ANTI-BIOFILM TECHNOLOGIES

PATHWAYS TO PRODUCT DEVELOPMENT

February 1-2, 2022

Proceedings

CENTER FOR BIOFILM CBE ENGINEERING

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Biofilm publishes multidisciplinary research on microbial cells that grow in multicellular communities – including surface-attached biofilms and suspended aggregates – and demonstrate different gene expression, growth rate, behavior and appearance to those that are in planktonic (free-living) state.

Biofilm welcomes research on:

- Bacterial, fungal, viral or mixed-species biofilms, from single cell adhesion to biofilm maturation and dispersal.
- Biofilms in their natural environment and/or clinical or industrial settings.
- Translational/applied biofilm research.

Topics include:

- molecular biology • genetics
- physiology • social interaction
- evolution • bioinformatics
- modelling • host-pathogen interactions

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SESSION 1: Surface Disinfection

Where to fit in? How to approach the EPA with a non-traditional technology

Presenter: **Chris Jones**, Director, R&D
Affiliation: Sharklet Technologies, Aurora, CO, USA.

Microbial contamination of surfaces serves as a vector of transmission, contributing to the spread of disease. Sharklet has developed a microtexture that can be applied to surfaces to limit the microbial transfer and contamination on abiotic surfaces. The goal of Sharklet microtexture is to reduce transfer of pathogens and limit the spread of disease.

One key feature of Sharklet is that it is a physical means of limiting microbial transfer. The texture itself is responsible for this reduction by utilizing three independent mechanisms. First, the texture increases the hydrophobicity of surfaces, reducing the transfer of fluid and the microbes that it carries. Second, the roughness of the surface reduces the strength of microbial attachment to surfaces. Third, microbes are sequestered into the base of the features upon drying, preventing transfer off the surface by subsequent interactions with the surface.

Sharklet's physical mechanisms of action stand in stark contrast to canonical methods of microbial control, which rely on embedded or applied antimicrobial compounds classified as pesticides. With these pesticides, there are many areas of concern including: longevity, antimicrobial resistance, effective concentrations, degradation kinetics, surface compatibility, toxicity, and leaching into the environment.

Though the Environmental Protection Agency is interested in each of these areas of concern, they have a long history of evaluating and regulating pesticides. The EPA has a mechanism for registering the active ingredients in each product and establishing the grounds to make antimicrobial claims regarding the product. But how do you apply to these programs to technology that is different and does not meet the definition of pesticides?

One approach is to attempt to register the technology as a "pesticide device", rather than a traditional pesticide. The EPA defines a pesticide device as: "An instrument or contrivance (other than a firearm) that is used to destroy, repel, trap or mitigate (lessen the severity of) any pest such as insects, weeds, rodents, certain other animals, birds, mold/mildew, bacteria and viruses."[1] The EPA further explains that a pesticide device "works by physical means (such as electricity, light or mechanics) and does not contain a substance or mixture of substances to perform its intended pesticidal purpose."[1]

Sharklet fits this definition and we have therefore requested to be classified as a pesticide device. In this presentation, we will share our experience in filing this request with the EPA. The goal is to make CBE member companies aware of the criteria, application process, regulatory impacts, claims, and benefits available through this alternative mechanism of pesticide device registration with the EPA.

[1] https://www.epa.gov/pesticides/pesticide-devices-guide-consumers

Regulatory and registration pathways for products making biofilm claims

Presenter: **Luisa Samalot-Freire**, Microbiologist
Affiliation: Antimicrobials Division, Office of Pesticides Programs, US EPA, Fort Meade, MD, USA.

The registration process for products making biofilm pesticidal claims is similar to other types of pesticides. There are several categories for pesticide products: conventional, biopesticide and antimicrobial. Biofilm pesticides are categorized as antimicrobials. An antimicrobial pesticide can make public and non-public health claims. If a product is making public health claims, efficacy data must be provided on the formulated product. The Agency conducts a thorough scientific evaluation of the product including active and inert ingredients, use patterns, label directions and possible adverse effects on human health or the environment. Product chemistry, acute toxicity, and product performance data (efficacy) may be required depending on the type of registration requested. Based on the registration PRIA fees and timelines (product registration statutory guideline) are determined for the review

process. Efficacy data for products seeking biofilm claims requires the use of specific testing methods and parameters. These methods and testing parameters can be found in the EPAs 2017 Biofilm Product Guidance (EPA Biofilm Guidance). Registrants are responsible for providing the Agency a complete application package that includes proposed label, data, application, confidential statement of formula, and others. The Agency conducts a review, at the end, the regulatory branches accept or deny registration for the product.

Data generation and development of nonpublic health or public health disinfectant biofilm claims

Presenter: **Denise Fernandez**, Senior Consultant
Affiliation: Scientific & Regulatory Consultants, Inc., Columbia City, IN, USA.

Biofilm claims on EPA-registered antimicrobial products may be classified as either public health or non-public health depending on the nature of the use and claims. Public health antimicrobial pesticide products bear claims to control pest microorganisms that pose a threat to human health, while non-public health biofilm claims are limited to control of microorganisms of economic or aesthetic significance. During product development, it is important to consider the types of biofilm claims desirable for the product and whether these claims would be considered public health or non-public health, as this distinction will impact test method selection, whether data must be generated in compliance with Good Laboratory Practices (GLPs), and what regulatory agencies may review the data. For all testing, it is recommended that screening strategies be developed to assess product performance in the relevant biofilm test methods prior to final data generation. Claims to disinfect human pathogenic bacteria in biofilms formed on hard, non-porous surfaces may be supported utilizing ASTM E3161-18 and ASTM E2871-19. Both EPA and California's Department of Pesticide Regulation (DPR) will require data submission to support public health biofilm claims. Public Health claims outside of the scope of EPA's biofilm guidance document will require a formal protocol review by EPA's Antimicrobial Division. In contrast, data used to support non-public health biofilm claims will be reviewed by California DPR but will not routinely be submitted or reviewed by the EPA. Testing for various non-public health claims surrounding cooling water systems and pulp and papermill water systems are addressed in EPA's Subdivision G guideline (92-4, 92-5) and includes both laboratory and field studies. Non-public health biofilm claims that fall outside of the scope of either of these Subdivision G biofilm categories will require new or modified test methods, which should be discussed with California DPR and the EPA to confirm the proposed test method will support the intended label claims.

Panel Discussion
Biofilm disinfection claims: Leveraging validated methods for new pathways

Panelists: **Denise Fernandez**; **Stacey Gish**, **Chris Jones**; **Josh Luedtke**, **Luisa Samalot-Freire**
Moderator: **Darla Goeres**

The focus of this session is biofilm disinfection claims and leveraging validated methods for new pathways. During the summer 2020 Montana Biofilms Meeting, the CBE presented the steps necessary to grow a regulatory science program. The first step in the process was to identify roadblocks in the regulatory biofilm pathway. A lot of exciting developments have occurred in the last couple of years and so the intent of the morning session of the workshop is to reassess previously identified roadblocks by looking at where we are and where we want to go considering the current guidelines, methods, and products on the market.

SESSION 2: Medical Technologies

Research relevance and evidence quality in assisting regulatory decision-making for antimicrobial claims

Presenter: **David Grainger**, University Distinguished Professor and Chair[1], Ole and Marty Jensen Endowed Chair[2]
Affiliation: [1]Department of Biomedical Engineering, University of Utah, Salt Lake City, UT, USA.
[2]Department of Pharmaceutics and Pharmaceutical Chemistry, University of Utah, Salt Lake City, UT, USA.

Evidence-based evaluation providing "substantial evidence" is a routine basis for regulatory judgement for *reasonable assurance* of safety and efficacy in implanted technologies. PMA guidance for Class III devices states:

> "Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness."

The evaluation process involves serial steps to assess both strength and quality of evidence as relevant to a particular new device or drug application, based on scientific studies and other data, eliminating those for which no valid conclusions about the relationship can be drawn, rating the remaining studies for methodological quality and evaluating the strength of the totality of scientific evidence in supporting claims, *reasonable assurance* of both safety and efficacy and indications for use.

Infection as an indication involves an inseparable engagement between infected host and pathogen. Infection is not generated on a benchtop assay (in contrast to microbial adhesion/contamination under simulated conditions), and infection in a rodent is distinct in many important respects from human infection. The pairing of infectious agent(s), the infection environment (e.g., in proximity to an implanted device), and the host response (across genetic variability and co-morbidities) is a critical relationship to characterize and understand to produce data important to antimicrobial efficacy and safety. Many in vitro microbial assays and rodent infection models lack validation and characterization sufficient to produce high quality evidence sufficient to aid regulatory decision-making. At a simplistic level, the central concept of "biofilm" lacks sufficient standard accepted definition to even standardize relevant assays to measure and report it to establish evidence quality.

FDA recognizes that science and clinical practice evolve, and that research tools, thinking, technological advances, and available evidence selection and quality also evolve. Hence, high quality scientific and clinical evidence must be carefully matched to each antimicrobial claim and indication for use. Effectiveness is then a matter of context specific to each indication, claim and device or therapeutic mitigation. This might also consider the more holistic clinical environment of infection risk: of medical device placement into non-sterile fields, highly variable patient health status, contaminated operating theatres and non-standard (frequently non-sterile) surgical protocols and post-op recovery theatres and recovery handling.

Given this multi-parameter testbed required to provide substantial evidence of safety and efficacy, this talk will discuss practical information on types of data and scientific evidence required for a biofilm-related effectiveness claims in particular device examples, and how current practices must be changed to yield substantial evidence and robust, high-quality data that regulatory agencies need to approve new antimicrobial device claims.

Innovative isn't enough: Advancing clinical technology

Presenter: **Topher Hunter**, Medical Science Liaison Manager
Affiliation: Next Science, Ltd., Jacksonville, FL, USA.

The classic image of technology innovation often consists either of the lone inventor in their garage or the academic genius discovering a new idea. The process then goes roughly patent-license-develop-sell. But this front-loaded model doesn't match reality, nor does it consistently drive new ideas to real-world implementation.

A more robust model might include identifying market need, developing a business case, solving development and manufacturing hurdles, obtaining regulatory approval, gaining market acceptance, and maintaining quality compliance. But even then, the separate stakeholders often fail to coordinate in an effective manner. Ultimately, we all want to bring safe and effective technology to improve patient care. However many promising technologies die before adoption, even if they truly benefit patients. What's going wrong?

This talk will discuss the current state of biofilm product innovation from one scientist's perspective, including thoughts on current barriers to innovation and what we can collectively do better.

Preclinical performance testing of medical devices with antimicrobial effects: Shifting the focus from 'bench' to 'bedside'

Presenter: **CDR K. Scott Phillips**[1], Consultant
Co-authors: Hao Wang[1], J. Alex Chediak[1,2], David M. Saylor[1], Benita Dair[1], David Kaplan[1], Enusha Karunasena[1],
Affiliation: [1]US Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Biology, Chemistry and Materials Science, Silver Spring, MD, USA.
[2]California Baptist University, Department of Mathematical Sciences, Riverside, CA, USA.

Infection is an Achilles heel that limits the ability of medical devices to improve patients' quality of life and exposes patients to potentially life-threatening risks. While the rate, severity, or type of infection varies depending on the device and use, risk of infection must be considered for the total product life cycle (TPLC). Devices with antimicrobial effects are designed and developed to reduce the risk of such adverse events, and many specifically target the unique challenges of microbial biofilms. Conventional preclinical in vitro methods for testing these devices are borrowed from early environmental research on biofilms, and have limited ability to predict clinical performance.

In this talk, we will discuss how preclinical testing tailored to antimicrobial devices might provide more reliable predictions of clinical outcome. Clinically meaningful challenges, realistic simulated environmental conditions, and reliable measurements of appropriate endpoints can be combined with material characterization and pharmacologic modeling, including computational simulation, to resolve the relationship between *in vitro* test parameters and patient outcomes. Finally, a systems approach is envisioned to dissect and understand the necessary relationships in vivo that should be recapitulated *in vitro* for a given scenario consisting of device, anatomy, and use. A rubric can be used to standardize a systems approach that is scalable and flexible, address the current lack of consensus, and enable rapid technological advancement to be incorporated in the preclinical test paradigm.

Panel Discussion
Medical biofilm claims: Supporting data and drawing consensus

Panelists: **David Grainger**, **Jeanne Lee**, **K. Scott Phillips**, **Laura Wahlen**
Moderator: **Garth James**, PI, Medical Biofilms Lab, CBE; Associate Research Professor, Chemical & Biological Engineering, MSU

The focus of this session will be the types of data that would provide adequate scientific evidence for biofilm-related medical device effectiveness claims. A wide variety of devices are used in medicine, ranging from short-term peripheral venous access and urinary catheters to long-term devices, such as pacemakers and orthopedic implants. With proper pre-, intra-, and post-operative procedures, infections associated with these devices remain generally low. However, when medical device related infections occur, they can result in complications that have considerable effects on morbidly, mortality, and healthcare costs. Understanding medical device related infection is complicated by a variety of factors such as the foreign body response and other immune reactions, which vary between individuals. Some of these factors are difficult to address using in-vitro and *in-vivo* (animal model) studies. Nonetheless, testing methods could be improved to better represent relevant conditions and, ultimately, help predict clinical effectiveness.

Biofilm Science and Technology for Regulatory Decision Making

CBE Research: New tools, new insights

Presenter: **Matthew W. Fields**, Director[1], Professor[2]
Affiliation: [1]Center for Biofilm Engineering, Montana State University, Bozeman, MT, USA.
[2]Department of Microbiology and Cell Biology, Montana State University, Bozeman, MT, USA.

The Center for Biofilm Engineering (CBE) continues to be a center of excellence for research, education, and outreach where students work with faculty and researchers in an interdisciplinary environment addressing both fundamental and applied questions. The majority of microbiological diversity and biomass on the planet resides as attached growth at phase boundaries—biofilm, and biofilms impact both applied and fundamental aspects of biology and engineering that require multi-disciplinary approaches in both research and education. The following presentation will include highlights of our upcoming acquisition of new imaging instrumentation, a multi-center collaboration to identify priority questions in biofilm research, ongoing work with a multi-center Task group for biofilm methods standardization, and multiple examples of recent research that ranges from sensing biofilms to controlling microbial growth to estimating biochemical capacity of active cells at surfaces.

The biofilm matrix as a therapeutic target

Presenter: **Kendra Rumbaugh**, Professor
Affiliation: Department of Surgery, Texas Tech University Health Sciences Center, Lubbock, TX, USA.

Biofilm-associated chronic infections are notoriously recalcitrant and exceedingly tolerant to antibiotic treatments. It is thought that the biofilm matrix, a hydrated layer of polysaccharides, proteins and nucleic acids that surrounds microbes in a biofilm, is a primary driver of chronicity and tolerance during infection. We hypothesized that by degrading these matrix components, we can expose the microbes inside the biofilm and increase antibiotic efficacy. Here I will discuss our pre-clinical evaluation of polysaccharide-degrading enzymes for wound infections, and what we have learned about the biofilm matrix of *Pseudomonas aeruginosa* during infection.

Designing and quantifying the accuracy of model systems

Presenter: **Marvin Whiteley**, Professor
Affiliation: Biological Sciences, Georgia Institute of Technology, Emory University School of Medicine, Atlanta, GA, USA.

For over a century, microbiologists have relied on laboratory models to study pathogenic bacteria. Due to obvious ethical prohibitions on human experimentation, laboratory infection models have become a cornerstone in bacterial pathogen research. These models range in complexity from standard laboratory media, to in vitro models specifically designed to mimic infection, to the most complex class of models, animal hosts. While these models have been tremendously useful for defining basic pathogenic mechanisms, the accuracy of these models has not been systematically evaluated. Until recently there has been insufficient data on bacterial behavior and physiology in human infections to effectively evaluate laboratory model performance, and beyond this limitation, there has been no formalized framework to do so. The lack of a systematic framework for model selection has left researchers to rely on intuition or ad hoc rationalizations for selecting their model. Here, I will discuss the development and implementation of a basic framework to evaluate the accuracy of human infection biofilm models using transcriptomics. This model 'accuracy framework' provides researchers with a grounded framework to choose among laboratory models depending on the scientific question of interest and provides an opportunity to improve existing experimental models.

Limits of detection in microbiology

Presenter: **Albert Parker**, Biostatistician[1], Associate Research Professor[2]
Co-authors: Andrés Christen[3], Julia Sharp[4], Steve Walsh[5]
Affiliation: [1]Center for Biofilm Engineering, Montana State University, Bozeman, MT, USA.
[2]Department of Mathematical Sciences, Montana State University, Bozeman, MT, USA.
[3]Centro de Investigación en Matemáticas, Guanajuato, MX.
[4]Colorado State University, Boulder, CO, USA.
[5]Utah State University, Logan, UT, USA.

Conventional approaches to defining the limit of detection (LOD) in chemistry focus on controlling Type I errors (false positives) and Type II errors (false negatives). These approaches are applied to microbiological count data from dilution series to calculate a LOD that describes how to interpret zero CFUs when studying bacteria or fungi, or zero PFUs when studying viruses. Results from the conventional Poisson model and the Negative Binomial model that accounts for over-dispersion, are presented. A novel computational Bayesian approach is also presented that does not presume that the counts are Poisson counts that focuses on controlling the probability that there really are bugs as opposed to Type I or Type II errors. These approaches that explicitly account for the LOD are preferred to simply using a substitution rule when there are lots of zeros.

Fluid modeling as a supporting tool for testing and regulation—A case study

Presenter: **Erick Johnson**[1], Associate Professor
Co-authors: Sang Won Lee[2], J. Alex Chediak[2,3] Hainsworth Shin[2], K. Scott Phillips[2], Dacheng Ren[4]
Affiliation: [1]Mechanical & Industrial Engineering, Center for Biofilm Engineering, Energy Research Institute, Montana State University, Bozeman, MT, USA.
[2]Center for Devices and Radiological Health, US FDA, Silver Spring, MD, USA.
[3]Mathematical Sciences, California Baptist University, Riverside, CA, USA.
[4]Biomedical and Chemical Engineering, Civil and Environmental Engineering, Biology, Syracuse University, Syracuse, NY, USA.

Textured breast implants have been linked to an increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), with evidence suggesting a correlation between the *amount* of texture and biofilm attachment. It is unclear if surface area alone is a sufficient metric to compare disparate surface textures or if other metrics, such as roughness and convex-edge lengths, should be considered as well. To understand the relationship between surface topology and BIA-ALCL, *E. coli* RP437/pRSH103 was grown on patterned surfaces with a new, high-throughput microplate method. Each well in a 96-well array contained a repeating, square pattern in polydimethylsiloxane (PDMS) of various lengths and spacings. The square pattern varied in length between 2-300 µm and distances between squares of 2-100 µm. The *E. coli* cultures were incubated for 4 hours at 37°C under both static and shaker flow conditions (200 rpm). Once incubated, the samples were rinsed three times with a plate washer prior to being prepped and analyzed. Three patterns showed a two-times greater biomass than the flat control ($p<0.05$, one-way ANOVA adjusted by Tukey's test). Additionally, *E. coli* cells demonstrated a preference for the edges of the patterns.

Of particular interest is how the fluid dynamics of rinsing may impact the findings. A rinse that produces shears in excess of the biofilm attachment strength would scour the middle, leaving the corners relatively undisturbed. While computational fluid dynamics (CFD) is still considered an experts' tool, the proliferation of computational resources has further expanded these capabilities beyond traditional engineering applications. Using CFD, the maximum shear forces found on a featureless surface and on two patterned surfaces were below 0.20 nN, with an example of the shear stress shown in Figure 1. The simulated shear forces are below a recorded attachment strength for *E. coli* of 0.5-24 nN. Moreover, the dispenser is off-center and the simulation shows a jetted shearing stress that is not uniform in either space or time as the flow swirls within the well. Flow separation occurs near the edges and produces pockets of shear moving in adverse directions within a single recess. And at the smallest pattern scales, the rinsing process may not even be able to intrude, creating temporary regions of stagnation. Through these results, CFD is demonstrated to provide a new tool to compliment ongoing biofilm research and can be used to inform the fluid dynamics and stresses observed, guide testing protocols, and aid in the design of new experiments.

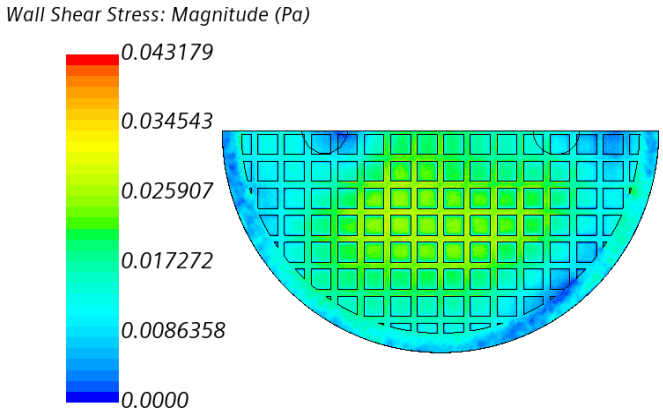

Figure 1
Representative wall shear stress on the 300 µm square at 100 µm distance after 0.0125 s of rinsing. Due to symmetry, only half of the well was modeled, with the dispenser represented by the half circle outline near the top right of the image.

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The need for a variety of biocide chemistries to prevent biofilms in paint and coatings

Presenter: **Greg Sarnecki**[1], Research Fellow
Co-authors: Rodney Rees[2], Tony Rook[3], Adrian Krygsman[4], Riaz Zaman[5]
Affiliation: [1]Behr Paint Company (Masco Corporation), Livonia, MI, USA.
[2]Thor Specialties Inc., Shelton, CT, USA.
[3]The Sherwin-Williams Company, Cleveland, OH, USA.
[4]Troy Corporation, Florham Park, NJ, USA.
[5]The American Coatings Association, Washington, DC, USA.

Over the past 30 years, as coatings have moved from solvent-borne to waterborne, and with subsequent reductions in VOC level, the susceptibility of paints and coatings to in-can spoilage has only increased. These days, in the era of low-VOC coatings, biofilm formation in paint manufacturing plants is a constant threat; if/when this occurs it requires significant effort to remedy.

Although it may seem that we have many molecules to solve in-can spoilage, most are not suitable or adequate for paints and coatings. Waterborne paint technology has evolved significantly over the last 15 years, further restricting what biocide chemistries can be used without negative interactions with the rest of the paint formulation. The chemistry and biochemistry of biocides and their interaction with paint's raw materials is not adequately understood by those outside the industry: not all biocides that can be added are stable, and others that could be effective are no longer available.

Further compounding the situation, most in-can biocidal molecules are currently under regulatory scrutiny. Dry film preservatives, necessary to avoid spoilage on a painted film's surface, are also in the regulatory spotlight. Reductions in the allowed usage levels for both these types of biocides are planned. Unfortunately, in the manufacturing environment, it is predicted that tolerance and acquired resistance will result; the consumer may well experience any resultant inadequate dry-film preservation with noticeable levels of mold and/or algal growth, both on the outside and the interior of a dwelling, and this could have serious health and safety implications.

Recap of regulatory workshop and paths forward

Presenters: **Darla Goeres**, Research Professor of Regulatory Science[1,2], Principal Investigator[2]
Garth James[1,3], PI, Medical Biofilms Lab, CBE; Associate Research Professor, Chemical & Biological Engineering, MSU
Affiliation: [1]Center for Biofilm Engineering, Montana State University, Bozeman, MT, USA.
[2]Standardized Biofilm Methods Lab, Center for Biofilm Engineering, Montana State University, Bozeman, MT, USA.
[3]Medical Biofilms Lab, Center for Biofilm Engineering, Montana State University, Bozeman, MT, USA.

Drs. Goeres and James will provide a recap from two panel discussions from the Day 1 of Anti-Biofilms Technologies: Pathways to Product Development, attended exclusively by CBE Industrial Associates. Dr. Goeres will recap the discussion titled, "Biofilm disinfection claims: Leveraging validated methods for new pathways," and Dr. James will recap, "Medical biofilm claims: Supporting data and drawing consensus."

UK perspective on biofilm regulation

Presenter: **Mark Richardson**, CEO
Affiliation: National Biofilm Innovation Centre, UK.

The National Biofilm Innovation Centre (NBIC) is funded by the UK Research and Innovation Council (UKRI) as an innovation Knowledge Centre to support and connect the UK biofilm community in industry and academia in order to drive both knowledge and technology translation for societal benefit. NBIC's primary focus is to harness and translate capability, knowledge and technology in the prevention, detection, management, and engineering of

biofilms across the UK in order to both tackle problems and harness opportunities created by biofilms. We have also worked to build relationships internationally, including forming alliances with the Center for Biofilm Engineering (CBE), the Singapore National Biofilms Consortium (SNBC) and the India Biofilm Society (IBS) to link and facilitate global collaboration between our academic and industrial partners.

Our membership and network now include 300 companies and 63 UK universities and leading science institutes, such as the LGC Group, the National Physical Laboratory, and the Quadram Institute. We aim to work with these partner organizations to identify unmet industrial and commercial needs relating to biofilms and possible scientific or technological solutions.

As part of this engagement with industry we have identified that the absence of standards and regulations within the UK and EU in relationship to biofilms is a key problem with respect to being able to develop, test and approve interventions across all sectors which aim to tackle or harness biofilms. Innovators have no available approved methodologies to assess products and submit normative data for approval.

In order to begin to address this deficit one of NBIC's aims is to influence regulatory and policy makers in the UK representing the biofilm community through providing impartial scientific evidence and industry perspectives to a number of regulatory and standards bodies, including the National Institute for Biological Standards and Control, the Medicines and Healthcare Products Regulatory Agency and the British Standards Institution). NBIC is also, along with the CBE, a founding partner in the International Biofilm Standards Task Group with global partners from the EU, Singapore, and the US. In this presentation the current status of these activities and our forward plans in the context of the UK environment will be shared and open to discussion.

Biofilm test methods, claims and regulation—The EU perspective

Presenter: **Florian Brill**, Managing Director
Affiliation: Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Hamburg, DE.

The presentation will discuss the current accepted option for getting biofilm claims on products in the EU. Examples for biocidal products and medical devices will be shown with their respective claims, regulation and the underlying methods. These will be products for treatment of wounds, catheters as well as water supply systems in dental chairs.

Center for Biofilm Engineering
a National Science Foundation Engineering Research Center

MONTANA STATE UNIVERSITY

CBE ENGINEERING

February 1-2, 2022

ANTI-BIOFILM TECHNOLOGIES:

Pathways to Product Development

Crystal City Marriott Hotel

1/26/2022 1:38 PM

Draft AGENDA

****All times are Eastern Standard Time (EST)**

Tuesday February 1

CBE Industrial Associate Workshop:

Exploring the gaps and opportunities in anti-biofilm product development and the regulatory process

Crystal City Marriott Hotel
Potomac D&E

7:30–8:15
Registration & Coffee
Potomac Foyer

8:15–8:20
Opening Remarks
Matthew Fields
Director, CBE; Professor, Microbiology & Cell Biology, MSU
Paul Sturman, Industrial Coordinator, CBE

SESSION 1: Surface Disinfection

8:20–8:30
Session Introduction
Darla Goeres, PI, Standardized Biofilm Methods Lab, Research Professor of Regulatory Science, CBE

8:30–9:00
Where to fit in? How to approach the EPA with a non-traditional technology
Chris Jones, Director, R&D, Sharklet Technologies

9:00–9:30
Regulatory and registration pathways for products making biofilm claims
Luisa Samalot-Freire, Microbiologist, Office of Pesticides Programs, Antimicrobials Division, US EPA

9:30–10:00
Data generation and development of non-public health or public health disinfectant biofilm claims
Denise Fernandez, Senior Consultant, Scientific & Regulatory Consultants

10:00–10:30 Break

PANEL DISCUSSION

10:30–12:00
Biofilm disinfection claims: Leveraging validated methods for new pathways
Denise Fernandez
Stacey Gish, STERIS
Chris Jones
Josh Luedtke, Ecolab
Luisa Samalot-Freire
Moderator: Darla Goeres

12–12:50 Lunch Potomac F

SESSION 2: Medical Technologies

12:50–1:00
Session Introduction
Garth James, PI, Medical Biofilms Lab, CBE; Assoc. Res. Prof., Chem. & Bio. Eng., MSU

1:00–1:30
Research relevance and evidence quality in assisting regulatory decision-making for antimicrobial claims
David Grainger, Distinguished Prof. & Chair, Biomedical Eng., Pharm. and Pharm. Chemistry, University of Utah

1:30–2:00
Innovative isn't enough: Advancing clinical technology
Topher Hunter, Medical Science Liaison Manager, Next Science

2:00–2:30
Preclinical performance testing of medical devices with antimicrobial effects: Shifting the focus from bench to bedside
K. Scott Phillips, Regulatory Research Scientist, Center for Device & Radiological Health, US FDA

2:30–3:00 Break

PANEL DISCUSSION

3:00–4:30
Medical biofilm claims: Supporting data and drawing consensus
David Grainger
Jeanne Lee, Next Science
K. Scott Phillips
Laura Wahlen, Baxter Healthcare
Moderator: Garth James

4:30–4:45 Wrap-up

5:00 Reception Chesapeake C

Wednesday February 2

Biofilm Science and Technology for Regulatory Decision Making

****All times are Eastern Standard Time (EST)**

Crystal City Marriott Hotel, Potomac D&E

7:45–8:25
Registration & Coffee Potomac Foyer

8:25–8:30
Session Introduction
Paul Sturman, Industrial Coordinator, CBE

8:30–9:00
CBE Research: New tools, new insights
Matthew Fields, Director, CBE; Professor, Microbiology & Cell Biology, MSU

9:00–9:30
The biofilm matrix as a therapeutic target
Kendra Rumbaugh, Professor, Dept. of Surgery, Texas Tech University Health Sciences Center

9:30–10:00
Designing and quantifying the accuracy of model systems
Marvin Whiteley, Professor, Biological Sciences, Georgia Institute of Technology

10:00–10:30 Break

10:30–11:00
Limits of detection in microbiology
Al Parker, Biostatistician, CBE; Associate Research Prof., Mathematical Sciences, MSU

11:00–11:30
Fluid modeling as a supporting tool for testing and regulation–A case study
Erick Johnson, Associate Professor, Mechanical & Industrial Engineering, MSU, CBE

11:30–12:30
The need for a variety of biocide chemistries to prevent biofilms in paint and coatings
Adrian Krygsman, Troy Corporation
Rodney Rees, Thor Specialties, Inc.
Tony Rook, The Sherwin-Williams Co.
Greg Sarnecki, Behr Corporation
Riaz Zaman, American Coatings Association

12:30–1:30 Lunch Potomac F

1:30–2:00
Recap of regulatory workshop and paths forward
Darla Goeres, PI, Standardized Biofilm Methods Lab, Research Prof. of Regulatory Sci., CBE
Garth James, PI, Medical Biofilms Lab, CBE; Associate Research Professor, Chemical & Biological Engineering, MSU

2:00–2:30
UK perspective on biofilm regulation
Mark Richardson, CEO, National Biofilm Innovation Centre, UK

2:30–3:00
Biofilm test methods, claims and regulation—The EU perspective
Florian Brill, Managing Director, Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology

3:00–3:15 Meeting Wrap-up