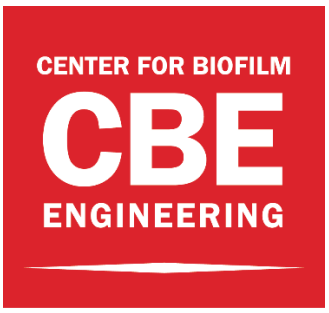
January 28–29, 2026

Executive Proceedings



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Keynote Presentation

ASTM International: A trusted source for standards based on science

Presenter: **Dan Smith**, Vice President of Standards and Membership
Affiliation: ASTM International

Purpose of this Research:
To define the process for ASTM in developing world-class test methods by using a trusted consensus process.

Methods and Results:
Regulators have success in participating in ASTM and then referencing the resulting standards as part of their rulemaking. ASTM test methods are trusted due to the rigorous precision statement requirements.

Next Steps:
Next steps would be to bring additional stakeholders from around the world to participate in the important work of Committee E35.15 on Antimicrobial Agents.

Industrial Relevance:
ASTM standards are used around the world by manufacturers, laboratories, scientists and government agencies.

SESSION 1: EU and UK Regulatory Pathways

Phage therapy for the control of biofilms: Translational research and regulatory pathways under the Portuguese magistral framework

Presenter: **Joana Azeredo,** Associate Professor, Health Biotechnology and Bioengineering
Affiliation: University of Minho

Purpose of this Research:
This presentation introduces bacteriophage therapy as an emerging anti-biofilm technology for controlling chronic infections. It will highlight both the therapeutic potential and current limitations of phage therapy, alongside translational and regulatory considerations using Portuguese clinical experience as a case example.

Methods and Results:
This talk integrates laboratory evidence, clinical experience, and regulatory practice.

Next Steps:
Future progress will depend on standardizing evaluation methods, defining performance criteria, and aligning regulatory expectations. Continued collaboration between academia, industry, and regulatory agencies will be essential for broader adoption.

Industrial Relevance:
Phage therapy represents a clinically relevant anti-biofilm therapeutic option for the management of chronic infections that are poorly responsive to conventional antibiotics. The Portuguese magistral phage framework offers a practical model for translating anti-biofilm phage therapy into approved clinical use.

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Giving regulatory context to anti-biofilm biocidal products under the GB BPR

Presenter: **Michael Davies**, Senior Efficacy Specialist
Affiliation: CRD, HSE

Purpose of this Research:
This talk will cover the background to biocidal product assessments under the GB BPR before looking more specifically at anti-biofilm products, including associated issues and how to overcome them.

Methods and Results:
As my talk is an overview of the regulatory process under GB BPR, specific to anti-biofilm products, no methodology or results are included.

Next Steps:
Any contacts made via my presentation or follow-up questions and/or meetings will be a welcome outcome of my presentation.

Industrial Relevance:
My talk should help industry and academia understand the GB BPR active and product assessment process better, with specific focus on biofilm efficacy testing.

Regulatory landscape surrounding biofilms and endoscopes

Presenter: **Lionel Pineau**, Scientific Director
Affiliation: Eurofins Hygiene Hospital

Purpose of this Research:
This work aims to clarify the role of biofilms in the reduced efficacy of endoscope reprocessing procedures and to determine the efficacy of current procedure to remove, inactivate, or inhibit biofilm.

Methods and Results:
Results obtained indicate that ISO 15883-5 biofilms were less sensitive to disinfectant than biofilms formed following ASTM E2562 or Konrat et al. methods, and that older biofilms had lower sensitivity to disinfectant.

Next Steps:
Future work will focus on developing harmonized, biofilm-specific test methods within ISO/CEN frameworks. Priorities include defining standardized approaches for assessing biofilm inhibition, removal, and inactivation using more reliable metrics such as protein and TOC quantification.

Industrial Relevance:
Improved biofilm-focused standards will help manufacturers design more effective detergents, disinfectants, and washer-disinfectors. This will enhance patient safety by ensuring that reprocessing technologies are validated under conditions that reflect real-world biofilm challenges.

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SESSION 2: US Regulatory Opportunity & Breakthrough

Dry biofilms affect bacterial surface survival with surface disinfection efficacy

Presenter: **Christopher Jones**, Research Professor of Biofilm Science and Technology
Affiliation: Center for Biofilm Engineering, Montana State University

Purpose of this Research:
Dry biofilms can form in a variety of ways, however a comprehensive definition of dried biofilm has yet to be determined. We hypothesize that biofilm tolerance to drying varies among strains and species, which affects their ability to persist in various environments and efficacy of antimicrobial treatments and cleaning approaches.

Methods and Results:
First, a screen of 20 strains was conducted to assess the desiccation tolerance of industrially relevant organisms. Dried biofilms exhibited varied resones to antimicrobial treatments based on species and desiccation of the biofilm, suggesting that species-specific biofilm properties and the degree of dryness alter the sensitivity and survival of the microbes.

Next Steps:
Future works will develop additional methods for generating dry biofilms and assess treatment efficacy of more bacterial species.

Industrial Relevance:
Reports indicate that dried biofilms survive longer than 12 months and are causative agents of healthcare-acquired infections (HAIs), industrial contaminations, and food contamination events. We describe an approach for determining the best methods for decontamination of surface with dry biofilms.

Transitioning a drug-led combination product through the FDA: The Purgo Pouch, FDA interactions, and meeting a major unmet need of biofilm-complicated, fracture-related infections

Presenter: **Dustin Williams**, Professor; CSO
Affiliation: Orthopedics, University of Utah School of Medicine; Purgo Scientific

Purpose of this Research:
Rates of fracture-related infection (FRI) have gone unchanged since the time fracture types were defined in the 1970s. Standards of care frequently fail; they do not target the biofilm phenotype, which underpins difficult-to-treat infections, and are not refillable. We are developing a refillable drug delivery device that sustains local, high-dose antibiotic therapy to kill biofilms in wound sites.

Methods and Results:
Using a sheep model of fracture-related infection, Purgo Pouch safety and efficacy were tested with various antibiotics, including tobramycin. In over 300 sheep tests, data showed that compared to standards of care (e.g., systemic antibiotics, antibiotic-loaded beads, antibiotic powders) the Purgo Pouch killed 10x – 1,000x more bacteria in the biofilm phenotype and maintained healthier host bone.

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Next Steps:
These data support FDA review for FRI treatment, leading to Breakthrough Device Designation from CDRH, and current CDER review under the 506(b)(2) regulatory pathway after the FDA determined the Purgo Pouch system is a drug-led combination product. First-in-human clinical trials under an IND are planned for 2027.

Industrial Relevance:
There is no medical technology today that is specifically indicated to treat FRI. Some local approaches are used off-label, but the Purgo Pouch has the potential to transform many aspects of clinical care as the first-of-its-kind refillable, local drug delivery system.

SESSION 3: The Role of AI in Regulatory Decision Making

Keynote Presentation

Positively irresistible: Designing novel cationic amphiphiles to overcome bacterial resistance

Presenter: **Bill Wuest**, Professor of Chemistry
Affiliation: Emory University

Purpose of this Research:
Our work seeks to develop novel next-generation cationic disinfectants that are effective against hard-to-treat pathogens that are resistant to current industry products. We also use these compounds to probe resistance mechanisms to these actives.

Methods and Results:
We use chemical synthesis to construct the molecules. We generate resistant mutants to understand the biological underpinnings. We perform MIC and MBEC plate assays along with confocal imaging to determine the efficacy of the compounds.

Next Steps:
We are leveraging our library of 1000+ novel compounds to develop an AI database to both train from and also help identify novel scaffolds to pursue.

Industrial Relevance:
Our patented compounds have superior activity profiles to currently used actives. In addition, our database is allowing us to probe new chemical space by leveraging AI software.

Panel Discussion

Panelists: **Anita Gupta**, MD, Board Certified Anesthesiologist
Marcia Ryder, Research Scientist, Ryder Science
John Sheppard, Norm Asbjornson College of Engineering Distinguished Professor, Computer Science, Montana State University
Bill Wuest
Moderator: **Darla Goeres**

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