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Reducing Bioaerosol Risks at Pharmaceutical Plants

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More than 45 years after the first known outbreak of Legionnaires' disease was linked to tiny, airborne droplets emitted by a cooling tower, such bioaerosols containing bacteria, viruses, fungi and other microbes continue to pose health risks to people who live and work nearby. A fresh look at pharmaceutical plant design can help to change that.

The need to understand bioaerosol exposure as a vector in infectious disease transmission first gained national attention in 1976. That is when Legionella, a new strain of bacteria, was found to have caused Legionnaires' disease, a serious lung infection contracted by people attending a Philadelphia convention of the American Legion.

In the years since, the ongoing emergence of infectious diseases — from seasonal flu to COVID-19 — has served as an enduring reminder of the role bioaerosols can play in public health threats. While vaccines, therapeutic drugs, improved ventilation, masks and other personal protective equipment can help reduce the risks of these and other airborne diseases, more attention is being directed at the source of the bioaerosols that transmit them.

Isolating these sources can be difficult. After all, bacteria, viruses, fungi and other microbes occur naturally in lakes, streams and other freshwater environments. Many, including Legionella, can become a public health concern when they grow and are aerosolized in human-made water systems.

Areas of Concern in Pharma Plants

Bioaerosols can be generated by a wide range of human-made sources, from hot tubs and public fountains to plumbing systems in buildings. Within the confines of a pharmaceutical plant there are two well-documented sources of bioaerosols: cooling tower operations and wastewater treatment aeration systems.

The warm, wet environment in process cooling towers is particularly conducive to the growth of bacteria, viruses, fungi and other microorganisms, which can multiply and become aerosolized as air cools the hot process water that recirculates through them. Cooling tower plumes can then carry the droplets into the atmosphere, where they can travel a considerable distance, creating an unseen risk to public health.

In research conducted by the Cooling Technology Institute, up to 60% of process cooling towers were found to contain Legionella. Process cooling towers have been implicated as the source of the Legionella bacteria in multiple outbreaks of Legionnaires' disease, including the original 1976 incident that left 25 people dead.

The aeration systems used in wastewater treatment at pharma plants also present bioaerosol risks.

The wastewater produced in these facilities often contains active pharmaceutical ingredients (APIs) and other organic matter. In the aeration process, air is mixed with wastewater to promote the growth of bacteria and other microorganisms that break down organic matter and remove pollutants from wastewater. However, these microorganisms can also encounter viral genetic material that may influence the microbe community and reproduce before being released into the air as bioaerosols.

Not all microbes are the same. For example, the COVID-19 virus has proven to be unstable in direct sunlight and wind. More robust microbes are sometimes more opportunistic, able to take advantage of environmental conditions.

Research to learn more about the characteristics and patterns of spread for various microbes is ongoing. For example, a study reported in the International Biodeterioration & Biodegradation journal found that a large wastewater treatment plant emitted the highest concentration of airborne bacteria — specifically mesophilic bacteria, total coliforms, fecal coliforms and mannitol-positive staphylococci — during the summer months.

The concentration and aerosolization rate of Staphylococcus aureus (S. aureus) and Escherichia coli (E. coli) bioaerosols from wastewater aeration tanks were found to present greater risks during the winter months than during autumn months, according to a study reported in the Science of the Total Environment journal. Other research has explored the risk of inhalation exposure to the Ebola virus in aerosolized droplets generated during wastewater handling and treatment. Many gaps in understanding the impacts of bioaerosol exposure remain.

Facility Design and Maintenance Implications

Given the limited data available, neither the U.S. Environmental Protection Agency nor the Occupational Safety and Health Administration has provided substantive guidance to date on how pharma manufacturers might address bioaerosol risks in facility design. State and local agencies in California, Virginia and elsewhere are just beginning to dip their toes in this water.

While there is still much to learn about the risks associated with bioaerosols, pharma manufacturers are still wise to factor emerging concerns regarding their impact on plant water quality and public health into their facility design decisions.

While existing facilities can be retrofitted to address these issues, financial impacts can be minimized by addressing bioaerosols in the planning process for new facilities. Issues that can be considered during planning and design include:

- **Risk characterization studies.** While it is known that cooling towers and wastewater treatment processes can produce bioaerosols that pose health risks, risk characterization studies of these emissions are not common. A smart first step might be a study that investigates these risks and characterizes bioaerosols produced at existing facilities. Ongoing monitoring of air quality for microbial contamination and prompt response to any identified contamination is also crucial.
- **Cooling tower setbacks and location.** Building codes typically dictate the distance that cooling towers are to be located from property lines. Many require pharma plants that use reclaimed water from a wastewater treatment plant — water that may contain pathogens — to have deeper than normal setbacks. Manufacturers concerned about bioaerosol dispersion go a step further and consider regional wind patterns when selecting cooling tower locations. By making use of the prevailing wind, it is possible to locate a tower so that the wind directs bioaerosols away from schools and other potential receptors to be avoided. The CTI also recommends locating cooling towers away from building air intakes to prevent tower drift and splash-out from being fed into building air supply systems. Contamination that reaches a pharma plant's air handling and heating, ventilation and air conditioning systems and then remains aerosolized can threaten product quality.
- **Cooling tower design.** The air at the top of a cooling tower is hot and humid, conditions that are conducive to the creation of bioaerosols. Designers may wish to consider design modifications that increase airflow at the top of the tower. Ventilation and air filtration systems can help reduce bioaerosol creation and dispersion. Cooling towers also benefit from high efficiency nesting-type drift eliminators that prevent water droplets that might contain bacteria from escaping, according to the CTI.
- **Cooling tower maintenance.** Preventing Legionnaires' disease involves proper maintenance and disinfection of water systems in buildings and facilities, particularly those with cooling towers and plumbing systems. Regular monitoring for the presence of Legionella bacteria and prompt response to any identified contamination are crucial.

- **Wastewater aeration system selection.** Another study cited in Science of the Total Environment included an investigation of S. aureus and E. coli bacteria that had been emitted in two different wastewater aeration modes. The research found that the bioaerosol concentration in a microporous aeration tank was an order of magnitude lower than that found in a rotating disk aeration tank, and the average aerosolization rate was 7.5 times higher with a mechanical aeration mode. While specific to the bacteria and aeration systems studied, these results suggest that some aeration treatment schemes and processes produce less bioaerosols than others. When designing pharma plant wastewater treatment systems, designers should be mindful of selecting and sizing options that consider the vectors that are likely present and that minimize the creation of bioaerosols.
- **Aeration system modifications.** Some pharma manufacturers may choose to install a Quonset hut over an aeration basin to prevent bioaerosol release into the atmosphere. Instead, emissions can be vented through an industrial scrubber that safely removes microbes.

Pharma Manufacturers Can't Wait to Act

Of all the potential sources of bioaerosols, pharma plants pose unique risks — both to their own products and to public health. Manufacturers must be vigilant in managing bioaerosols to prevent the transmission of infectious disease and to preserve the safety and quality of their products. The application of appropriate control measures, along with ongoing monitoring and testing, is critical to maintaining a sterile and controlled production environment.

Because multiple factors affect bioaerosol content, and research data on individual bacteria and virus transmission is limited, the precise health impacts of bioaerosol exposure are still poorly understood. But that is changing. By taking proactive measures now to mitigate risks within their fences, pharma companies can take a leadership role in protecting human health and their industry's reputation.

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