BIOFILM ALLIANCE
Regulatory Science Network

Biofilm Alliance Forum

1-2 July 2025, Manchester Metropolitan University, UK

WORKSHOP REPORT

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Contents

BIOFILM ALLIANCE FORUM: WORKSHOP REPORT

Executive summary

The Biofilm Alliance Forum hosted at Manchester Metropolitan University (1–2 July 2025), brought together representatives from academia, industry, regulators, and standards organisations to discuss current practices, challenges, and opportunities in biofilm management and regulation across UK industry sectors.

Participants agreed that biofilms remain a widespread but insufficiently addressed issue affecting food production, water systems, industrial processes, and the built environment. Biofilms contribute to contamination, corrosion, and system inefficiencies, posing risks to public health and infrastructure. Yet, despite their impact, the UK lacks a coherent regulatory or methodological framework to manage them effectively.

Discussions revealed that testing and control methods vary greatly across industries, with many relying on modified microbiological assays that fail to reflect real-world biofilm conditions. The absence of harmonised standards and clear regulatory guidance creates major uncertainty for manufacturers, laboratories, and end-users. Post-Brexit regulatory divergence has added complexity, particularly for companies operating across both UK and EU markets.

Participants emphasised the urgent need for clearer, evidence-based and sector-specific guidelines on biofilm control and product efficacy testing. Stronger collaboration between regulators, academia, and industry was seen as essential to establish consistent methodologies, support innovation, and enable safe, effective antibiofilm technologies to reach the market.

The workshop also highlighted the need for of awareness raising and training among various groups of stakeholders, about biofilm behaviour, resilience, and risks. Delegates called for targeted education and capacity-building programmes to integrate biofilm understanding into system design, operation, and maintenance practices.

Cross-sector discussions underscored the value of collaboration and knowledge exchange. Participants also noted growing opportunities in novel diagnostics, antimicrobial coatings, phage-based solutions, and AI-driven data analysis, provided these are supported by validation and regulatory clarity.

The forum identified key priorities, including:

- Development of standardised, sector-specific biofilm testing and monitoring methods reflecting real-world conditions.
- Establishment of a central resource of experts, organisations, and shared case studies.
- Development and provision of training and certification programmes for regulators and industry practitioners.
- Building and strengthening cross-sector partnerships to align standards and accelerate innovation.
- Advocating for investment in validation and metrology to support new antibiofilm technologies.

Overall, the workshop confirmed the need for a coordinated national approach to biofilm management.

Background

Biofilm Mitigation and Control Across UK Industry Sectors

Microbial biofilms and communities collectively represent the largest biomass and activity centre on the planet playing a major role in the biology of the environment, both natural and engineered. Compared to unbound bacteria of the same species, biofilms are typically resilient to biocides and so can be challenging to control.

Biofilms can present both a major challenge and a significant opportunity across industry sectors. In healthcare, food production, water systems, and industrial processes, biofilms contribute to contamination, corrosion, and reduced efficiency, posing risks to public health and infrastructure. At the same time, understanding and harnessing biofilm behaviour offers opportunities for innovation in areas such as antimicrobial coatings, bioremediation, and sustainable production. Our estimate is that biofilms impact about $5,000bn of economic activity, approximately twice the Gross domestic product (GDP) of the UK.

In the UK, several regulatory bodies oversee microbial safety but there remains a notable lack of regulations and guidance specifically addressing biofilms.

In the food sector, microbial control is governed by several key regulations and standards. The UK Food Standards Agency (FSA) oversees food hygiene and safety, guided by Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, which remains part of retained UK law post-Brexit. Additionally, the Food Safety and Hygiene (England) Regulations 2013 and food hygiene rating (Wales) Act 2013, provide a legal framework for food businesses to manage hygiene risks. Central to these efforts is the implementation of Hazard Analysis and Critical Control Point (HACCP) principles, which help identify and control potential hazards, including those posed by biofilms, throughout the food supply chain.

In the water sector, biofilm management is critical to maintaining water quality and public health. The Drinking Water Inspectorate (DWI) regulates public water supplies in England and Wales, ensuring compliance with the Water Supply (Water Quality) Regulations. These regulations set standards for microbial and chemical safety, including measures to prevent biofilm formation in distribution systems. The Environment Agency and Natural Resources Wales also play a role in overseeing water quality in natural and treated water systems, particularly in relation to wastewater and environmental discharge. The Health and Safety Executive (HSE) provides regulatory oversight for the wet leisure sector, with the Pool Water Technology Advisory Group (PWTAG) providing practical guidance to operators.

The industrial sector faces biofilm challenges in manufacturing, processing, and equipment maintenance. The HSE provides regulatory oversight, particularly where biofilms may pose risks to worker safety or product integrity. Compliance with ISO standards, such as those related to industrial hygiene, contamination control, and cleanroom environments, is essential for managing biofilm risks in sectors like pharmaceuticals, biotechnology, and chemical manufacturing. Detection and management of biofilms in the gas and oil sector present unique challenges due to the nature of the environment.

In the built environment, biofilms can affect infrastructure, indoor air quality, and occupant health. Regulatory oversight includes adherence to Building Regulations, which govern construction and maintenance standards. The HSE also issues guidelines for managing risks associated with water systems (e.g., Legionella species in plumbing) and ventilation systems (e.g., HVAC maintenance). Standards for indoor air quality and moisture control are particularly relevant in healthcare, residential, and commercial buildings where biofilms can form on damp surfaces and within mechanical systems.

Existing regulatory frameworks tend to overlook the unique behaviour, resistance, and persistence of biofilms on surfaces and within systems. This gap creates ambiguity in how antibiofilm claims are evaluated and how risks associated with biofilm formation are managed. Targeted regulatory guidance is therefore needed to ensure that emerging biofilm technologies are assessed consistently, robustly, and in line with real-world conditions.

Biofilm Alliance

The Biofilm Alliance is an initiative, funded by Innovate UK, to create a transformative network dedicated to bringing biofilms to regulatory attention. The Biofilm Alliance is a partnership between the National Biofilms Innovation Centre, Manchester Metropolitan University, Swansea University and Industrial Microbiological Services Limited.

By bringing together experts from academia, industry, metrology, regulatory bodies, and standardisation organisations, Biofilm Alliance aims to bridge the gap between state-of-the-art research and effective regulation, promoting collaboration and fostering innovation in biofilm mitigation and control technologies. Biofilm Alliance focuses on four broad industry areas:

1. Industrial Processes: Addressing the impact of biofilms on manufacturing efficiency and contamination risks.
2. Water Systems: Tackling biofilm formation in drinking water, wastewater treatment, wet leisure, and industrial water applications.
3. Food: Managing biofilm risks in food production, processing, storage, and packaging.
4. Built Environment: Understanding and mitigating the impact of biofilms in buildings and infrastructure.

Forum on Biofilm Methodologies and Cross-Sector Regulatory Challenges

Settings and Aims

The forum was held at Manchester Metropolitan University from 1-2 July 2025. Representatives from academia, industry, and regulatory professionals were brought together to discuss current practices, needs, trends, and expectations regarding biofilm methodologies used within the UK, and to foster active participation from both industry and regulatory stakeholders to guide future developments in this area.

The intended outputs of the day were:

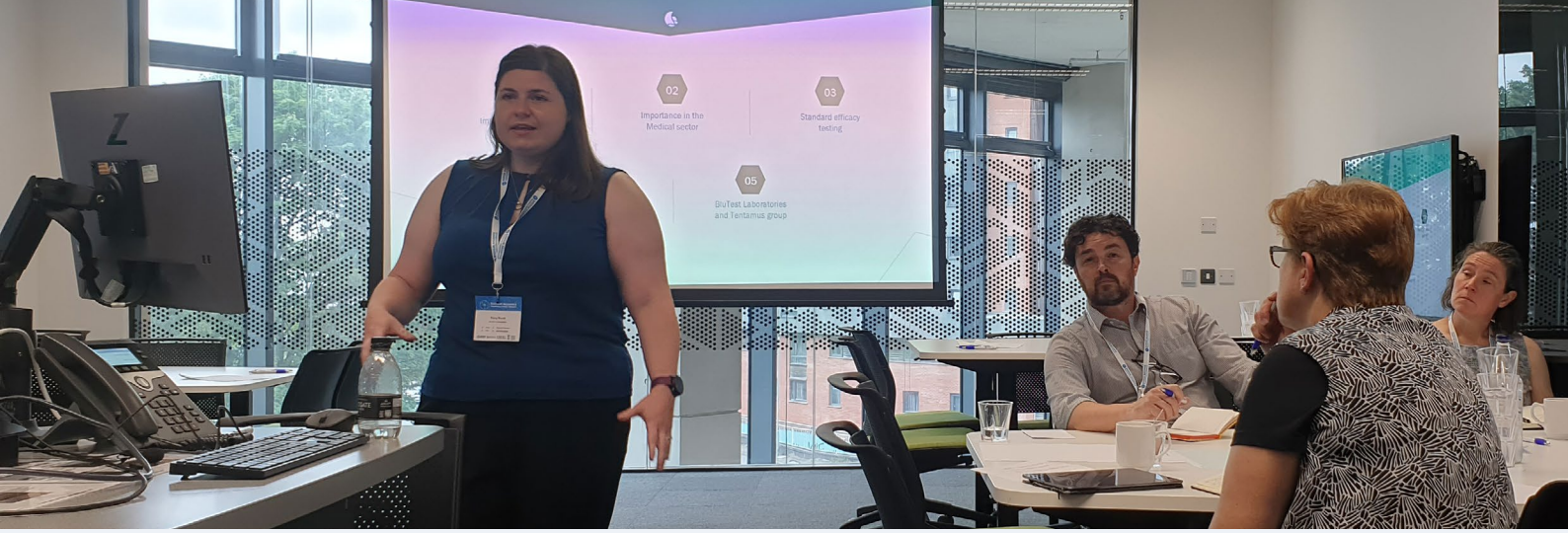
- To create discussion summary notes for distribution to all attendees and for wider dissemination
- To identify a set of next steps for the community, and the Biofilm Alliance, to undertake to ensure progress in creating consensus on biofilm methodologies, progress standardisation, and influence the future regulation in the industry sectors.

To provide input to the meeting and to ensure candid and informative discussions during the meeting all delegates were asked to consider and debate the following questions:

1. What biofilm methodologies are industries currently using to meet regulatory requirements?
2. What are the challenges and needs in addressing biofilms in industry?
3. What solutions could be proposed to address the above difficulties?
4. Cross-sector collaboration and sector-specific discussion.

To set the scene for the discussions, guest speakers: Tracey Rivett (BluTest Laboratories) and James Lee (Hydro Finesse) shared insights into biofilm challenges from two distinct industry perspectives. Tracey's presentation, "Into the Unknown – The Implementation of Biofilm Standards within the Efficacy Testing Landscape," explored the commercial implications of introducing biofilm standards into disinfectant and antimicrobial testing. She highlighted the gaps in current regulatory frameworks and the potential disruption to product validation processes. James Lee's talk, "Understanding and Managing Biofilms in Recreational Water Industries," focused on the operational challenges of biofilm control in pools, spas, and other wet leisure environments. He emphasised the need for sector-specific guidance and stronger collaboration between industry and academia to ensure practical, evidence-based biofilm management strategies.

The delegates were divided into five groups, each having a mix of representatives from different disciplines (industry, academia, regulations) for focused discussions around the predefined questions and to identify the main priorities and next steps.



Discussions and Outputs

Biofilm Methodologies

The discussion on biofilm methodologies explored current practices, challenges, and future opportunities for detecting, managing, and regulating biofilms across multiple industry sectors. Participants examined how diverse approaches are applied with varying success, reflecting sector-specific needs but also revealing a lack of standardisation and regulatory clarity. Specific points raised were as follows:

Approaches to Biofilm Control

- Industries employ a variety of methods to detect and manage biofilms, with a predominant focus on surface treatments and biocidal agents to meet hygiene and regulatory standards. Current practices include regular sampling or monitoring devices to detect biofilms and biocide application, mechanical removal, or chemical cleaning regimes to prevent biofilm formation or to remove formed biofilm. These methods vary widely in cost, reliability and skills required.
- Certain sectors have developed sector specific strategies and tailored approaches to managing biofilms. For example, water systems, and wet leisure water industries adapt biofilm control to their unique risk profiles, infrastructure, and end-user needs, while sectors concerned with chemical engineering often prioritise design features such as flow-through systems and the minimisation of dead-ends in pipework to limit biofilm formation.

Challenges and Barriers

- There is a persistent lack of industry and performance standards accounting for biofilms. Biofilm testing methodologies are inconsistent or even ineffective, based often modified versions of standard microbiological assays, with no sector-wide consensus.
- Current biocide efficacy standards fail to account for the variability of microbial species and strains and often do not reflect real-world conditions. It has been also noted that introduction of requirements for testing simulating or in real-world conditions could delay time to market for new products and incur huge testing costs.

- There is little consistency in monitoring biofilm regrowth after treatment, undermining long-term control strategies.
- There is no single, independent organisation that exists which can act as a neutral authority to define and oversee how biofilm testing should be done in different industry sectors. Testing methods are often developed and promoted by individual companies, research groups, or sector-specific organisations, each using their own preferred protocols or metrics. Without a neutral body to coordinate biofilm testing can be potentially biased, and unreliable across sectors.
- In biofilm management, pressure often flows from end-users to manufacturers, test labs, and regulators. While this can highlight known problem areas, current regulatory frameworks do not always incentivise proactive innovation, especially when compliance is prioritised over improvement.
- Stricter biofilm standards have the potential to drive innovation, but they may also expose limitations in existing biocidal products. This can lead to industry resistance, particularly if companies fear that their current solutions will not meet new expectations.
- Without clear regulatory incentives or pathways for innovation, manufacturers may be reluctant to invest in new technologies or testing approaches. This slows progress and limits the adoption of more effective biofilm control strategies.

Case Example: Commercial Water Systems/Wet Leisure

- Biofilm risks in commercial water systems remain under-recognised. A real-world example was discussed, where the lack of water circulation in flooded cover pits was only detected after customer complaints. Treatment using chlorine and mechanical removal was reactive rather than preventative. Notably, chlorine is effective against planktonic cells but often fails to eliminate established biofilms, especially in areas like grout between pool tiles.

Industry Collaboration and Support

Effective progress in biofilm control requires strong, transparent, and well-coordinated collaboration between industry, academia, and regulators. The discussion highlighted key challenges in achieving this:

- Progress in biofilm management will depend on collaboration with ‘influential stakeholders’ - companies that are either large and well-established in their markets or have a strong voice within an industry, that can advocate for better standards and not resist scrutiny.
- Without strong voices from major manufacturers or end users, progress may be fragmented and slow.
- Some influential individuals or organisations may unintentionally (or deliberately) share inaccurate biofilm information, which can lead to poor practices not supported by academic evidence. This undermines progress and can compromise safety and effectiveness.
- Weak engagement between industry and academia remains a barrier. Strengthening collaboration is essential to ensure that innovations are informed by robust science and translated effectively into practice.

Current Methodologies and Standards

Multiple standards are referenced across different applications, yet none are universally adopted. A few examples have been discussed, including:

- IBRG (International Biodeterioration Research Group) Methods: Common in cooling tower scenarios, involving triplicate testing at three biocide concentrations with at least one failure required to pass.
- ASTM E645 and ASTM E1839 standards are recommended by the Biocidal Product Regulation (BPR) Guidelines for e.g. Product types (PTs) 11, 12 or 21, relevant to specific sectors (e.g., slimicides in paper mills, antifouling in marine contexts).
- ASTM E3321-21: Medical-specific standard for urinary catheters and antimicrobial surfaces.
- ISO 4678:2023: An emerging international framework for biofilm methodologies, aiming to bring greater alignment across sectors.
- HSG274: Legionnaires' Disease: Technical guidance
- Approved Code of Practice (ACoP) L8: Legionnaires' disease: The control of legionella bacteria in water systems.

Research and Future Opportunities

- There is growing interest in bacteriophage products as a potential solution for biofilm control, though further research is needed to assess their viability across sectors.
- Many paint and coatings companies are interested in the development of antimicrobial surfaces, yet also reluctant to invest in R&D due to the complexities of regulatory requirements.
- Prevention of deposits such as limescale could present opportunities to delay or prevent biofilms from establishing on surfaces (biofouling), though further research is needed to assess viability across sectors.

UK Regulatory Challenges

Workshop participants discussed the complexity of the UK regulatory landscape and raised several key points:

- Navigating the UK regulatory environment for biofilm control is notably complex. Requirements differ across sectors, and post-Brexit divergence from EU regulations has further complicated compliance efforts. Companies operating across jurisdictions must now interpret and satisfy multiple, sometimes conflicting, sets of rules.
- Demonstrating efficacy of biocidal products or surface treatments against biofilms requires substantial investment in testing and documentation, often percieved without clear regulatory guidance on acceptable methodologies, what places a significant burden on companies, particularly affecting SMEs. This can stifle innovation in bringing new products to market
- The absence of specific, harmonised standards for biofilm testing creates uncertainty for manufacturers and testing labs. Companies frequently struggle to identify which protocols regulators will accept. Clearer, sector-specific guidelines are urgently needed to support consistent and meaningful evaluation of biofilm / antibiofilm products and processes.
- There remains a general lack of awareness among regulatory stakeholders and industry professionals (extending into e.g. building planning, design and construction) regarding the unique challenges posed by biofilms. Training and educational programmes would be beneficial to build understanding around biofilm ecology, risks, and the limitations of current disinfection practices.
- Joint efforts and deeper collaboration between regulators, industry, and academic researchers are needed to support the development of practical, evidence-based standards and foster innovation in biofilm affected areas. Equally, cross-sector partnerships would be key to creating feasible, scalable and transferable solutions to accelerated biofilm innovation and its alignment with regulatory expectations.

Cross-Sector Discussions

Workshop participants discussed the complexity of the UK regulatory landscape and raised several key points:

The forum's cross-sector discussions provided valuable insights into the shared and unique challenges faced across industries regarding biofilm detection, control, and regulatory compliance. Despite sectoral differences, several common themes and priorities emerged, particularly around the need for improved collaboration, communication, and access to expertise.

Knowledge Sharing and Collaboration

A strong call was made for the creation of a central expert registry and a database of companies actively engaged in biofilm research or directly affected by biofilm-related issues. Such a resource would allow organisations to identify potential collaborators, share case studies, and facilitate real-world application of academic research. It was also suggested that structured opportunities be created for researchers, regulators, and solution providers to visit manufacturing sites and sector-specific facilities to better understand biofilm-related challenges in situ and explore potential interventions.

Training programmes for installers and industry professionals, emphasising the critical role of correct system design, installation, and maintenance in preventing biofilm formation would be beneficial. Embedding this awareness into standard industry practices would help mitigate long-term risks.

Sector-to-Sector Education

Participants emphasised the value of cross-sector education, noting that terminology, practices, and assumptions vary widely across industries. For instance, some sectors refer to biofilms as “slime” or “sludge,” terms which may obscure the microbial nature of the issue. A shared glossary of key terms would help align language and understanding, particularly in interdisciplinary settings or regulatory discussions.

Continued Engagement and Capacity Building

To maintain momentum, there was consensus on the importance of ongoing workshops, online meetings, and training sessions to build awareness and expertise. These activities were seen not only as knowledge-sharing forums but also as essential vehicles for trust-building and alignment between industry, academia, and regulators.

A notable gap was the limited engagement of biocide manufacturers in biofilm-specific testing. Currently, many do not see the commercial value in developing biofilm efficacy data, as regulatory pressure is lacking. Encouraging their involvement through regulatory reform, standardisation, and education was identified as a key next step.

Regulatory Clarity and Innovation Pathways

The differences between UK and EU regulatory frameworks post-Brexit continue to cause confusion. Participants called for clearer guidance and pathways tailored to the UK context, particularly in relation to antimicrobial surface claims and biofilm testing protocols. The development of standards for antibiofilm/antimicrobial surface testing, including physiological and biological performance parameters, was seen as essential to enabling innovation while maintaining safety and efficacy.

A potential pilot for assessments made collaboratively between regulatory bodies working together, modelled from the learnings from other sectors for example, the innovative devices access pathway (IDAP) for medical devices

Diagnostics and Monitoring

Interest was expressed in molecular diagnostics for determining the presence or absence of biofilms, particularly methods that go beyond traditional culture techniques. These tools could also help detect residual dead cells and biofilm matrix components that may remain post-treatment, offering a more accurate picture of microbial risks.

Additionally, there was a call to increase awareness of how biofilms recover and persist, especially in areas considered “clean.” For example, surfaces can become nutrient sources for surviving microorganisms, contributing to regrowth. Simple human interactions, such as contact with taps, can introduce contamination post-disinfection, highlighting the need for ongoing, context-specific monitoring, particularly in sensitive settings like healthcare or food processing.

Simplification of Data and Decision-Making

There is a pressing need to translate complex scientific and diagnostic data into actionable insight. Participants encouraged the development of simplified tools and decision-support systems that can be easily adopted by non-specialist users. This would help bridge the gap between advanced diagnostics (e.g. metagenomics, AI-driven risk models) and day-to-day operations.

Emerging Opportunities

To support continued work in this area, alternative funding pathways were discussed, including grants for joint workshops and conferences, the development of an open-access journal, and the provision of private consultancy services to support biofilm risk assessment and strategy development across sectors.

AI was also highlighted as a promising tool for surfacing sector-specific challenges through literature mining and analysis of industry publications. This could provide a valuable feedback loop, enabling trend detection and supporting data-driven policy and innovation.

Promotion of Fundamental and Applied Research

Continued investment in research would be essential to advance the understanding of biofilm behaviour in industrial environments. Priority areas include early detection, surface interactions, resistance to biocides and anti-biofilm agents, and the real-world performance of new biocidal technologies.

Increased funding for product testing, validation, and innovation will encourage the development of new tools and interventions. This includes support for startups and SMEs working on novel approaches to biofilm control.

Conclusions

The Biofilm Alliance Forum highlighted the widespread and often overlooked impact of biofilms in water systems, industrial operations, and the built environment. Biofilms continue to challenge safety, efficiency, and infrastructure resilience across these sectors. Although awareness is increasing, many organisations still lack the tools and expertise needed to detect and manage biofilms effectively, particularly in small and medium-sized enterprises.

Existing approaches to monitoring and treatment are inconsistent and frequently fail to address biofilms under realistic conditions. Common cleaning and disinfection practices are not always sufficient, especially when biofilms are well established. The absence of clear, practical, and sector-specific standards contributes to uneven implementation and regulatory uncertainty.

In the United Kingdom, biofilm-related risks are not consistently addressed within water quality regulations, industrial hygiene protocols, or building codes. The regulatory environment remains complex, and the shift away from European Union standards has introduced new challenges. However, this also presents an opportunity to develop more targeted and effective guidance.

Despite these issues, participants expressed strong interest in working together across sectors to improve understanding and develop better solutions. There is a clear need to connect academic research with industrial practice, create accessible tools for early detection, and integrate biofilm awareness into routine operations and infrastructure design.

To support progress, the following priorities were identified for the Biofilm Alliance and its partners:

1. Support the creation of reliable and sector-specific methods for identifying biofilms, testing treatment effectiveness, and conducting regular monitoring that reflects actual working conditions.
2. Build a central resource listing experts and organisations involved in biofilm research and management, making it easier for companies to find support and share knowledge.
3. Assist in creation of training and education programmes tailored to technicians, installers, and decision-makers, including online materials and certification options.
4. Encourage collaboration across sectors to share insights, align standards, and present a unified approach to regulatory development.
5. Evidence the need for investment in innovation. While direct funding may not be available, the Alliance can help build the case for investment in technologies such as antimicrobial surfaces, phage-based treatments, and genetic tools; supporting the community in securing funding and translating research into practical solutions.

In summary, addressing biofilm challenges in water systems, industrial processes, and the built environment requires coordinated action, improved communication, and sustained investment. The Biofilm Alliance is well placed to lead this effort by bringing together stakeholders, shaping policy, and promoting innovation that meets the needs of these critical sectors.

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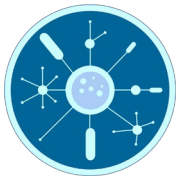

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