



Quality air solutions ensure integrity of cleanrooms

Dhirendra Choudhary

As the name suggests, cleanrooms are workplaces with highly controlled contamination. It provides a conducive environment for extremely sensitive and intricate processes by ensuring low levels of airborne pollutants like dust, microbes, aerosol particles, bacteria, chemical vapors etc.

Cleanrooms are required across a wide range of industries from the electronic industry to aerospace, information technology, automotive but it finds major application in the pharmaceutical industry to abide by the stringent manufacturing conditions. The requirement of cleanrooms is increasing with the growing emphasis on zero tolerance of defects, quality checks, and control to meet the Food and Drug Administration (FDA) and Current Good Manufacturing Practice (cGMP) certification.

Considering that pharmaceutical sector is vulnerable to contamination as it forms an intricate part of the healthcare industry, it is crucial to ensure

the highest quality end products. Hence, the cleanrooms are designed and constructed in a manner that suffices a controlled environment with intensively regulated and monitored temperature, humidity, air motion, air pressure flow patterns, viable organisms, airborne particles etc. to render sterile and pure drugs along with germ-free atmosphere for medical and biological applications.

Therefore, quality air is essential for cleanrooms. But considering that the cleanrooms are large spaces, it becomes difficult to maintain the sterility of the area. Moisture is a constant source of trouble intervening with the various pharmaceutical processes. Uncontrolled humidity is the major cause of microbial growth and corrosion. It is responsible for condensation on work surfaces leading to schedule delays and inferior quality products. In addition to this, humidity often causes product spoilage resulting from contamination.

Delving deep into the issue, the various pharmaceutical

products are highly hygroscopic in nature and moisture-sensitive. Therefore, in the presence of high humidity in manufacturing facilities, fine powders tend to absorb moisture and disrupt the powder feed to the tableting press as a result of clogging. The powder inconsistency arising from moisture absorption is the major factor responsible for the crumbling and clogging of tablets.

Compounding the already existing problems, there are instances of heat damage and moisture intrusion resulting from difficulty in adjustments in bed temperature and spraying rates due to variations in humidity. Additionally, humidity in air duct work offers just the right moist environment fostering the growth of bacterial colonies, further expediting the process of contamination.

Therefore, effective humidity controlling mechanism should be in place to curb the moisture menace. Desiccant dehumidification technology is the most suitable solution for maintaining the dew points

consistently at very low levels, achieving -60°C. It keeps the cleanroom relative humidity between a narrow range of 35-40 per cent RH for all round-the-year operations. Humidity is very critical in cleanrooms. As stated above, on the one hand where too high humidity promotes bacterial growth, metal and equipment corrosion, condensation, and water absorption, on the other hand, low humidity results in static build-up and discharge issues. Furthermore, poorly controlled humidity leaves uncomfortable working conditions for the employees.

The desiccant-based dehumidification rightly provides the RH level that is constantly maintained within the close bandwidth of ±2 % RH at a temperature below 20°C (70°F). The technology is highly efficient at reducing air moisture beyond the level achieved by a standard HVAC-grade refrigeration system. The desiccant dehumidification works on the principle of passing the air through the desiccant medium which adsorbs moisture. It

comes with greater dehumidifying power, hence making use of a desiccant system along with air conditioning substantially reduces the load on the HVAC system. It is a great source of saving energy by adding to the efficiency of the HVAC system and also reduces its chances of wear and tear.

Along with humidity, air contamination is another reason for concern in the cleanroom environment. Unclean air can take a toll on the employee's health due to its hazardous nature full of harmful contaminants like hydrogen sulphide, sulphur dioxide, etc. that cause respiratory problems, headache, fatigue, and low productivity. The Gas Phase Filtration System is the most economical and effective process for the removal of corrosive gases.

Cumulatively, the desiccant dehumidification and gas-phase filtration together protect the integrity of the processes and products within the cleanroom environment in the pharmaceutical industry. ♦

(The author is CEO of Bry-Air)

Steps needed to improve industry

CONTINUED FROM p13
Strength & weakness

Growth prospects are high across the East Asian, South Asian & Middle East & African healthcare sectors, while technological advancements in the production of cleanroom equipment are anticipated to create significant opportuni-

ties for cleanroom equipment. Furthermore, maximum operational safety, ease in functioning, ease of disposing, cost-efficiency, and low maintenance are highly anticipated to propel the demand for cleanroom equipment across various end-use industries. Key restraining factors such as low

replacement rate of maximum cleanroom equipment, the complex installation process of cleanroom equipment, and reluctance in setting up a cleanroom facility in developing and undeveloped economies, may hinder growth over the forecast period, Shetty pointed out.

The use and maintenance

of cleanroom equipment is a complex process. Proper SOPs and standards need to be developed & regulated to stay abreast of the large technological growth in cleanroom equipment. Regulations need to provide requirements with respect to the environmental, product, or facility parameters which are

expected from the equipment. Training and protocols of installation need to be provided by the manufacturer to ensure no damage occurs to end users' facility, personnel, or product. Cost-effective replacement of parts should be developed to reduce the replacement rate of the equipment. ♦

Ventilation important for toxic gases to escape

CONTINUED FROM p17

You can also use an electronic diffuser for essential oils or automatic sprayer that sprays the concoction every few minutes into the air of your bathroom or living room. Soda lime is a good ingredient that absorbs gaseous CO2 present in air. You can keep some quantity of soda lime in a bowl in open if you do excessive cooking, heating or burning activity.

■ **Ambient air fresheners** – Incense sticks and aroma candles are widely used for spiritual practices like meditation or worshiping. Burning incense sticks in the balcony or open spaces in the unit will spread the aroma of essential oils in the ambient air that will diffuse in the surrounding air to create a positive and freshening effect. A poor quality incense

stick produce a lot of smoke on burning so it is important that you purchase a good quality incense stick or aroma candle.

■ **Air ventilation** – Ventilation is the most important factor that throws unclean indoor air in the surrounding environment and allows fresh air from the outside to come in. Exhaust fans, house ceiling fan, air suction and air flow units, doors and windows are all important components of air ventilation.

Ventilation becomes more important if you have air conditioning, heating or cooling system installed in your indoor units. The gases released from air conditioners can cause suffocation through built-up of air pressure especially when the air conditioner is turned off. It is a

good practice to allow enough ventilation before and after the use of air conditioners.

Laminar flow cabinets used in testing laboratories have air convection system fitted inside the cabinet to release heat and gases during operations. Ventilation is important for toxic gases and VOCs trapped in the indoor air to escape. Make sure that your indoor processing units have sufficient ventilation.

■ **Air purification** – There are different types of air purification systems employed for domestic, commercial and industrial use. Use of chimney on top of cooking station and fire-burner helps to prevent built-up of combustible gases and VOCs during cooking. High Efficiency Particulate Air Filtration (HEPA) purifiers

and catalytic converters can be installed in domestic, commercial and industrial settings to obtain clean and hygienic air.

Thermal oxidizers can be used at places where there is excessive use of solvents to prevent accumulation of VOCs in large quantities. Vacuum cleaner is another type of air purification system that absorbs all dust and suspended particles present on surfaces. Vacuum cleaner is efficient for cleaning and sanitization purpose that does not disperse particles in air during surface cleaning. UV lights have also proven to be effective in eliminating microbes and free radicals from surrounding air.

In addition to the common practices described for managing air pollution, practices to prevent built-up of air pollution should

also be adopted in the industries. It includes some of the following strategies such as proper cleaning and sanitization, recycling of waste materials, reduction in burning of materials, use of alternative green renewable technologies for energy production or transportation etc. Methods of personal safety to prevent oneself from hazards of air pollution includes wearing of N95 and surgical masks, regular washing and cleaning of body parts, sanitization of clothes and other household surfaces. By adopting these simple, cost-effective and affordable procedures we would definitely gain a positive experience and set a course of clean and hygienic life. ♦

(The author is MD & CEO of VMG Biotech Consultants)