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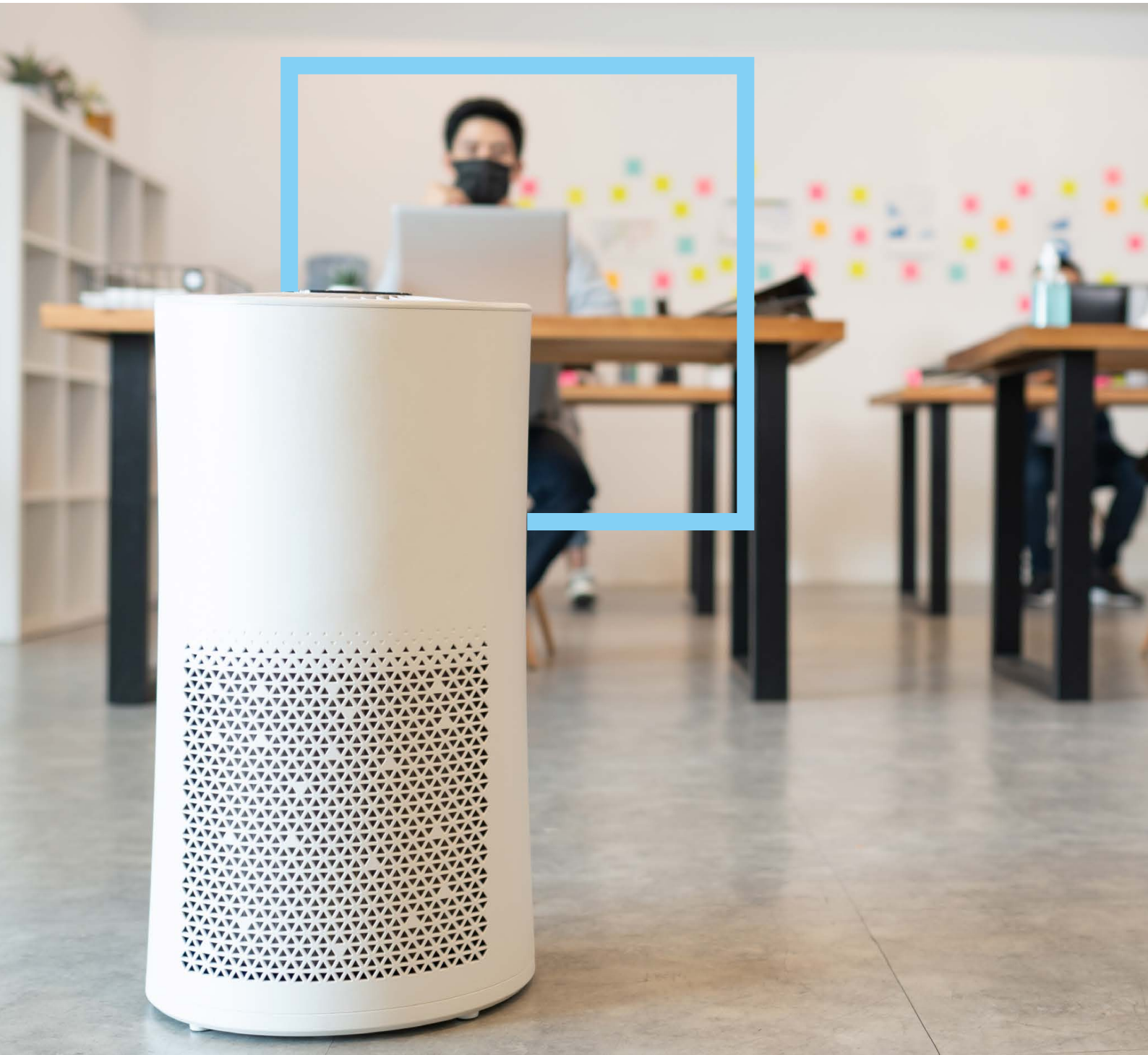
Improving indoor air quality: a window of opportunity

With COVID-19 amplifying interest in air quality devices, we look at technical and regulatory matters that product developers need to consider.



The market opportunity for air treatment products has expanded as the world learns to live with COVID-19. Demand for solutions that improve indoor air quality is high across multiple sectors. It's an area that's ripe for innovation, and manufacturers are exploring new approaches for domestic, commercial and medical applications. One category gaining attention is air treatment devices. Here, we look at enabling technologies and the associated technical innovation challenges. We also consider the complexity of getting these products to market, spotlighting the regulatory landscape in the United States. Our goal is to help innovators and manufacturers accelerate progress with the creation of compelling products that satisfy customer needs and stringent regulatory requirements.

Air treatment in the age of COVID-19

The importance of managing indoor air quality has been understood for some time, and the COVID-19 pandemic brings new significance to this. As people increasingly think in terms of 'life with COVID' rather than 'life after COVID', demand for technology to improve indoor air quality is set to grow.

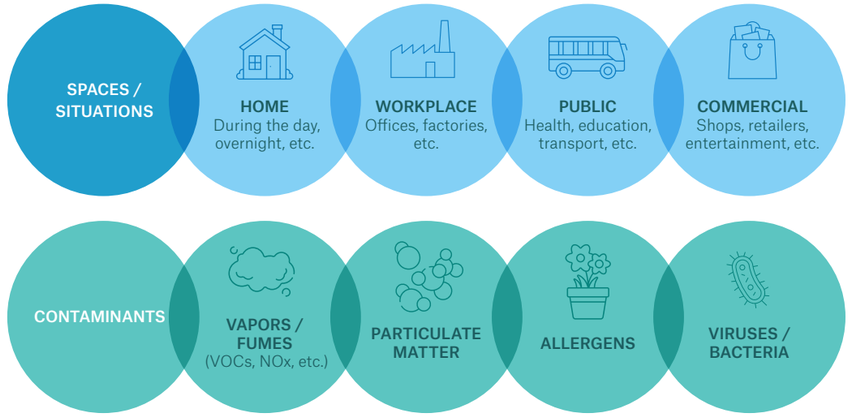


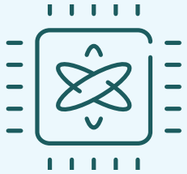
Figure 1: Air quality can be a matter of concern in the home, at work and in public spaces

Current guidance from the Centers for Disease Control (CDC) indicates that the principal transmission of COVID-19 happens via exposure to aerosolized infected respiratory fluids. In other words, inhalation of SARS-CoV-2 is a major risk factor in contracting the virus. Consumers are acutely aware of this, and the antimicrobial marketplace has been quick to respond.

Products which target airborne contaminants and microorganisms are of particular interest to consumers and commercial buyers alike (see Figure 1). They are also attracting the attention of authorities which regulate such products' properties and claims.

The window of opportunity for air treatment product innovation is wide open. However, the complexity of technical and regulatory matters presents risks that could hinder progress.

This whitepaper offers insights to help navigate challenges and accelerate the journey. We focus on 'air treatment' as opposed to 'air purification' since purification has a distinct regulatory definition which we'll refer to later.



Removing hazards which compromise indoor air quality is preferable on many levels. Air treatment technologies are a user-centric solution.

All eyes on indoor air quality

Heightened public concern about airborne transmission of SARS-CoV-2 is driving new behaviors and expectations. Pre-COVID the use of facemasks was popular in Asian countries; a year and a half into the pandemic they are ubiquitous. However, widespread use does not mean facemasks are an ideal solution. In fact, there are several groups – such as children, professionals, the elderly, and disabled people – for whom their use is either impossible or impractical. Inadequate use of facemasks means inadequate protection.

Removing hazards which compromise indoor air quality is preferable on many levels. Air treatment technologies are a user-centric solution. They integrate seamlessly with people's surroundings and routines rather than diverting time, attention and focus from desired or high value activities.

In general, air treatment technologies target suspended particulates and gaseous pollutants, biological or photolytic processes. Gaseous pollutants include volatile organic compounds, carbon monoxide and nitrogen dioxide. Particulate pollutants are generally categorized according to size, and include dust, pollen, and mold spores as well as bacteria and airborne viruses.

Figure 2 indicates the various points to consider for applying air treatment technologies.

Intervention type			
Radiation	Mechanical	Chemical	Biological

Target use	
Individuals	Spaces

Delivery mode	
Contained	Released

Action mode	
Catch	Kill

Embodiment			
Formulated products	Conventional devices	"Smart" devices	Building integrated systems

Figure 2: Summary of air treatment interventions, delivery and application

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To create effective solutions, product developers need to overcome technical challenges and regulatory complexity.

The COVID-19 pandemic has led to increased demand for antimicrobial air treatment technologies. Therefore, the race is on to create new products which mitigate airborne pathogens such as SARS-CoV-2.

There are opportunities for solutions geared towards domestic, commercial and medical settings which existing manufacturers and new market entrants are keen to explore. However, any business operating in this space must contend with the need for robust efficacy data to underpin compelling claims which satisfy stringent regulatory criteria.

Air treatment technologies for the removal of harmful viruses and bacteria can be segmented according to three core product types:

- Air treating antimicrobial chemicals which are aerosolized or sprayed into the air
- Air treating antimicrobial devices which reduce airborne pathogen load through physical means
- Combination products which use both of the above in unison

To create effective solutions, product developers need to overcome technical challenges and regulatory complexity. The following section considers this in relation to the development, manufacture, and sale of devices which reduce airborne pathogen load through physical means. We focus specifically on technologies which could potentially be used to help combat COVID-19.

Device technologies to improve indoor air quality

Ultraviolet-C (UV-C) has a long history of use in the treatment of air, as well as water and nonporous surfaces.

UV-C lamps

Ultraviolet-C (UV-C) is the shortest wavelength of the three forms of UV (at approximately 100-280 nanometers [nm]). It has a long history of use in the treatment of air, as well as water and nonporous surfaces.

UV-C lamps can be deployed in a wide range of ambient air applications. For instance, they may be used for the irradiation of upper portions of air in occupied spaces and complete irradiation of unoccupied spaces. They can also treat air as it passes through confined HVAC spaces or within self-contained air-recirculation units.

Consumer interest in UV-C lamps during the COVID-19 pandemic prompted the US Food & Drug Administration (FDA) to publish information regarding their safety and effectiveness.[1]

The FDA's Q&A states:

The effectiveness of UV-C lamps in inactivating the SARS-CoV-2 virus is unknown because there is limited published data about the wavelength, dose, and duration of UV-C radiation required to inactivate the SARS-CoV-2 virus. It is important to recognize that, generally, UV-C cannot inactivate a virus or bacterium if it is not directly exposed to UV-C.[1]

The US Environmental Protection Agency (EPA) may also regulate UV lamps depending on the specific use and claims made. This will be addressed in more detail below.

Blue light products

Air treatment devices incorporating antimicrobial blue light with its 405nm wavelength have similar use patterns to UV-C air treatment devices. Blue light is considered an emerging technology in the air treatment space. Advantages over UV-C include a lower risk to human eukaryotic cells, reducing the possibility of tissue damage linked to UV light exposure.

Air ionization units

Air ionization is an established method of air treatment which has been used commercially for some time. Conventional units use high voltage to electrically charge air molecules, creating negatively charged ions. This electrostatic process has been shown to reduce airborne particulates, contaminants, and allergens in treated spaces.

In response to COVID-19, a new form of air ionization has emerged: bipolar air ionization. Also known as 'needlepoint ionization', this process creates negative and positive air molecules and removes airborne contaminants.

The EPA has acknowledged the potential for bipolar ionization to remove viruses, including SARS-CoV-2, from ambient air. However, to be compliant with regulations, products attributed with such claims must be backed by supporting data. Though the agency stance around this technology is generally positive, there has been some enforcement action surrounding false and misleading claims. EPA has also highlighted toxicity concerns related to the generation of ozone as an operational by-product.

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When combined with UV-C light panels or air ionization components, HEPA filtration technology can target smaller airborne bacteria and viruses.

HEPA filtration units

The versatility of High-Efficiency Particulate Air (HEPA) filtration means it is easily combined with other air treatment technologies for enhanced rates of particulate removal.

As a standalone technology, HEPA filters are required to remove 99.95% (EU Standards[2]) or 99.97% (US Standards[3]) of airborne inanimate and animate particulates with a diameter equal to 0.3µm. This can include pollen, dirt, dust, and some bacteria and viruses as well as other aerosolized particulates. In recent industry testing, HEPA filtration units have proven efficacious against airborne SARS-CoV-2 droplets. This has resulted in a surge of consumer demand for these air treatment devices.

However, it's important to recognize that the requirement to remove 99.95% / 99.97% of 0.3µm particles are industry performance standards; they don't necessarily match the performance criteria for regulatory approval for filters which claim to inactivate or kill public health pathogens.

This has led to the influx of combination devices which include UV-C light panels or air ionization components with HEPA filtration technology in an attempt to satisfy stringent regulatory requirements. Manufacturers are finding the regulatory landscape of these multi-method air treatment devices complex and evolving.

In-situ ozone generators

Ozone generators are self-contained units which produce ozone gas in situ to 'decontaminate' the surrounding air or nearby surfaces. These products are often marketed to consumers as 'safe' or 'natural', but EPA has issued multiple notices[4] objecting to such claims.

EPA skepticism, coupled with a history of false and misleading claims, has heightened the regulatory challenges facing ozone generating device registrants. We'd advise manufacturers who intend to distribute these devices to review current FDA, EPA and relevant state guidance to understand the agencys' current stance and data requirements.

The innovation opportunity

Development of air treatment technologies requires specialist scientific and engineering expertise. Practical considerations which may impact uptake – such as noise, power consumption and longevity of components – need attention as well as matters relating to efficacy.

It's important to interrogate the core design at an early stage to ensure any limiting factors or usability requirements are identified and addressed.

For instance, the development of devices using filter technologies needs to account for the fouling of filters and potential microbial growth as well as the ease and expense of replacing them.

Of particular importance is to ensure that the design of the device prevents unintentional release/generation of UV-C light, ozone, formaldehyde, particulate matter or other byproducts into the space being cleaned.

Unless a device is releasing an active element, all air treatment must occur within it. However, ensuring air from all parts of the room passes through can pose a challenge. The device itself might be 99.99% effective, but this is less compelling if it only treats 15% of the air in a given space.

Another area to consider is the potential lack of untreated external air being brought into the space. Repercussions of this might include CO_2 build-up and drowsiness.

Providing real-time evidence of effectiveness is another area that may require dedicated innovation. There have been huge steps forwards recently in the capability of air quality monitors and some air treatment devices are beginning to incorporate air quality sensors and indicators. It's relatively straightforward to measure levels of CO_2, PM2.5 and Total Volatile Organic Compounds (TVOCs), as long a high degree of precision is not required. However, sensing viral presence is much more challenging. Nevertheless, sensing technologies could still prove useful in this context; there may be proxies that can be measured if the target pollutant can't be detected directly.

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Regulatory frameworks

Companies operating in or entering the air treatment space need to consider technology limitations as well as opportunities.

Understanding the efficacy standards required by regulatory agencies in target markets is an essential part of this. Products must be designed to meet or exceed any established performance standards related to claims made about them.

Who regulates air treatment technologies?

The first step is to determine which regulatory agency (or agencies) has jurisdiction over the device's air treatment technology (or technologies). In the US, this may fall under the authority of EPA, FDA, or potentially both. The regulatory approval process, data requirements and overall path to product approval differs greatly between pesticidal and medical devices, as Table 1 indicates. This can have significant repercussions for costs and timescales.

	EPA	FDA
Types of air treatment device covered	Pesticidal devices considered "an instrument or contrivance (other than a firearm) that is used to destroy, repel, trap or mitigate (lessen the severity of) any pest" including mold/mildew, bacteria and viruses."	Air purifying devices intended for medical purposes to "kill pathogens/microorganisms in the air by exposure to UV radiation, removal through filtration, or electrostatic precipitation." *Electrostatic precip is a required characteristic of Class II Medical Devices under product code FRA.*
Key points to note	Pesticidal devices are regulated by EPA, but do not require federal registration, however a handful of states do require registration.	FDA would clear an air purification device through the 510(k) premarket notification or *de novo* classification request processes.

Table 1: US regulatory agencies with jurisdiction over air treatment devices

Other markets, such as the EU, have similar levels of regulatory complexity. Any product *"used with the intent to destroy, deter, render harmless, prevent the action of, or control, harmful organisms"* is considered a biocide in the EU.

Therefore, air treatment devices may be subject to EU Biocidal Products Regulation (BPR) 528/2012 concerning the market placement and use of biocidal active substances and products.

Balancing innovation and regulation

Threading the needle through the regulatory fabric is critical when considering air treatment product innovation. Having a good understanding of the regulatory requirements during the innovation process will accelerate the development of compliant products with a competitive edge.

Drawing on regulatory expertise at an early stage is beneficial and in-depth knowledge of relevant technologies is also key. Combining this with practical engineering input underpins effective and efficient innovation.

This is where TSG Consulting and Sagentia Innovation can help. We work independently and collaboratively to bring clients' ingenuity to life in the real world. Our scientists, engineers and regulatory specialists navigate complex challenges that might otherwise stall progress. In the burgeoning, competitive field of air treatment technology, this can bring significant commercial advantage.

TSG recently published a whitepaper focused on the US regulatory landscape for pesticide devices, available at https://www.tsgconsulting.com/advisory/pesticide-devices-us-regulatory-landscape.

We are currently preparing dedicated whitepapers looking at air treatment in medical, commercial and consumer settings. These resources will cover chemicals as well as devices.

About Sagentia Innovation

Sagentia Innovation provides independent advisory and leading-edge product development services focused on science and technology initiatives. Working across the medical, industrial, chemicals and energy, food and beverage, and consumer sectors, Sagentia Innovation works with a broad range of companies from some of the world's leading and best-known brands, to start-up disruptors, new to the market. It is part of Science Group (AIM:SAG), which has more than ten offices globally, two UK-based dedicated R&D innovation centres and more than 400 employees. Other Science Group companies include Leatherhead Food Research, TSG Consulting and Frontier Smart Technologies.

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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 France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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Science Group plc (AIM:SAG) is a science-led advisory and product development organization. The Group has three divisions:

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