Expansion Is the Backbone of Success

Limiting dry room downtime as your company grows

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Fast growing biotech companies that manufacture and market products will soon realize that expansion is the only way to meet the increasing demand on manufacturing capacity. In one such company with revenue growth exceeding 50 percent a year, working in a construction zone was part of the daily routine. New facilities and equipment were frequently in the process of being built and delivered. When the final products are diagnostic test kits that can only be manufactured in a climate-controlled environment between 5 percent to 20 percent relative humidity, capacity planning is no easy task. In some companies, production is shut down when the room environment exceeds 12 percent relative humidity. This makes the facility design combined with the performance and reliability of the HVAC systems essential to enable consistent production, 365 days a year. The issues are how to plan for, design and build new manufacturing facilities quickly enough to keep up with the increasing sales of popular products. This article addresses these issues and provides some of the best practices for the design of dry room facilities.

How to Operate at 100% Capacity

A Fast Growing Industry: Hospitals and laboratories comprise the primary market for diagnostic tests, but doctors' offices and individuals represent new growing market segments. In the year 2000, U.S. firms shipped more than $10.5 billion worth of test kits[1]. In 2002, the global market was $17.9 billion and was expected to grow 4.5 percent annually between 2003 and 2008. Diagnostics is a global business today, dominated by some of the largest pharmaceutical companies, such as Roche Diagnostics, Abbott Laboratories, Johnson & Johnson, Bayer Diagnostics, and Dade Behring. The increasing market demand is forcing biotech and pharmaceutical companies of all sizes to maximize their manufacturing capacities, and to expand or build new plants in order to generate a competitive advantage.

Capacity planning: In the design stage of a new or expanding manufacturing facility, the desired output or capacity per day is determined by demand forecasting and projections over several years by the manufacturer. The accuracy of demand forecasting combined with capacity planning and operations, all linked via an ERP system[2], are key factors when determining future capacity requirements. Many smaller companies do not have ERP systems and simply make decisions based on experience and expected demand.

There is typically a combination of automation equipment and manual labor in the manufacturing process of diagnostic test kits. Mapping the value-added steps and identifying bottlenecks in existing operations can help apply just-in-time and lean manufacturing[3] concepts applied already at the design stage of the new facility. The layout of production lines or cells should be designed to meet or exceed the desired target capacity. If multiple products are to be manufactured in the same facility, flexibility has to be integrated in the design to minimize set-up times. The design capacity is the same as the "best operating level," where the average unit cost is minimized.

Is It Time For a New Facility?

If the demand of a bestseller product exceeds the forecast, the operations manager will be pressured to produce more. At some point, the capacity utilization rate[4], defined as: Capacity used divided by best operating level, will approach 100 percent. As an example, a manufacturing plant already has three shifts, but wants to produce more products the next quarter...even when the capacity utilization is at 100 percent. One option is to review each process again and find out if any further waste can be eliminated to increase the throughput and available capacity. However, if this is a process that already has been

tested and it is known that the facility cannot produce one more diagnostic test kit per day, someone should try to convince management to invest in a new facility.

In the meantime, there may be a contract manufacturer available to make your product, but if you have not outsourced manufacturing before it may be a while before their quality meets your expectations. Since you have to have a specialized dry room facility to make the diagnostic test kits, it's not likely that there is extra capacity available in your region. Outside of the U.S. there are a few companies utilizing less expensive labor that can possibly meet your criteria at lower cost per unit, but then manufacturing is even further away from your control plus you may be subject to trade agreements, currency fluctuations, and to increased shipping costs.

Dry Room Lead Time

From design to occupancy of a new dry room within an existing building, the typical lead-time in California, for example, is three to six months. Half the time would be spent in the design phase and seeking permits from the city, while the other half would be spent in construction. When the pressure is on to accelerate production, the lead time can be reduced to about three months, if the new design is similar to the old design and the longer lead-time items are ordered early.

If your company forecasts continued steady growth and you have the option to expand your existing dry room operations, this is best to do in a modular step-by-step approach. Over time you would standardize a reliable dry room concept and incrementally add capacity as needed. Because of the three to six month project lead-time for a new facility, capacity planning has to inform management at least six to eight months ahead of the forecasted need to add capacity. The incremental approach is a cost effective way to expand capacity, but precise timing and planning are critical.

When to Start Planning

When you anticipate that your existing facility will become completely built out from converting existing warehouse space or through expansion of existing rooms, you need to start planning for a new larger production facility. If it makes sense, you may consider moving the entire operation to a new location. This is a major undertaking and should preferably start years before you approach the absolute ceiling of capacity, the 100 percent capacity utilization. If your biotech company has a significant research and development department with several products in the pipeline, the release or approval by the Food & Drug Administration (FDA) of each new product tends to accelerate the need for increased production capacity. The timing of these events should be considered when planning for the future needs of your production facilities. When a decision is made to build a new manufacturing plant, it has to meet the overall company strategy, budget and return on investment.

How Is Inventory Affected?

When your new larger facility is under construction, you start planning for "the move." The goal is to accomplish this with minimum downtime. If you are moving any of the existing process equipment into the new facility, you have to plan for some production downtime until the line is moved, reinstalled, tested and ready to produce. One way to avoid lost sales during this period is to increase inventory levels ahead of time. Your chances are limited, since demand has to slow down enough for you to have any extra capacity. Your holding costs would increase, but at least you would keep shipping products to your distributors and keep customers satisfied.

Quality Manufacturing Needs Quality Environment

The dry room environment is necessary to manufacture quality diagnostics products. Because air conditioning systems have only limited dehumidification capacity, adsorption dehumidifiers that attract moisture through a desiccant agent create the dry environment. The following describes the engineering effort that goes into making sure that a new manufacturing facility will meet the owner's requirements for specification and budget.

The Process Flow of an Expansion Project

Every time a facility is expanded in California and many other states, you need to apply for building permits from the local city. Since detailed plans have to be provided for architectural, mechanical, structural, and electrical designs, you need to have professional consulting teams in place. An architect and consulting engineers would draw up the plans necessary to obtain permits and develop the construction plans. For dry rooms, the sizing of the mechanical HVAC system is one of the most critical tasks. A close working relationship between the team members, consisting of, for example, a consulting engineer, facilities manager and manufacturer's representative, is essential when plans have to be developed and submitted quickly. When the team has moved along the learning curve a few times a modular design takes form. If a facility design team is asked to consider lean manufacturing principles in the facility layout to maximize throughput and capacity, this would qualify as a lean design with potential for significant, long-term cost savings.

The urgency to keep up with the demand for more capacity means that you may need to order any critical equipment, such as desiccant dehumidifiers, while the plans are still a work-in-progress. An experienced construction

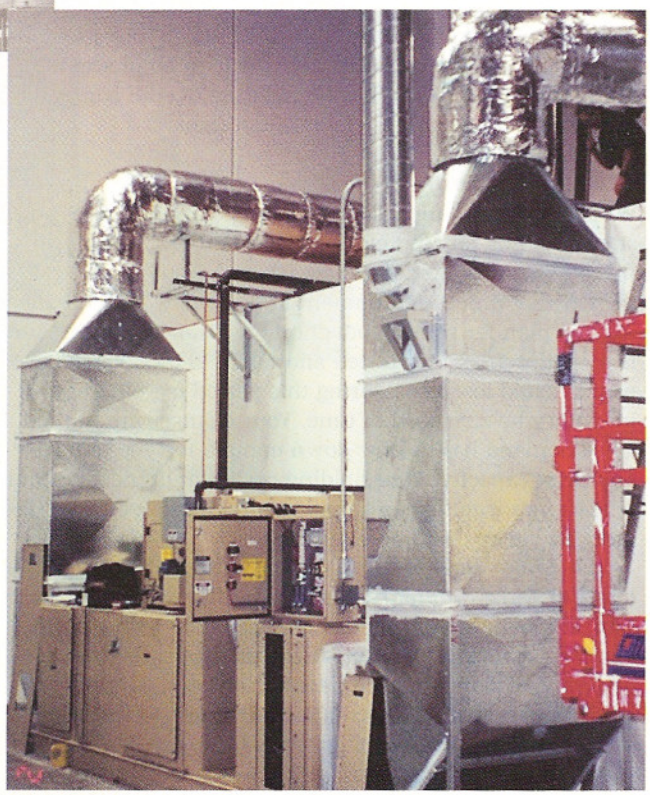

Figure 1. Process flow of an expansion project.

contractor will be selected and commit to a construction lead-time for the overall project. This expansion process is described by the flow diagram in Figure 1. It has been a successful roadmap in many biotech projects during the past decade. When construction is completed there will be start-up of systems, testing, quality control checks on the finished product, and training of new personnel. As soon as validation is completed, it's time to start manufacturing.

Validation Interacts Throughout Construction Phase

Validation is required for every new, relocated, modified system or facility used in any of the multiple manufacturing steps toward the finished product. Biotech manufacturing facilities are subject to inspection by the FDA. The agency sets standards for safety and quality in manufacturing for products sold in the United States. Obtaining necessary documentation from contractors will usually take the duration of the construction project and your validation engineer is well advised to start the process at the beginning of the construction phase. Occasionally, a validation engineer provides valuable input to the design team on documentation or testing requirements. When construction is completed, testing of the facility will take a few days, reports are generated and approved and then the task of validation is completed.

Best Practices in Dry Room Design

Will it be a manual or automated operation? Your choice affects capacity and system design. The engineering of the HVAC system begins with establishing the design parameters and the total moisture and heat loads for your new dry room. The main moisture load is determined by the number of people required for manufacturing. Since each person adds moisture from breathing and perspiring, the engineer needs to know the maximum number of people for the process as a basis of design. If your process or assembly operations were automated there would be just a few operators and a rather small moisture load, but a greater heat load from the added equipment instead. If you plan to use manual labor for an assembly or packaging process, the number of people would increase significantly, affecting the overall system design. This is often the case in manufacturing of diagnostic test kits.

If your company has had the opportunity to apply lean manufacturing and remove any non-value added steps, you have probably already achieved a most efficient process with a maximized throughput. For many companies that have not made this effort yet, the design input is based on the wrong number of people, leading to a redesign when process improvements are finally completed. The quantity of outside air required for ventilation increases with every person. For example, if you plan to have 26 people working within the room, 375 standard cubic feet per minute (SCFM) of outside air is typically used as a load factor (15 SCFM per person). This is one of the largest sources of moisture and it's most efficient to remove it in a dehumidifier, outside of the dry room. A slight positive pressure in the critical dry room also helps to keep moisture from finding its way in, an essential step in trying to maintain a low humidity level and to keep particles out of the room.

Most diagnostics manufacturers maintain a room dry bulb temperature between 68°F and 72°F and a relative humidity between 5 percent and 20 percent. In the design phase, the estimated number of door openings in and out of the dry room is taken into account, as each one will bring in moisture from an adjacent space.

Sizing of the HVAC Systems

As best described by chapter five in "The Dehumidification Handbook"[5], all moisture loads are summarized into a total internal moisture load for the dry room and a separate outside air load. If, for example, the internal moisture load is estimated to be 15 lbs/hr for a room that should maintain a humidity ratio of 10 gr/lb (grains per pound of dry air) and the desiccant dehumidifier is capable of supplying dry air at 4 gr/lb to the room, an air volume[6] of 3890 SCFM would be required to remove the internal moisture

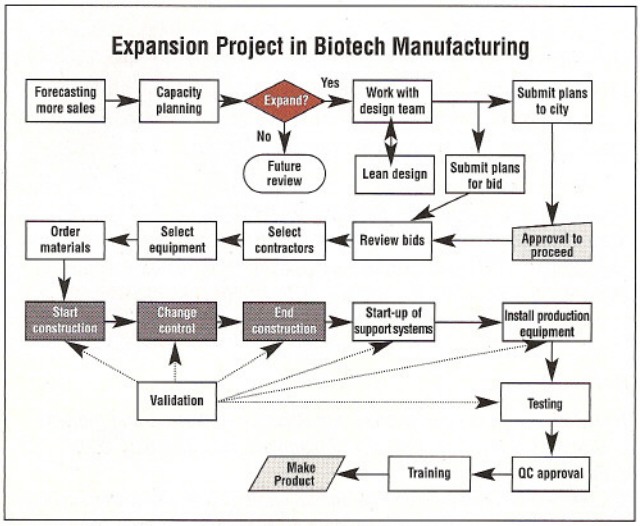

Figure 2. Flow diagram of a typical 4000 SCFM dehumidification system design for a dry room.

load from the space. Thus, the next size dehumidifier would be selected for supplying at least this air volume to the dry room.

The performance of a typical design for a desiccant dehumidification system used in a dry room application is described by the flow diagram in Figure 2. The desiccant wheel would be impregnated with silica gel that attracts moisture from the air by adsorption. A separate reactivation air stream is heated up by a gas burner and removes all of the moisture from the wheel and discharges it to the outside in vapor form. Face and bypass dampers are built in to achieve precise humidity control.

If any of the assumptions about the moisture loads change, the sizing of the dehumidifier has to be verified. A picture of an installed 4500 SCFM size dehumidification system for a dry room is shown in Figure 3. The system consists of filters, a gas fired desiccant wheel dehumidifier with a post-cooling coil to control both the humidity and temperature in the dry room, and a supply fan. The ASHRAE .4% peak outside humidity design condition can be 10-15 times higher than the desired dry room humidity level in the United States. Therefore, the outside air quantity should be minimized and door openings should be controlled. The design engineer also has to check the room heat load for guidance in finalizing the overall system air volume, since there is often just one supply fan in the system. In general, for dry room applications the air volume required to maintain the low humidity level will be more than sufficient to remove the internal heat load, when the supply air is cooled down to the conventional 55°F. There is an additional heat load generated by the desiccant dehumidifier that has to be taken into account when sizing the cooling system. Some biotech

Figure 3. Example of a dehumidification system installed for a diagnostics dry room.

companies require their dry rooms to be clean rooms as well; thus, the number of air changes and filtration level has to be part of the overall design. An experienced engineer, representing the dehumidifier manufacturer, in consultation with your mechanical consulting engineer and the owner, best performs optimizing the design and system selection.

Prevent Moisture Infiltration By Design

A dry room that is built to maintain a humidity level of 10 gr/lb or less has to be vapor tight. A standard drywall construction allows too much permeation of moisture, so the builder has to include a vapor barrier within the walls and ceiling. This may be polyethylene sheets that overlap or aluminum foil. The dry room ceiling cannot consist of a false ceiling unless there is a hard ceiling and walls above to create an enclosed plenum, much like a clean room design. The hard ceiling without any false ceiling is preferred, since the volume would be reduced, and there would be higher air changes within the room and less risk of leakage. The vapor barriers are in addition to any insulation necessary to minimize the heat load from the adjacent spaces.

If your production process allows for higher humidity levels, say between 20-40 gr/lb, another approach is to apply a vapor retardant paint on all interior surfaces. This will reduce the cost of construction, but will not be as tight and not last as long as a permanent vapor barrier. If the floor is a concrete slab you should apply two layers of epoxy coating to seal the floor to prevent moisture migration from the ground. The designers and installers should make an effort to minimize the number of penetrations for ductwork, sprinkler piping, process piping and electrical conduit through the vapor barriers in the walls and ceiling. Every penetration has to be well sealed or moisture will infiltrate, increasing the equipment and energy loads.

An Air Lock May Be Installed

If your dry room will have more than about 10 door openings per hour, it is a best practice to install an airlock to serve as a buffer between the adjacent environment and the dry room. There would be a door at each end of the airlock and one door would close before the next one can open, reducing the moisture infiltration to the dry room by about half. People and material may pass through the same airlock or there could be a larger one for moving pallets or carts of material in and out of the room. The size of the airlock should be as small as possible as the moisture present in the airlock will enter the room every time the door to the dry room is opened.

The product flow rate of raw materials and finished goods in and out of the room is valuable information when estimating the maximum number of door openings per hour for the operation. It is, however, counter productive in this application to bring in small quantities of material as preferred in lean manufacturing. The frequency of door openings would be too high; the moisture load would increase as well as your first cost and operating cost of the dehumidification system. More than likely you would still practice batch manufacturing. An alternative approach is to design a continuously moving conveyor belt that moves the finished product out through a small wall opening, instead of piling up the product on a pallet. The room would have to be pressurized accordingly, but this is a small price to pay compared with the gain in throughput with flow manufacturing.

Estimated Cost For Dry Rooms

The construction costs have increased for biotech facilities in the past few years. In our dry room example within an existing structure in California, the overall construction cost per square foot in 2003 was in the range of $225-275 per sq. ft. The cost drivers behind continued increases in 2004 are cost of materials, such as steel, drywall, concrete, and installation labor. As these are critical facilities for the success of the operation, the increasing costs affect the bottom line and could eventually result in more automation, outsourcing or moving manufacturing to areas where costs are lower.

What if these guidelines are not followed? Whenever there is leakage in the room construction, ductwork or equipment, allowing moisture to infiltrate the system, it results in the dehumidification and cooling systems working harder to achieve the desired room set points. If doors are left open longer than necessary, the same thing occurs. This is a waste of energy and occasionally the room will be out of specification, resulting in evacuation of the room and shutdown until it has recovered. If a redundant HVAC system were part of the design, then you would have a buffer of extra capacity to maintain room conditions. In critical dry room applications, this is now becoming the best practice. Needless to say, cost-cutting in construction of dry rooms and their support systems is likely to cost the owner several times more in lost production time or retrofits in the future.

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6. *Q(scfm)=W(lbs/hr) x 7000 / (4.5 x (HR inside (gr/lb)- HR supply air (gr/lb))*