HVAC/R • PROCESS COOLING • BUILDING AUTOMATION

TECHTALK

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Drug Compounding Outsourcing Facilities Subject to Stringent HVAC Standards

Drug compounding is the process of combining, mixing, or altering pharmaceutical ingredients to create a medication tailored to the needs of an individual patient. Compounding can be as basic as the addition of flavoring to a poor-tasting medication or as advanced as the large-scale production of sterile drugs prescribed by hospitals or other medical facilities.

There are many community and hospital pharmacies that offer basic compounding, and most are only loosely regulated by the FDA and (to varying degrees) from state to state. Registered **outsourcing facilities** that compound and distribute sterile drugs, on the other hand, are subject to stringent state board of pharmacy regulations, inspections, and FDA CGMP standards. These include strict requirements for maintaining specified temperature, humidity, and air quality controls for safe production and storage of sterile compounded medications.

The HVAC systems typically utilized in these compounding facilities are 100% outside air once-through systems that incorporate HEPA filtration and tight operating ranges for both temperature and humidity. Room pressure and negative airflow must be precisely controlled, as well. Environmental integrity is continually monitored and trend-logged to prove compliance and alert users when excursions or other abnormalities occur. Redundant supply and exhaust systems are often present in compounding pharmacies to provide emergency backup and system maintenance, and some employ redundant exhaust in a lead/lag scenario to ensure that negative pressurization is not interrupted should a fan go down. Backup generators and uninterruptible power supply (UPS) are considered vital.

Regular, facility-specific HVAC preventive maintenance is critical to maintaining optimal environmental conditions in compounding pharmacies. Without it, systems can drift from setpoints for temperature, humidity, air changes, airflow, and static pressure. Proper PM helps prevent the excursions, alarms, failing systems, and other problems that can potentially shut down the production of urgently-needed medications.

MSC has extensive experience in the preventive maintenance, service, diagnostics, and design/build of cleanroom HVAC systems in drug compounding facilities. We work closely with our clients to design

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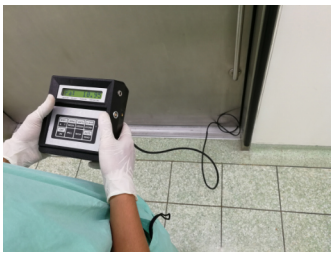
Outsourcing Facilities Subject to Strict HVAC Regulations and Standards



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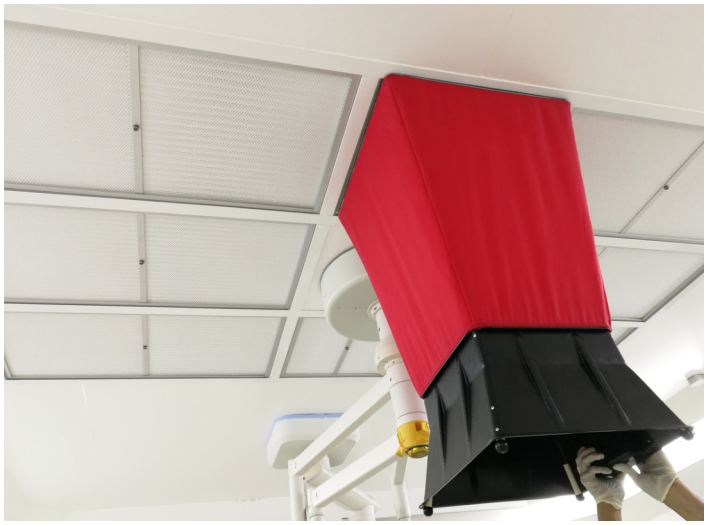
systems that accurately and effectively control their environment and to develop PM programs tailored to their specific needs. MSC can also assist compounding pharmacies in writing a comprehensive standard operating procedure (SOP) to ensure consistency, repeatability, and full regulatory and business standards compliance.

CASE STUDY: Hospital Service Call Becomes Retro-Commissioning Project

MSC service technicians were dispatched to a large New Jersey healthcare facility to address multiple complaints in an area that had undergone extensive renovation less than two years prior. Prolonged spans of excessive temperatures were occurring in some spaces while others were experiencing short, intermittent temperature fluctuations. Airflow and humidity sensors were drifting, and facilities maintenance staff found themselves unable to properly control the environmental conditions.

Our service technicians noted abnormally high temperatures when they arrived at the facility and immediately set about discerning the source of these and other problems. After ruling out numerous possible causes, we decided to install data loggers in strategic areas throughout the building to record conditions over a 3-day period.

At the end of the third day, we had our answers. In addition to confirming the temperature swings that had been reported, a comparison of the newly-logged data to original balancing reports revealed reductions in airflow in several areas ranging from 10% to 18.5%. Several errors were discovered in the dehumidification sequence, and we also found that the RH sensor had never been calibrated. HEPA air filters were overly loaded with particulates. Our suspicion that commissioning had only been partially completed prior to start-up was confirmed by the lack of certain commissioning documents.



We reported our findings to the client and prescribed a small retro-commissioning project. An air balance was performed, and all HEPA filters and final filters were replaced. Reheat valve functionality and performance were checked and adjusted where necessary. A number of problems found during a re-verification of the sequence of operation prompted several building automation programming changes. All temperature and humidity sensors were recalibrated and an existing RH sensor was replaced with a high-quality dew point sensor for better accuracy and control.

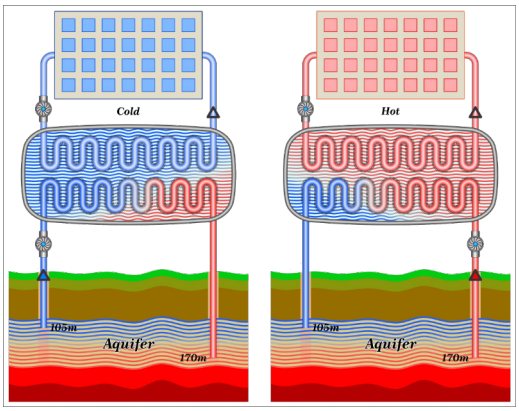
Finally, we assisted the client in tailoring a new, more-detailed SOP for preventive maintenance to be performed yearly, rather than every two years as had been original specified. MSC is now under contract to perform facility maintenance on an annual basis.

Retirement Announcement: Congratulations Mike Hartigan

MSC would like to extend our best wishes and heartfelt thanks to Mike Hartigan, who will retire this month after nearly 40 years of dedicated service. Mike is a treasured friend, colleague, and brother, and has been a true mainstay of our company's growth and continuing success.

Mike first joined MSC in 1984 after earning a bachelor's degree in communications from Boston College, where he attended on a football scholarship. He began his tenure here as a parts and service manager before moving to outside sales in 1989. In 2000, he took on an inside sales leadership role and has served in that capacity ever since. Looking back at his career, Mike says his most cherished experience was working side by side with his brother and MSC founder, Harry Hartigan, and his nephew and company vice president Tim Hartigan. Mike's everyday presence will be missed here at MSC, but we are delighted to wish him and his wife, Michele, a bright and happy future filled with all manner of leisurely pursuits. Congratulations, Mike!

Aquifer Thermal Energy Storage Shows Promise for Greener Future



For thousands of years, humans have relied on aquifers for their drinking water, irrigation, and countless other uses. The huge quantities of water contained in these underground storehouses tend to remain at a stable temperature, which prompted an interesting question: Could these aquifers be used to store energy for heating and cooling? The resulting technology is called **aquifer thermal energy storage,** or **ATES**, which essentially utilizes aquifers as naturally occurring underground batteries, and it's gaining traction here in the U.S.

The way ATES works is fairly simple. Cool water is pumped from the ground during summer months and building heat is transferred to the water via a heat exchanger to meet cooling demands. The now-heated water is then pumped back into the ground for storage until winter when the still-warm water is brought back up and used to provide building heating. This cooled water is returned to the ground and the process continues indefinitely.

There are currently about 3,500 ATES systems in operation, most of them in the Netherlands, but the technology is not yet widely used in the U.S. This may be about to change. A recent study published in *Applied Energy* suggests that, when paired with wind and solar energy, ATES systems can potentially reduce the amount of natural gas and electricity consumed for heating and cooling in the U.S. by as much as 40%, which is tremendous considering that HVAC accounts for about one-third of our energy consumption. ATES systems require little to no space compared to above-ground energy storage and are easily scalable for larger heating and cooling systems. As our summers become hotter and winters harsher due to climate change, ATES systems will only become more efficient by taking fuller advantage of these temperature extremes. And because ATES cooling systems use very little electricity beyond what's needed to pump water, our future grid will be more resistant to the power outages that have become increasingly common during heat waves.