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INSIGHT

Antimicrobial efficacy:
five ways to improve data planning

Time pressures often lead companies to skimp on the planning phase in their eagerness to get data development underway. But this can be counter-productive.

Proving antimicrobials can kill target microorganisms, with data that satisfies regulatory agencies' requirements, is the cornerstone of successful product registration. However, generating efficacy data in a cost-effective way is not easy. Our efficacy team lead, microbiologist Milady Brutofsky, says placing greater emphasis on data planning is the secret to a seamless registration journey.

Antimicrobial pesticide registration falls into three core phases: data planning, data development, and the preparation of application documents. Registrants need to provide evidence that their products are safe and efficacious against target microorganisms.

Time pressures often lead companies to skimp on the planning phase in their eagerness to get data development underway. But this can be counterproductive.

Efficacy data requirements of the US Environmental Protection Agency (EPA) are highly complex. The same is true of international agencies that regulate antimicrobials, such as Health Canada and the European Chemicals Agency (ECHA). In the case of the US and Canada, while there is some overlap in requirements, the differences that do exist have significant implications.

To maximize efficiency, it's advisable to invest time establishing exactly what data the agencies in target markets will require and under what conditions it needs to be generated. Ideally, one efficacy testing program should generate the necessary depth, breadth, and quality of data to satisfy all eventualities. If key data needs or nuances between different agencies aren't acknowledged upfront, it may be necessary to conduct duplicate testing programs. For instance, Canada requires efficacy data to be generated according to Good Laboratory Practice (GLP) principles for non-public health products whereas the US does not. Failure to account for anomalies like this at the outset can incur additional costs and cause delays which may harm commercial performance.

This article outlines five ways to enhance the planning phase so that antimicrobial data generation is comprehensive, effective, and efficient.

Antimicrobial efficacy data requirements in the US

In the US, antimicrobial substances intended for use on inanimate surfaces are subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), whereas those for use on or in living animals or humans are subject to the Federal Food, Drug, and Cosmetic Act (FFDCA). Some antimicrobials may be subject to both Acts, for instance if they are intended for use on food contact surfaces.

All antimicrobial products need to be registered prior to distribution in the US, and they must also be substantiated with efficacy data. These efficacy data requirements are dictated by a product's claims and intended use and may vary quite significantly across different product types.

Registrants of 'public health' products, which claim to control microorganisms that pose a risk to human health, must submit efficacy data at the time of product registration. Common public health products include those which claim to sanitize, disinfect, sterilize, and purify.

For 'non-public health' products, efficacy data must be generated but it only needs to be submitted if requested by the EPA.

Antimicrobial pesticides can be devices or chemical products. Typical categories include:

- Food-handling/storage
- Commercial, institutional, and industrial
- Residential
- Medical premises and equipment
- Drinking water systems
- Materials preservatives
- Industrial processes
- Antifoulant paints and coatings
- Wood preservatives
- Swimming pools and spas
- Aquatic areas
- Pesticide devices

Five ways to enhance efficacy data planning

1 Identify efficacy requirements and data bridging opportunities

There is no one-size-fits-all approach to antimicrobial efficacy testing, so the first step is to pinpoint the role of a product in its use environment. It's important to do this as early as possible in product development, as efficacy testing is central to the substantiation of marketing claims. A tailored approach is beneficial here, with individual products considered according to their merits and intended use.

It's also worth taking time to identify any potential opportunities for data bridging at this stage. Data bridging is when more than one product cites a core set of data. Sometimes this 'bridge' is supported through the generation of additional data to support the use of the remainder of the dataset for all products.

2 Interpret guidelines and regulations

Antimicrobial regulations and efficacy test guidelines are often complex. It can be hard to ascertain which requirements apply to a given product to support desired claims.

For instance, in the US, the EPA's Series 810 Product Performance Test Guidelines should be consulted for products which fall under FIFRA. Group B of Series 810 includes nine separate antimicrobial efficacy test guidelines, ranging from those for public health antimicrobial pesticides and sanitizers for use on hard surfaces, to air sanitizers, and disinfectants and sanitizers for use in water.

The interpretation of these guidelines and others like them may vary according to the claims made on a product's labeling. Underestimating or misinterpreting requirements may result in registration being denied and/or tests having to be conducted multiple times. On the other hand, overestimating the requirements could lead to unnecessary expense. Dedicating time and expertise to this process helps strike the right balance.

3 Develop protocols and test method designs

Once a product's antimicrobial efficacy data requirements have been determined, attention can turn to protocols and test methods. Ideally, a single testing program should be developed to generate one comprehensive set of data satisfying relevant agencies' requirements. In this way, testing can be streamlined to satisfy disparate agency needs while keeping laboratory costs under control.

Sometimes existing protocols and test methods can provide a blueprint, but with novel applications or new technologies it's usually necessary to start from scratch. Before engaging a contract laboratory it's important to develop a data generation strategy which clearly sets out objectives and expectations. This helps ensure testing and research proceeds smoothly and stays on course to deliver the required outcomes.

4 Draft and review study design

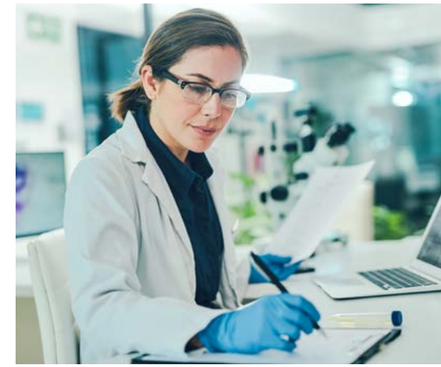
Antimicrobial efficacy studies challenge the test product with a panel of microorganisms to demonstrate its ability to kill them or minimize their growth. One commonly used approach is the 'hard surface carrier' method where a test surface – usually a disposable glass carrier – is inoculated with microbial cultures then treated with the product.

Whatever method is used, studies must be designed to maximize the quality and integrity of data generated. If agencies with which the product will be registered require tests to be performed in line with GLP principles this must be accounted for in all aspects of study design, from planning and monitoring to recording, reporting and archiving.

Regulatory requirements do evolve and get updated over time, so once the study has been designed it should be given a final review to ensure full alignment with current standards.

5 Review protocols

Before efficacy testing begins, the protocol should be interrogated to ensure tests will deliver the right data under the right conditions according to all applicable standards. Protocol is an important aspect of testing that validates the quality and integrity of data, ensuring it can withstand scrutiny. It provides the rationale behind every step of the process and should clearly convey the study's objectives and methods, detailing various components that will be used and how the final data will be captured, verified, and analyzed. Protocol reviews help mitigate risk and give added assurance that the testing will yield the expected outcomes.



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Better data planning saves time and money

Generating antimicrobial efficacy data is expensive, so upfront investment to get the process right first time will pay dividends. This is especially important for companies planning a global launch or looking to make novel antimicrobial claims. Such scenarios may result in additional or different data needs. Accounting for these ahead of data strategy development makes the whole process more streamlined and cost-efficient.

TSG Consulting can provide extensive support for efficacy claims related to the following microorganisms and antimicrobial applications:

- Air sanitizers
- Biofilms
- Disinfectants
- Fungicides
- Mildewstats
- Sanitizers
- Sporicidal
- Towelettes
- Tuberculocides
- Virucides

Find out more about how we can address your antimicrobial product registration needs here.

About TSG Consulting

TSG Consulting provides companies with high quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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