramatically increased over the last decade. It is estimated that between 20-30% of the U.S. population have at least one tattoo. The process of tattooing involves the injection of different inks into the skin, thereby breaking the epithelial layer that serves as a protection from infection. If inks used for tattooing contain microorganisms, there is the chance for infections to develop. This research found that microbial contamination in commercial tattoo inks and related products is not rare and might be potential sources of human infections, presenting a significant public health concern. With the growing tattoo industry and the global supply chains for tattoo inks, a deep understanding of the microbial contamination in these products is important. A recent publication describing this work is available in the journal, *Frontiers in Public Health*.