Comparison and analysis of an existing HVAC system and modern systems in a pharmaceutical factory

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Aim of the Project

To investigate and compare the HVAC system in a pharmaceutical facility before and after a major upgrade. The goal was to identify system weaknesses, specify suitable replacements, and evaluate the impact of the new design on temperature control, efficiency, and regulatory compliance.

Background

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HVAC systems are essential in pharmaceutical facilities, where strict temperature, humidity, and air cleanliness levels must be maintained to meet ISO 14644 and GMP requirements. Even minor deviations can compromise product quality and regulatory compliance. In this case, the existing system could not maintain stable conditions within critical areas, leading to operational risks.

This project focuses on evaluating the HVAC upgrade carried out in a cleanroom environment within a large-scale pharmaceutical plant. The upgrade was driven by repeated temperature control failures in a production suite. Using engineering documentation, technical specifications, and time-series performance data, the project outlines how the new system was selected, designed, and implemented. It also assesses the effectiveness of the upgrade by comparing the pre- and post-installation system performance.

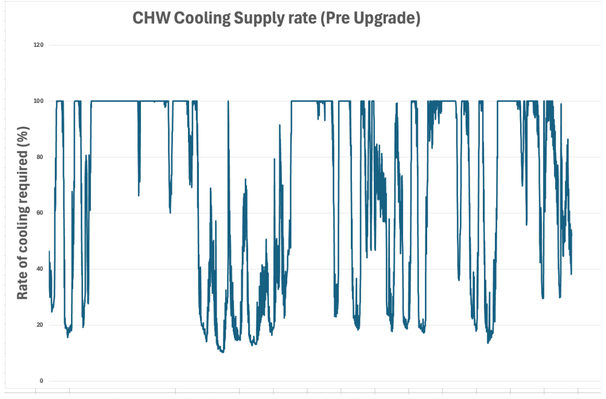

Figure 1 : Cooling requirement for Cleanroom (Pre Upgrade)

The study highlights how proper HVAC system design and commissioning can directly impact cleanroom stability, product integrity, and overall operational efficiency in pharmaceutical manufacturing.

Issues Pre-Upgrade

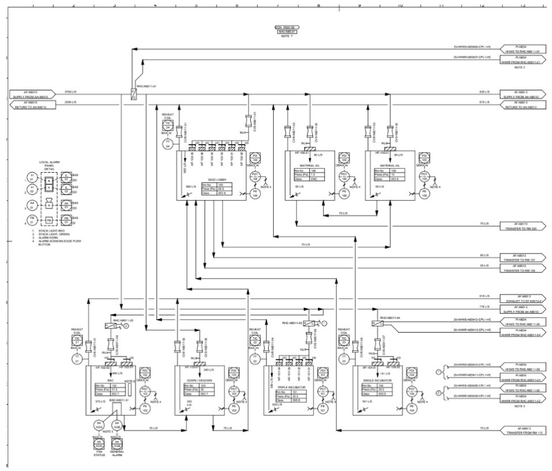

Figure 2: Drawing of layout (Pre Upgrade)

The facility's cleanroom HVAC system was unable to handle the increased heat load generated by upgraded equipment in the upstream manufacturing suites. Each cleanroom housed multiple Bahnson ES2000-C Incubators and Wave Bioreactors, which together produced a total heat gain of 6.27 kW — far exceeding the existing HVAC cooling capacity of 3.58 kW per room.

As a result, the system frequently failed to maintain target temperatures. One documented temperature excursion (Investigation EOE23-0112) involved an incubator exceeding its temperature range, compromising a critical shake flask culture. The root cause was identified as an environmental failure due to insufficient cooling — specifically, the HVAC system being offline, which prevented heat from being properly dissipated.

This highlighted the need for additional cooling capacity, better environmental control, and more robust system redundancy to prevent future failures in these critical process areas.

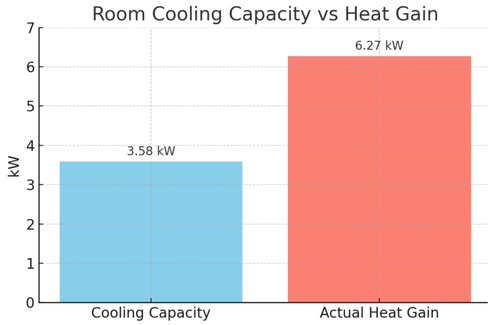

Figure 3: Cooling capacity v Heat Gain Chart

Upgrade Process

Identifying a Suitable HVAC System

To address the heat load issues, a new HVAC system was specified to deliver improved cooling capacity, reliability, and compliance with pharmaceutical standards. The selection process focused on:

- **Cooling Capacity**: Sized to meet peak internal heat gains from incubators and bioreactors.
- **Precision Control**: Enhanced temperature regulation using upgraded control loops and better sensor coverage.
- **Redundancy & Reliability**: Designed to avoid downtime and support continuous operation, even during maintenance.
- **Compliance**: Fully aligned with ISO 14644 and GMP requirements for cleanroom conditions.

Engineering documents, vendor specifications, and plant layout constraints were reviewed to identify a system that could be seamlessly integrated into the existing infrastructure while ensuring long-term performance and environmental stability.

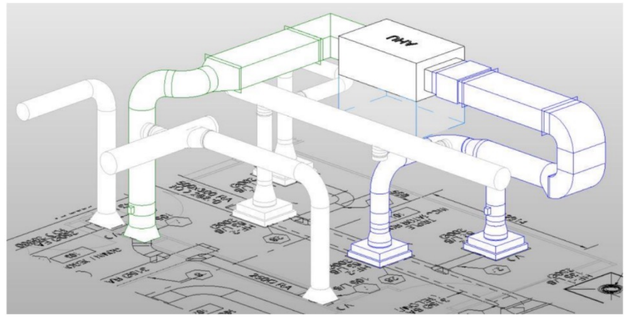

Figure 4 : Ducting Arrangement Post Upgrade

The HVAC upgrade involved replacing outdated components and integrating a redesigned system tailored to the room's load requirements and cleanroom standards. Key steps included:

- **Component Upgrades**: New AHUs, CHW coils, supply/return fans, and ductwork sized for peak thermal loads.
- **Control Systems**: Updated PLC-based controls and additional sensors for tighter temperature feedback and alarm capability.
- **Integration with Existing Infrastructure**: Designed to fit within physical and operational constraints of the facility.
- **Documentation & Validation**: Full design-stage calculations, control philosophy, and engineering drawings supported the installation and commissioning phases.

Installation was coordinated with minimal production disruption, and post-installation validation confirmed that the system met GMP and ISO cleanroom specifications.

Conclusion

Figure 3 : SystemAir Split-system outdoor unit & Air handling equipment

The HVAC system upgrade successfully resolved critical environmental control issues within the pharmaceutical cleanroom. By addressing equipment-driven heat gains and integrating a modern, compliant design, the new system now delivers stable temperature, improved airflow, and full regulatory alignment.

This project demonstrates the importance of engineering-led system evaluation and highlights how data-driven design and implementation can significantly improve performance in controlled environments.

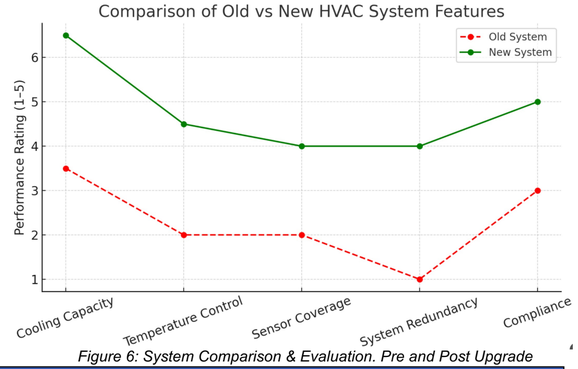

Figure 6: System Comparison & Evaluation. Pre and Post Upgrade

Acknowledgements & References

I'd like to thank my project supervisor Dr. Adrian Chaplin for his advice, guidance and help throughout.

References:

1. ISO 14644-1:2015 – *Cleanrooms and associated controlled environments – Classification of air cleanliness by particle concentration.*

2. EU Guidelines to Good Manufacturing Practice (GMP) – Annex 1: *Manufacture of Sterile Medicinal Products.*

⊡3. Systemair. (n.d.). *SYSPLIT Outdoor Unit Technical Catalogue.* Retrieved from: www.systemair.com