

HVAC Efficiency within a controlled cGMP Environment

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In the summer of 2007, a strategic decision was made, by our client to decommission their existing cGMP Cell Banking facility and replace it with a new cGMP Cell Banking facility. As a note, cGMP facilities are expensive to design, build and historically expensive to operate. A key design element of the new facility was to improve on the existing inefficient and unreliable HVAC system, while creating a more environmentally stable and robust facility containing mechanical redundancy. In this effort, the existing design parameter of a 100% outside air unit was replaced with several, smaller and redundant fan coil units all served by a dedicated outdoor air system. In addition, HVAC redundancy, air segregation for multiple products, and greater temperature and humidity controls were all key design parameters for this project.

The new facility encompasses four (4) Class 10,000 (ISO 7) process rooms, with a Class 10,000 (ISO 7) “clean” corridor on the entrance side of the process rooms, and a Class 10,000 (ISO 7) “dirty” corridor on the egress side of the process rooms. Access into the clean and dirty corridors is via a Class 100,000 (ISO 8) gown-in and gown-out room, respectively. The above rooms make up the classified cGMP spaces of the project and were constructed with modular wall/ceiling technology.

Outdoor air is provided via a dedicated outdoor air handling pre-treatment unit. This outdoor air unit is sized to pressurize the Cell Banking suites. This amount of outdoor air is also sufficient to ventilate the spaces. This feature is a key differentiator between the old and new facilities. A dedicated outdoor air system (DOAS) system provides reliable room environmental control with the added benefit of reduced energy costs. Each individual room, as well as the corridors and gowning rooms, are served via independent fan-coil units. These units recirculate air, which significantly increases energy efficiency, while maintaining room air segregation, as well as enhance the control aspects of temperature and humidity. These attributes are particularly critical in a multiple product GMP environment and are also important while trying to maintain 65°F room air within humidity specifications.

The old and new facilities both encompassed approximately 2,000 square feet of actual GMP production space. Calculations were performed for air moving, cooling, and reheat costs across both facilities. These factors cost \$117,228 in the old facility versus \$40,034 in the new facility, which equates to an annual savings of \$77,194.

These figures are based on the following calculations:

- Old Facility
 - 10,665 CFM central AHU– 7 in SP (as balanced)
 - 82 Tons of cooling
 - 45 GPM of 20F reheat
 - Total

- New Facility
 - 6,000 CFM Pre-Treat – 1.3 in TSP (as balanced)
 - 11,165 CFM Indiv. AHU's – 2.0 in TSP (as balanced)
 - 44 Tons of cooling (53% of Old Facility Capacity)
 - Individual Suite Cooling Controls to 65F ONLY WHEN NEEDED
 - 0 GPM reheat (as recorded for 1 full year)

Based on the facility operating 24/7, the projected energy costs are as follows:

- Original Facility Costs
 - Air Moving \$ 19,915
 - Cooling \$ 59,687
 - Reheat \$ 37,626
 - TOTAL \$117,228

- New Facility Costs
 - Air Moving \$ 8,030
 - Cooling \$ 32,004
 - Reheat \$ 0
 - TOTAL \$ 40,034

The key items are obvious. The lack of required reheat because of the use of a DOAS system is an enormous energy saving item. This is not just calculated or projected; it is also proven via design and trending information. The design of the fan coil units does not include reheat coils; the heating coils are in a pre-heat position. Also, the trending data indicates that those heating valves are always closed.

The air moving costs are much less because of the actual balanced static pressures associated with the fans. Because of the longer duct runs from the large air handler, the old facility unit was operating at 7 inches of static pressure. The new facility has close coupled rooms and fan coil units which operate at 2 inches of static pressure. Finally, cooling is obviously operating at a lower cost since the outdoor air quantity is reduced by almost 50%.

These costs may appear astronomical for such a small production facility, but we hope that they provide a dramatic example of the inefficiencies experienced in many highly specialized laboratory and GMP production environments. Often times, the “easy” answer of 100% outside air is utilized in these facilities, when there are alternatives to this paradigm. We encourage others to challenge what is done elsewhere and look beyond the easy answer to more efficient alternatives. We would like to think that this small example offers up an excellent opportunity for far greater savings in many other GMP, or other controlled environments.