



LABS FOR THE 21ST CENTURY

Healthcare/Pharmaceutical Industry Roundtable

Issue Paper

Background

As part of the Laboratories for the 21st Century (Labs21) conference, a Healthcare/Pharmaceutical Laboratory Roundtable was held on **January 9, 2002**. The purpose of the Roundtable was to bring together a diverse group of laboratory professionals (owners, operators, managers, designers) from the pharmaceutical industry for a focused discussion on the issues and challenges faced in improving laboratory energy and environmental performance. This document summarizes the discussion at the session, as well as potential next steps for the Roundtable participants.

Issue #1. Lead: Jim Ricigliano, PWI Energy

How to encourage scientific staff to recognize there are limitations with existing laboratory space and building services and to meaningfully participate with facility managers to:

- Manage and operate research equipment properly
- Consider energy and water consumption in purchasing decisions
- Reduce the amount and toxicity of chemicals used in the laboratory
- Increase the number of laboratory operating shifts per week as an alternative to building additional laboratory space

Manage and operate research equipment properly:

A system should be developed to encourage researchers to practice elementary energy conservation. In its simplest form, this might mean not turning on equipment until researchers are required and then shutting equipment off when the tasks have been completed. On the contrary, laboratories are full of electrically-operated devices that are kept on in case they are needed (e.g., constant temperature baths).

Next, a system should be developed to encourage researchers to operate their equipment efficiently. Some examples might be keeping the sash closed on fume hoods, keeping refrigerators full, and grouping tests to take advantage of devices that are capable of processing multiple samples.

Laboratory managers, safety personnel, as well as security and housekeeping personnel, are part of the forces mustered to encourage scientific staff to follow established company guidelines for the operation of laboratory equipment. Leaving the fume hood sash open, lights on, and water

running to drain are just a few of the bad habits that scientific personnel are continually reminded to avoid.

In the orientation of scientific staff, safety personnel include a portion on recommended hood operation along with laboratory safety. Additionally, safety personnel conduct monthly and/or at a minimum quarterly safety meetings with scientific staff reminding them of laboratory operational procedures. Housekeeping and security personnel do everything from report offenders to department heads, to leave reminder notes for offenders when a violation of recommended operations is observed. Laboratory managers also hang colorful posters promoting laboratory compliance with cGLP. Further, laboratory managers need to be held accountable for the implementation of energy conservation and energy efficiency programs. With all this effort there is still an opportunity to save huge amounts of energy by the scientific staff through compliance with established laboratory procedures. One method to encourage scientific staff to improve in this area is simply to reward compliance with a bonus – share the savings with the scientific staff.

Consider energy and water consumption in purchasing decisions:

After all safety issues have been satisfied plus aesthetic and budget issues are resolved, researchers must consider energy and associated consumption issues in a very deliberate manner. Standards should be set for acceptable energy efficiency criteria for laboratory equipment. Best practices should be set for the acceptable use of water. Again, laboratory managers must be held accountable for the purchasing practices of researchers. Facility engineers must make the scientific staff aware of energy and associated consumption issues and they will become a more important part of purchasing decisions.

Reduce the amount and toxicity of chemicals used in the laboratory:

Before a procedure is finalized for implementation in the laboratory the researcher should examine all phases of the procedure with the intent to reduce the amount and toxicity of chemicals used. Standards should be set for researchers' selections of chemicals. For example, in a development lab, a standard can be set that mandates that methylene chloride will not be used for solvent extractions, or methyl bromide will not be used. Once the researcher is focused on the reduction it will be accomplished.

Increasing the number of laboratory operating shifts per week as an alternative to building additional laboratory space:

As an alternative to expanding laboratory facilities, consider the use of multiple operating shifts for laboratories. Laboratories can be viewed as any production facility and their use should not just be limited to one shift per day.

General Discussion:

- Participants discouraged the use of bonuses as a way to encourage lab researches to practice energy conservation. They felt that researchers have strong preferences about how equipment is used in the laboratory and would not be swayed by bonuses. Participants also felt it would not be effective to link a laboratory's energy budget to the department's broader operating budget for similar reasons.
- Participants suggested making energy reduction a part of a facility manager's daily interactions with laboratory staff about safety and other issues. This helps raise awareness

about energy issues and sends a signal to researchers that environmental protection in the lab is important.

- Bristol-Myers Squibb suggested using alarm systems on fume hoods to alert facility staff to problems and better control air flow through fume hoods.
- One participant suggested improving education of undergraduate and graduate students to emphasize the importance of energy efficiency in the lab. Also, training programs can improve employee awareness of energy-related issues.
- One participant noted that organizations are constantly competing for high-quality researchers. Thus, they are reluctant to impose any policies or procedures that will inhibit their recruitment efforts. The trend, instead, is toward increased automation of equipment, which reduces the burden on scientific staff to control energy consumption.
- Numerous participants cited energy awareness campaigns as an effective strategy.
- Participants discouraged the idea of increasing laboratory shifts to offset building new lab space. They felt this could succeed with research teams that are already collaborating, but would not work otherwise because researchers are reluctant to share bench space. Staff at EPA's lab in Research Triangle Park, North Carolina, however, have successfully shared research space, including a vivarium, because of the expense of building and maintaining these facilities.

Issue #2. Lead: Harry Yekel, Wyeth-Ayerst Pharmaceuticals

How to design attractive, sustainable, efficient laboratories that:

- Accommodate changes in space and equipment needs due to evolving research demands throughout the life of the laboratory
- Eliminate the potential for cross contamination and other hazards resulting from non-conventional lab design
- Maintain effective air dilution or exhaust

This is a significant challenge in even a conventional laboratory design, primarily because the effectiveness of fume hoods can be jeopardized if hoods, equipment, benches, and/or passageways are reconfigured. It may be too optimistic to expect that the function of a laboratory can change easily (for instance, changing an analytic QA/QC lab to a discovery lab), or that a laboratory can be easily expanded, with only a thoughtful initial design. It is quite reasonable, however, to expect a laboratory to be adaptable and adjustable within its function and space.

To maximize the adaptability and adjustability of a laboratory while accommodating safety and cross contamination concerns, the following concepts and features should be considered in the design:

- Central, shared support activity spaces
- Air flow isolation of “dirty” operations, and precious or delicate operations
- Modular design of laboratory spaces and fume hood systems
- Use of “gray” areas for utility services and fixed equipment
- Use of mini-environments

General Discussion:

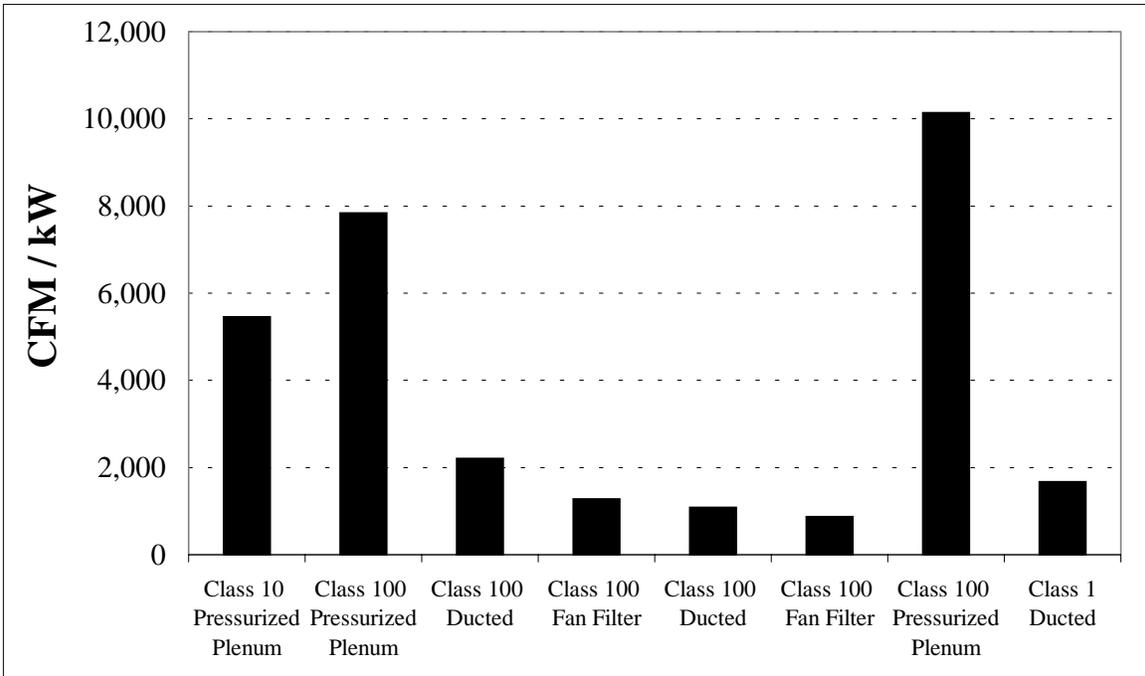
- To accommodate design changes in a lab, a National Institute of Health representative suggested designing labs with three discrete types of space: 1) fixed areas where there is no adaptability, 2) intermediate areas with some adaptive space, and 3) flexible areas that are totally open to change. This allows some flexibility in the laboratory and clearly defines for users the level of adaptability possible.
- Other participants noted that design for flexibility does not mean a lot of “bells and whistles”; instead, it can refer to a laboratory where each lab module is designed the same. This allows for some customization, but not for lab space to be totally redesigned. Researchers may not get all of their wishes, but labs can be customized much more quickly. Instead of it taking 6 to 18 months for lab space to be reconfigured, it can take 1 month or less and a fraction of the cost.
- Participants agreed this is an issue worth further discussion at next year’s Labs21 conference.

Issue #3. Lead: Bill Tschudi, Lawrence Berkeley National Laboratory

How to improve efficiency in recirculation air systems in pharmaceutical cleanrooms. System design considerations may need to overcome institutional barriers in order to reduce airflow. An independently developed scientific basis is needed to convince regulators that lower airflow rates are scientifically justified.

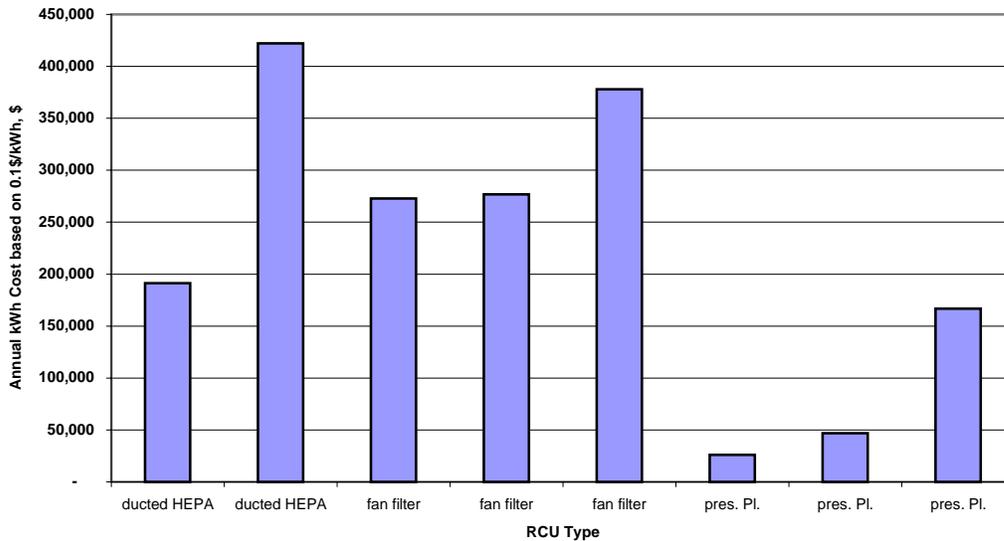
Cleanroom Air Recirculation – An Opportunity

Air recirculation in cleanrooms is a major contributor to their high energy intensity. Cleanroom energy benchmarking performed by Lawrence Berkeley National Laboratory confirms that there is a wide variation in performance of recirculation systems. The huge variation in efficiency can be seen in the following figure:



Operating costs for recirculation air systems are large:

**Annual energy costs of RCU fans per cleanroom
(Class 5; 20,000 ft²)**



The configuration of the recirculation system has a large effect on its performance. In general, low pressure drop systems perform best. There are several configurations commonly used in cleanrooms. Owners and designers need to understand the relative energy performance of the

selected design and weigh this with other issues such as ease of maintenance, ease of modification, etc.

Once a configuration is selected there is still a wide range of performance influenced by system pressure drop (sizing), component selection, filter efficiency, etc. Benchmarking will identify performance ranges and best practices.

Once the recirculation scheme is established and optimized, another issue needs to be considered. Air change rates can have a very large impact on recirculation system energy use. Decades ago, recommended air change rate ranges were established by the IEST (Institute of Environmental Sciences and Technology) based upon rules of thumb. Benchmarking has confirmed that there is a wide range of design and operational practice when it comes to air change rates and related filter velocity (the velocity of air as it exits a HEPA filter).

Acceptable cleanroom performance can be achieved at lower air velocities as cleanroom operators learn by trial and error. Since fan energy varies approximately as the cube of the air velocity there is an enormous opportunity for energy saving by simply designing and operating at lower air velocities. In the pharmaceutical industry, a defacto standard has evolved corresponding to the high end of the IEST recommended ranges for air velocity (90 ft/min). Since the industry is subject to a long history of cGMP (current Good Manufacturing Practices), and since the FDA regulates the industry based upon past “best practices”, there is little desire to investigate the acceptability of lower air change rates. The FDA theoretically would accept lower air change rates but the burden would be on the industry to prove that the change is technically sound. Experimental work in other industries has confirmed that cleanrooms operate effectively at lower air change rates. For example, Sematech has confirmed that product yields are not adversely affected by lowering air velocity and many companies have lowered airflows accordingly. For the pharmaceutical industry, a scientific basis is needed to provide technical justification for lowering air velocity in cleanrooms.

Other related energy opportunities exist in laboratories and cleanrooms. For example, cleanroom laboratories with 100 percent outside air would benefit from a reduction in airflow through the HEPA filters and additional opportunities exist for reducing airflow or recirculating air during unoccupied times.

General Discussion:

- Bill Tschudi explained that LBNL’s research is part of a larger project to develop a roadmap for the California Energy Commission. The research takes into account the large variations in energy efficiency in cleanrooms and is ultimately intended to help reduce energy use by allowing lower air flow rates through these facilities.
- Participants noted that the research team should carefully consider all of the risks involved in lowering air flow rates in cleanrooms. Participants also noted that by over-estimating air flow needs, laboratories have an added “safety factor” in place to account for any unforeseen air circulation needs.

Issue #4. Lead: Nancy Carlisle, National Renewable Energy Laboratory

Justifying the cost of an energy efficiency project.

Traditionally, efforts to save energy and water in laboratories are avoided because they can increase initial costs. One approach to address this issue is to adopt energy and water efficiency

upgrades that more closely match the expected useful life of the facility. A related approach is “bundling” upgrades so that projects with a short payback period can be used to offset the costs of projects with longer payback periods.

General Discussion

- One effective strategy is linking energy efficiency to complementary goals within an organization. These include linking energy improvements to an organization’s efforts to create a positive image or strong community relationships. It also includes justifying the safety benefits of energy efficiency measures and making a connection to the outdoors with green amenities such as daylighting. Many of these attributes can assist in recruiting or retaining high-caliber scientists and researchers.
- Lifecycle costing is another important strategy, allowing an organization to accept a higher initial cost for an energy efficiency project because costs are amortized over a longer time period.
- Bundling projects with different payback periods together can allow an organization to demonstrate new technologies and gain experience with new equipment and procedures.
- Several pharmaceutical companies noted they typically operate with payback periods of three years or less. This makes it difficult to justify large energy upgrades. It compares with government payback periods that can be 10 years or more, providing a much more favorable climate for investments in energy efficiency.
- Another participant stated that maintenance staff typically do not pay the utility bills, so they have no incentive to be efficient and reduce energy use.

Other Issues for Discussion:

Participants also identified the following issues for future discussion, perhaps at future Labs21 conferences.

- Need for case studies that demonstrate cost and energy efficiencies given any laboratory configuration.
- Need to define meaningful security (both physical and information) for a laboratory and determine how to offer it effectively.
- Explore the health and safety issues associated with energy recovery technologies, including heat recovery wheels. Involve a broad spectrum of participants including equipment manufacturers, facility engineers, scientists, and health and safety personnel.
- How to maximize opportunities for energy efficiency, water conservation, and increased environmental performance when designing new or retrofitting existing pre-production testing facilities or pilot plants.
- How to promote information sharing on new technologies and best practices.

- Need for a LEEDTM rating system for pharmaceutical laboratories.