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Responding to COVID-19 in Pharma Facility Design and Operation

Manufacturers are adapting with virtual work, remote monitoring, and re-evaluation of facility design to ensure worker safety.

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When the COVID-19 pandemic struck, pharmaceutical manufacturing continued as a highly essential industry, but companies were suddenly faced with the challenge of many employees working remotely and the need to ensure that operators working in-person have a healthy workplace.

“Operational teams had to become instantly virtual, which increases risks,” says Andreas Eschbach, CEO of Eschbach, which focuses on software for plant process management. He notes that operations teams need solutions to make informed decisions confidently and to reduce the stress of vastly changing work conditions and procedures. “Helping the workforce confidently collaborate and communicate electronically using digital tools is of utmost importance to maintain productivity and cohesiveness among manufacturing teams now working remotely or socially distanced,” says Eschbach. Digital monitoring of adverse events in production, quality, and safety, for example, can ensure that managers have up-to-date information for effective decision-making among remotely dispersed teams, he explains. As another example, the company’s interactive product suite provides digital shift handovers to improve communication among manufacturing team members, even with social distancing.

Evaluating facility changes

Pharma manufacturing companies have been evaluating what needs to be done to minimize the risk that workers in the facility are exposed to the novel coronavirus. Cleanrooms are already low risk with strict controls on air quality, cleaning, and control of the movement of people and materials, but non-classified areas and non-production areas might need new approaches.

“In addition to current thoughts on people, product, and material flows and how to adapt to the post COVID-19 era, we are also exploring new and novel approaches to protecting all areas of the facilities we design, beginning with how people initially enter the property and facility, including maintaining safe working distances, long-before they get near (or into) the production areas,” says Dave Watrous, vice-president, Advanced Technologies and Life Sciences at Fluor Corporation. Changes include adjusting designs of heating, ventilation, and air-conditioning (HVAC) systems and related air-cleaning technologies for non-production environments, as well as increasing cleaning and limiting human interactions. “There is a balance between automation, cost, and levels of effective protection in non-production areas,” notes Watrous.

HVAC systems serving classified spaces are considered very low risk because they use extensive filtration and are designed and validated to manage contamination, but HVAC systems serving non-classified and non-good manufacturing practice (GMP) areas are designed differently and should be evaluated, says Keith Beattie, director at life-science specialist Energy Efficiency Consultancy EECO2, which has put together a document about managing risk in pharmaceutical HVAC systems (1). The document points to building readiness guidance from the England-based Chartered Institution of Building Services Engineers (CIBSE) (2) and ASHRAE, the American Society of Heating, Refrigerating and Air-Conditioning Engineers (3). A risk assessment should “account for all direct and indirect consequences of modifying HVAC systems with respect to a hazard that is not fully understood at this time, rather than following blanket recommendations, which may not be suited to a specific system or space type,” the EECO2 document cautions (1). For example, increasing airflow may be beneficial for some areas, but doing so in an area that adjoins a GMP or pressurized space could disrupt the pressure balance. EECO2 has developed a risk assessment tool that can be used to assess HVAC system risk and recommend appropriate and practical mitigation actions.

Computational fluid dynamics (CFD) analysis is one way to visualize and evaluate airflow. CFD can be used to model the airflow inside a room or cleanroom to evaluate air movement and find solutions to any problems with the HVAC distribution, adds Curt Firestine, senior mechanical engineer at CRB. He notes that Grade C and higher cleanrooms typically have ceiling high-efficiency particulate air (HEPA) filters, low-wall returns, and high air-change rates. “But in lower classification cleanrooms (Grade-D or

ISO-9) and in unclassified support rooms, we often see ceiling supply and [ceiling] returns for HVAC systems. These areas operate at lower air-change rates, which are typically less than 15. This combination of ceiling supply and return air devices without low-wall returns does not sweep the room. … Airflow does not get down to the occupants," explains Firestine. Additional concerns include the number of people in the room and how closely together they are working, as well as what level of gowning they are using, Firestine noted in a *Pharmaceutical Technology* Editor's Series webcast [2] on facility design (4). Solutions might include increasing air-change rates, using low-wall returns or exhaust registers, improving HVAC system filtration, or increasing gowning and facemasks for workers.

While CFD can visualize airflow, other simulation tools can be used to visualize the movement of people and materials in an operation. "Process simulation techniques [can] determine how operations could be improved while distancing employees inside the room," says Firestine. Another problem might be that, with reduced numbers of operators, getting materials in and out may become an issue, Firestine noted in the webcast (4). "CRB has utilized simulation tools successfully to demonstrate manufacturing process improvements including personnel and material flow changes," he says.

Increased automation

There has been a long-term trend toward automation in pharmaceutical production, which may accelerate due to the pandemic, notes Watrous. He says there is a rising demand for automation in non-production areas, such as warehousing and building management systems, as well. "We are already designing several post COVID-19 facilities that have less non-production space, meaning it will include more automation but spread throughout a smaller footprint," says Watrous.

Remote monitoring tools that allow manufacturers to evaluate machine health without entering the cleanroom have been becoming more widely used in pharmaceutical manufacturing (5), and this trend has been accelerated by the travel restrictions caused by the pandemic.

"Our customers are telling us that machine health and remote collaboration matter more than ever to them, and they want to expand their deployment of digital solutions in these challenging times," said Saar Yoskovitz, CEO of Augury, in a May 2020 press release announcing its machine health monitoring tools could be installed by users in new facilities even when access is restricted, with remote guidance from Augury personnel (6).

Although automation and remote monitoring tools can reduce some of the human interactions with the process in the cleanroom or the lab, expertise will still be needed. "While automation looks like a good solution to workplace congestion, the infrastructure and support required to maintain automation is not insignificant," suggests Bikash Chatterjee, chief operations and science officer at Pharmatech Associates. "The lab may begin large deployments of automated solutions to run high volume assays, [for example]. However, anyone who has ever developed and implemented these systems knows they do require care to remain productive and effective."

"There is no doubt the workplace will look very different post-COVID-19," concludes Chatterjee. He predicts that remote work will continue, virtual collaboration solutions will be prevalent, the use of data management solutions will expand as the need to remotely evaluate data increases, and manufacturing automation will continue to increase.

References

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