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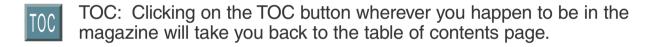
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RANKUMS

The magazine of contamination control practices, processes and technology



Volume 18, No. 2, February 2004

GOOD CORPORATE

CRUNCH. CLEANROOM OPERATORS ARE RALLYING TO TAME THE HVAC BEAST. IT'S TIME TO JOIN THE FIGHT

see Special Report p12.

CleanZone

Homing in on life science cleanroom issues

ORLANDO, FLA.—Day two and three of the CleanRooms East/PDA SciTech Summit next month will feature a cornucopia of conference sessions that will cover everything from decommissioning controlled environments to determining wiper efficiency and particle removal to an open forum on isolators and gloveboxes

The event will be held March 8-12 at the Orange County Convention Center, and it promises to be a one-stop shop for life science professionals. The schedule for March 9-10 includes

S1—EH&S Focus: Cleanroom Facilty Decontamination/Decomissioning, presented by Allan Chasey and Arnold Canales of Arizona State University's

continued on page 6

www.cleanrooms.com

Philips, E Ink launch world into paperless era with pliable LCD

BY MARK A. DESORBO

AMSTERDAM—Purveyors of paper may potentially be perturbed once Philips Electronics starts mass-producing a slim, book-sized panel that will let consumers download newspapers, magazines and other print media.

The Dutch firm announced in late January that it was preparing to manufacture the 5-inch display, which can show detailed images and be rolled up into a pen-sized holder. If connected to a mobile phone, it can also be used to download Web pages, a book, or e-mail.

"We can produce this in batches," says Bas van Rens, general manager of Philips' polymer division. "It's no longer a research project. We're going to build a pilot line that should be ready in 2005 to make one million displays a year.



Researchers at E Ink Corp. show the elasticity of the flexible transistors that are at the heart of paper-like pliable LCDs being introduced by Philips Electronics

Philips says it has created the displays using electronics circuits made of plastics, which power a monochrome display created in the ISO Class 4 and ISO Class 6 cleanrooms continued on page 29

Experts: Spin coat design put workers at risk

BY MARK A. DESORBO

SANTA CLARA, CALIF.—While the spin coater has been described as makeshift ingenuity, two plaintiff witnesses in the cleanroom cancer case against IBM Corp. and one semiconductor equipment design engineer say a phonograph-like contraption did everything to preserve the integrity of the disk drives, but nothing to protect the workers from exposure to harmful chemicals.

Spin coaters are perhaps as old as the semiconductor and microelectronics industries, and experts who spoke with CleanRooms claim they are not only the technological brain-

continued on page 8

IBM begins cancer suit defense, yields points

"This is a very

political thing.

lot of effort in

off the stand."

They put an awful

trying to keep me

BY MARK A. DESORBO

SANTA CLARA, CALIF.—The plaintiffs in the cleanroom cancer suit against IBM Corp. have rested their case,

and at press time, Big Blue was ready to present a defense that will challenge testimony from former company nurse, Audrey Misako Crouch, who said it was an unwritten policy among the com-

puter giant's medical staff to never utter chemicals as the cause of worker ailments.

IBM's defense presentation was scheduled to begin Jan. 22 and last two weeks. Lawyers will also crossexamine an ex-IBM manager who

testified that to prevent "mass hysteria," there is an unwritten company policy discouraging them from talking to workers about possible chemical poisoning.

The plaintiffs, who will have an opportunity to call rebuttal

witnesses, surprisingly declined to present additional testimony on the

continued on page 31

















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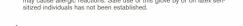


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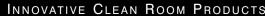


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VIEWPOINT

Re-discover energy efficiency...now



What happened to that refreshing fuel-efficient zeitgeist that put Honda Civics, Volkswagen Rabbits and Toyota Tercels

into millions of American driveways following the fuel crisis of the mid-1970s?

It was the "gas crunch" scare that had us all studying the MPG portion of showroom stickers; and it was a similar, more recent "energy crunch" in California that will, hopefully, usher in a re-awakened awareness of the power we're pumping into our clean manufacturing facilities.

Over the past three months, I've had a series of conference calls with a group from California's Lawrence Berkeley Laboratory's (LBL) Environmental Energy Technology Division, which is being headed by Dale Sartor and Bill Tschudi.

Over the past four years, Tschudi and Sartor have worked to create what *CleanRooms* contributing editor Chris Anderson has aptly called "the hub of

information for running energy-efficient cleanrooms." In 1999 and 2000, the group, with financial backing from local utility Pacific Gas & Electric (PG&E), was able to jump a few "proprietary" hurdles to procure data from participating clean manufacturers showing real-time energy usage. The data was just a start, allowing the team to publish a cleanroom programming guide that gives owners and architects information that will help them make smart design moves early in a project.

If you're interested in cutting energy costs in *your* cleanroom or designing smarter facilities, first read Anderson's Special Report, "Good corporate citizens unite" (page 12), and then consider contacting LBL's team about feeding your energy information into the benchmarking process.

If you'd like to learn more about LBL's work, the team will be presenting the session "S-14—Moving Towards Energy Efficient Cleanrooms & Stan-

dards," on Wednesday, March 10, at CleanRooms East 2004/PDA SciTech Summit in Orlando, Fla. Go to www.cleanrooms.com to register.

Take a step forward and share your data. It can only lead to a smarter future.

Parting is such sweet sorrow

Since I've accepted another chief editorial role, this will be the last time I share my thoughts to readers concerning cleanroom technology and its fascinating end-user markets.

There isn't enough time or space available for me to say good-bye to all the good friends and contacts I've made over the past four years. So, instead, I bid you all adieu until our paths cross again.

Michael A. Levans

n_this ISSUE

Magic carpet ride
University discovers wafer levitation.

10 Keep it clean

What to know about outsourcing cleaning services.

Taming of the beastCleanroom operators tackle HVAC issues.

Smoking out troubleNew developments in fire suppression systems.

Probing parenteral problemsHow to troubleshoot for visible product particles.

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Product Spotlight (Wipers)...p30

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Inventor's Corner, p15

analysis instrumentation ultrapure solutions

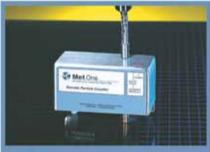


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NEWS

University takes cue from Aladdin for 'magical' wafer levitation

BY MARK A. DESORBO

MUNICH—When it came to finding a new way to handle meticulously patterned wafers without ever touching the somewhat sterile substrates, the Technical University of Munich found inspiration in Aladdin's magic carpet and developed a method of levitating them on a posh pillow of ultrasonic vibration.

"The technique allows complete non-contact handling when used for mere transportation of the wafer," says Michael Schilp, a member of the university's assembly technology team at the Institute for Machine Tools and Industrial Management (IWB). "No particles are produced by the handling process."

Moreover, Schlip told CleanRooms via e-mail, the process does not disrupt the cleanroom environment, and process gases can be used. Wafers also can be transferred in and out of cassettes and buffers, and moved between tools while levitated on their 1-mm to 2-mm cushions.

"As the ultrasonic cushion does not need additional air, the airflow is not disturbed by air blown into the cleanroom, like with Bernoulli grippers or air tracks," Schilp says.

According to the team of researchers, "a near-field or squeeze-field" levitation is applied to lift a wafer by direct radiation of its underside within the near field of a high intensity ultrasonic transducer. The wafer runs along a track, levitated by a 24 kHz beam vibrator on each side, and kept on track by side barriers. Speed and direction are controlled by using smaller, diagonally positioned ultrasound generators, or by gravity so as to tilt the

continued on page 34

Good bacteria a blow to foodborne pathogen's gut

FAYETTEVILLE, Ark.—Scientists from the U.S. Department of Agriculture's (USDA) chief scientific research agency have found several promising intestinal bacteria that could protect live chickens from salmonella, campylobacter and other pathogens that cause foodborne illnesses in people who eat poultry.

Annie Donoghue (right), a poultry physiologist at Agricultural Research Service's (ARS) Poultry Production and Product Safety Research Unit, is leading a team of ARS and University of Arkansas researchers in finding new, healthful bacteria that, when fed to live birds, help them resist harmful pathogens and grow more efficiently.

According to the USDA, pathogens like salmonella can be found on several kinds of food, but especially on raw meat, eggs, dairy products and seafood. It is blamed for 1,000 deaths every year and 40,000 cases of salmonellosis.

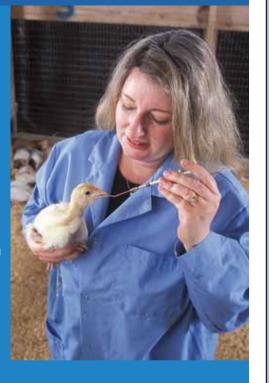
According to researchers, preventing contamination means eliminating pathogens from taking hold inside the intestinal tracts of the live birds. ARS scientists are getting a better understanding of how live beneficial bacteria, or probiotics, influence the intestinal

microbial environment as well as how it interacts with other bacteria. Probiotics contribute to the intestinal tract's health and balance.

Using a concept known as competitive exclusion, probiotics are fed to newly hatched chicks. Once inside, the probiotics occupy sites in the young bird's intestinal tract where the pathogens would normally attach and grow. Since probiotics get there first, they reduce the opportunity for pathogenic bacteria to become established in newly hatched chicks when they are most susceptible to infection.

The team has already screened more than four million intestinal isolates to come up with several promising probiotic combinations. The University of Arkansas and ARS have filed a patent on the selection techniques.

By using pre-selected "good" microbes, researchers hope to produce inexpensive, identified bacterial cultures with the ability to reduce or exclude specific pathogens and enhance enteric health in poultry. They have developed multiple in vitro selection systems for identifying potential probiotics. These new selection techniques make probiotics production less expensive. This could lower the price of poultry and make it less likely to be a source of foodborne illness.



Cha-ching for China

BEIJING—China's economy grew a surprising 9.9 percent in the final quarter of last year, the country's National Bureau of Statistics reported in late January, signaling a quick recovery from SARS-induced economic fallout and foreshadowing a favorable outlook for this year.

Investment and foreign trade helped drive the country's annual gross domestic product growth to 9.1 percent, according to the official figures released by the bureau.

At \$1.4 trillion (11.7 trillion yuan), full-year GDP growth was the highest since 1997, Li Deshui, the bureau's commissioner said at a January 20 press conference.

"It was a hard-won, successful achievement, after the outbreak of the SARS epidemic and frequent natural disasters," Li says, adding that he and other officials are pleased to see rapid economic growth, a stable consumer price index and improvement in employment.

Economic growth is China's main goal, and it has pledged to its citizens fast development and increasing living standards.

The full-year GDP rise exceeded market consensus, and was much higher than the 8.5 percent predicted by Xie Xuren, China's State Taxation Administration commissioner.

For this year, Li projected at least 7 percent growth, with a lively first quarter backed by continued investment. He also said consumer demand will be stronger, while export growth was likely to slow.

The pounding China received from severe acute respiratory syndrome (SARS) last spring kept people and investors away for months, and caused equally rampant worry of long-term economic hardship.

The strong fourth quarter and full-year GDP growth may raise further concerns that China's economy may be overheating. Li, however, explained that while some "select regions and select sectors" may be showing signs of overheating, the overall picture is sound.

Fake fabrications

TAIPEI—An ongoing analog chip shortage and strong demand before the Chinese New Year holidays have led to more fake analog chips showing up in China, according to anonymous sources at Taiwanbased analog IC design companies.

According to sources, the fake chips —designed by small Chinese IC design companies and manufactured at 4- and 6-inch fabs—are passed off as power management (PWM) ICs and metal-oxide semiconductor field effect transistors (MOSFETs) made by international or Taiwanese companies for use in consumer electronics.

The counterfeit chips are priced 10 to 20 percent lower than their genuine counterparts, sources said. The fake chips reportedly have wrecked some Chinese-made consumer electronics products. Some Taiwan-based IC design companies have been wrongfully accused by the Chinese consumer electronics makers and plan to take legal actions against the counterfeiters, sources said.

Safeguarding their intellectual property (IP) has been the major concern for companies that are considering outsourcing production to the Chinese foundries, sources said.

Upticking Taiwan

TAIWAN—Government officials are looking for a boost to the nation's economic strength from increased private investment as it projects private investment will jump by around 20 percent this year.

"Taiwan's private investment is expected to increase to about \$25 billion this year, buoyed by a strong economic recovery at home and abroad, said Minister of Economic Affairs, Lin Yi-fu, at a recent press conference.

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February 2004



















Mad cow disease corralling continues in northwest

BY MARK A. DESORBO

mad cow disease.

At press time, investigators from the U.S. Department of Agriculture (USDA) had located four more animals in Washington state from a herd of 81 cows that came from Canada. So far, 23

On Dec.23, the USDA announced that the first U.S. case of mad cow disease had been discovered in a Holstein from a dairy farm herd in Washington state. A recall of beef from that cow sparked a beef recall in eight states and in the U.S. territory of Guam. Also, authorities subsequently slaughtered 129 cows from the Sunny Dene Ranch and ordered them tested for the brain-wasting disease.

So far, the USDA says, 30 samples from the destroyed cows have been tested, and all were negative. Of the 23 Canadian cows, 10 were found at a Mabton, Wash., ranch, three were from a Tenino, Wash., facility, six were found at a farm in Connell, Wash., one was located at a dairy farm in Quincy, Wash., while another three were found

in addition to three known to be from Canada, were killed "in the abundance of caution, to ensure the safety of the food supply and U.S. beef," Nolan Lemon, a USDA spokesman in Yakima told KOMO-TV.

Lemon explained that animals that they were part of the 81—namely, because ear identification tags may have fallen off—are considered a potential risk and will be euthanized as well.

Mad cow disease is a public health

concern because humans can get a related illness variant, Creutzfeldt-Jakob disease, from eating contaminated meat that contains tissue from infected animals—specifically, from the brain and spinal cord, according to Donna Gilson, a trade and consumer protection spokeswoman for the Wisconsin Department of Agriculture in an interview with The Associated Press..

In addition to culling animals and instituting beef recalls, the USDA has unveiled additional protection food supply safety measures regarding:

- · Downer animals: USDA will ban all downer, sick or injured, cattle from the human food chain.
- Product holding: USDA Food Safety and Inspection Service (FSIS) inspectors will no longer mark cattle tested for BSE as "inspected and passed" until confirmation is received that the animals have tested negative for BSE.

continued on page 35

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WASHINGTON D.C.—North America continues to grapple with a food safety problem that turned Europe upsidedown nearly three years ago: Bovine Spongiform Encephalopathy (BSE), a.k.a.

of the 81 cows have been found.

at a farm in Mattawa, Wash. Cows culled from the Mattawa farm,

cannot be excluded from the possibility

CleanZone

from page 1

Construction Research and Education for Advanced Technology

S5—Water System Design for Clean Scientific Laboratory Facilities, presented by Dale Gordon, regional business manager for Millipore Corp.'s Lab Water Division.

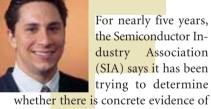
S10—Determining the Dynamic Wiping Efficiency and Particle Removal Ability of Cleanroom Wipers, presented by J.M. Oathout, Senior Research Associate, DuPont Nonwoven Division.

P12—Open Forum: Isolators/ Gloveboxes Issues and Answers, which will be hosted by manufacturers and officials of the American Glovebox Society.

For more information on the 2004 CleanRooms East/PDA, visit www.cleanrooms.com. To reserve a booth, call Richard Arzivian, exhibit sales manager, at (603) 666-6623, fax (603) 891-9200; e-mail dicka @pennwell.com.

ON THE BEAT

Where's that SIA cancer study?



whether there is concrete evidence of increased cancer risk for people working in cleanrooms.

The SIA even goes as far to say that data is insufficient, and the information does not conclude whether exposure to chemicals or other hazardous materials has or has not proliferated cancer cases.

For too long, this has been an accepted answer from a trade association representing certain companies that have been trying to avoid being responsible for the health and wellbeing of their employees. Why else would attorneys for IBM Corp. work so hard at keeping the jury from hearing what is undoubtedly damaging testimony in the ongoing cleanroom cancer case?

SIA, along with many industry play-

ers, are stalling—sitting back on their ever-swelling laurels, as fab after fab is built—dismissing the leaking underground storage tanks, chemical plumes, birth defects, miscarriages and cancer rates that shatter national averages.

Contamination-control experts and cleanroom end users alike must ask themselves just how valuable a study, if it ever materializes, will be coming from an organization that is biased and has failed to take quick, corrective actions.

The data is insurmountable, and it isn't a question of whether a cancer study is feasible. It is a matter of who can conduct the study comprehensively and fairly with the ultimate goal of preventing this from ever happen-

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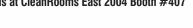












Cleaning system ensures one swell FOUP

BY HANK HOGAN

AUSTIN, TEXAS—Like many involved with contamination control, Bob Groves, project leader at International Sematech, worries about what he can't see because he knows what you can't see can kill your product.

As the semiconductor industry moves into production of 300-mm wafers, Groves and others are concerned with particles that measure much less than 1 µm. With the new wafer size comes new technology, specifically a healthy dose of robotics, automation and the Front Opening Unified Pod (FOUP).

FOUPs seal wafers in and keep contaminants out, providing protection as wafers travel from station to station. But these new wafer carriers aren't an unmitigated blessing.

"When compared to 200-mm wafer carriers, the design and construction of 300-mm wafer carriers present unique challenges to cleaning them effectively," remarks Groves.

Sematech recently installed a TFC-802 FOUP cleaning system from Technovision, Inc. (Kawagoe, Japan). The company makes a variety of cleaning products for the semiconductor and flat panel display industries. According to Groves, Sematech plans to use the cleaning system in an attempt to head off potential contamination problems.

Made of a combination of transparent and opaque antistatic plastic, FOUPs consist of a wafer carrier, which is either attached to or molded from the surrounding shell. A lid—the front opening part of the FOUP attaches to and seals the shell. Groves notes that it's the gap between the wafer carrier and the shell that presents the most cleaning problems. This small area is surrounded with plastic on all sides but one, so it's difficult to send water and cleaning agents down into the gap with enough force to dislodge contaminants.

A number of products are intended for FOUP cleaning that are used in existing manufacturing lines at the beginning of the production cycle. Particle counter tests indicate that, for the most part, FOUPs stay clean throughout a manufacturing run. But not all wafer carriers encounter normal, uneventful tours of duty. A few suffer catastrophe. It's these abnormal events that pose the most contamination-control problems for FOUPs. One arises when 300-mm wafers, which are thin silicon disks one foot across, break inside the carrier.

"If somebody breaks wafers in one of these, then all bets are off," says Groves. So, Sematech plans to evaluate the performance of Technovision's cleaning system, which uses deionized water heated to 40 to 50 degrees Centigrade and pressurized to 0.5 megaPascals. The evaluation will be done with surface particle analyzers, witness wafers and liquid particle counters. Results will guide additional system tuning and tests. III

Spin coat design from page 1

child of IBM Corp., but an un-patented platform that was adopted worldwide and is still used today—safety hazards and all.

"The people who designed the machine...had little to no knowledge of ventilation," says Robert Morris, a cleanroom ventilation expert. "[IBM] created the spinner technology. It uses nasty chemicals, and the exhaust was not designed correctly. What stuns me is that IBM's design for the spinners was copied by the industry.'

Morris, president and chief executive of Flow Safe Inc., a Denville, N.J.-based manufacturer of airflow and control systems, is a key witness for the plaintiffs in the ongoing case against IBM. He, along with Scott Reynolds, an engineer at Binghamton, N.Y.-based Computer Aided Engineering Solutions, created computational fluid dynamic models to simulate airflow and working conditions in the cleanrooms, where two plaintiffs, Alida Hernandez and James Moore, worked.

Hernandez, 73, and Moore, 62, worked at IBM's disk drive and printed circuit board manufacturing facility in San Jose starting in the late 1960s and early 1970s. Both allege that exposure to chemicals at IBM later caused their cancers.

Morris and Reynolds say the virtual reality models they created would have unveiled not only severe cleanroom airflow problems, but also design flaws in spin coaters that, despite being packaged inside fume hoods, still put workers at an unusually high risk of acute chemical exposure.

"But it doesn't take a rocket scientist to figure out that you have clogged exhaust systems and you're exposing people," Reynolds says.

The spinners, he says, were clogged, and in all cases Reynolds and Morris were able to figure out chemical concentrations in the cleanrooms, which ranged from threshold limits to on-the-spot-poisoning. And whether there were 30 air changes per hour or 100 air changes per hour, it didn't make any difference.

"The faster the air was turned over, the more it was mixed and spread around and the concentration stayed the same," Reynolds adds "The cleanrooms were working just fine in terms of particulate control, but there was an added burden of chemical control, and they did not do a good job at controlling that."

Reynolds explains that the spin coater, or spinner as it is often called, operated at low revolutions so it could apply such chemicals as isophorone, acetone, formaldihide, xylene and ethyl amyl ketone to the disk or wafer.

"Then, there's a spin-off cycle, at high revolutions per minute to spread the coating uniformly to very thin layers," he says. "Then, they slow it way down to magnetize and dry it."

The machine, Reynolds says, has a spindle that holds the disk in place as it is spun at revolutions as high as 5,000 RPMs. It is at the perimeter of the disk where

continued on page 34



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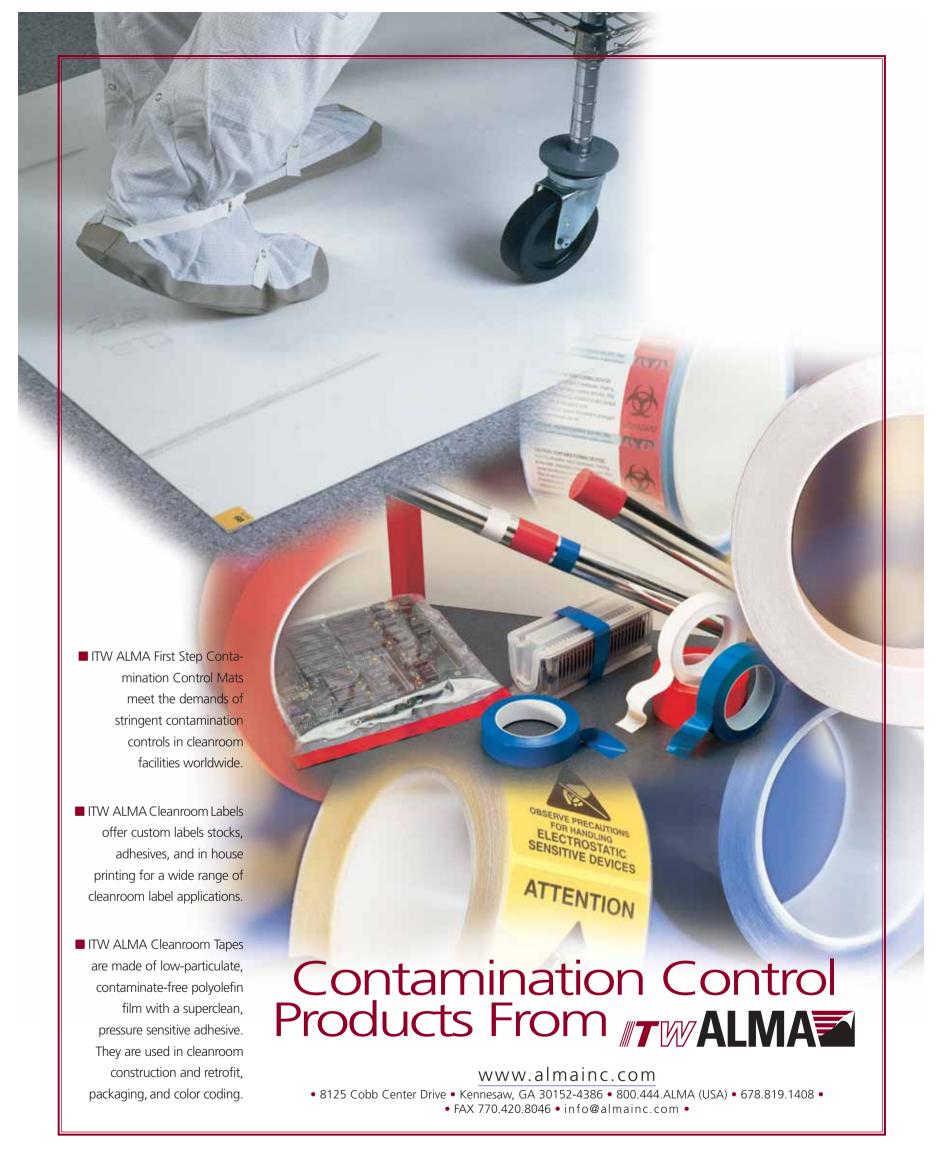












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Establishing an RFP for outsourcing cleanroom cleaning

BY GREG JONES

There comes a time when each department is asked to consider outsourcing some segment of its operations; typically, the operation in question is a manufacturing process or facility service that could be performed more efficiently by outside suppliers.

Aseptic gowns and cleanroom qualification are two that immediately come to mind; and as time goes on, and outsourcing evolves into a successful relationship with a provider, more requests are made to continue budget reviews and other areas are put up for consideration.

One operation that is being outsourced more readily these days is cleanroom cleaning. But before estimates are gathered, it's imperative that cleanroom owners take a step back, evaluate your specific needs and take the following steps on the way to a decision that's right for your particluar cleanroom, schedule and budget.



Cleanroom cleaning should be considered as important a discipline as cleanroom assembly—possibly more so. It's the cleaning process that ends and begins every cleanroom.

With all the technology, sophistication and knowledge available, cleanrooms are not measured for cleanliness, but by how many particles per certain area actually exist. Taking cleaning down another level, it's more important to manage viable and non-viable particles.

Viable particulates won't be distinguished for several days, usually after the operations commence, so it's critical to know what's required within the operation now as well as before outsourcing is considered. Once you've written down your cleanroom systems and requirements, ask what objectives need to be accomplished when outsourcing:

- What is the square footage of the controlled area?
- What are the classifications and maintenance requirements?
- What type of orientation and qualification programs are required and monitored for staff personnel to enter and work in these areas?

By simply checking off the points indicated in the sidebar

If you're preparing to

contract with an outside

cleaning service, get ready

to do your homework

to this article ("Checking it twice," page 33), you can create a checklist review for most considerations to be reviewed and answered. Ask any operator/technician working in these areas and they will tell you what is expected. Ask any manager involved in running the operation and that person should be able to respond, in depth,

addressing budget, corrective action and process improve-

One key to a successful evaluation is having all of these issues written and answered, not just conceptualized. It's important to decide and include all costs, such as supplies, equipment and all labor, in an effort to obtain a fair compar-

ison to switching to an outside service supplier.

What do you want to accomplish? Answer the following questions to get to the bottom of your reasoning:

- Is this a financial decision?
- Is the company wishing to gain expertise in the area of cleanroom cleaning?

Your company may feel that, by outsourcing cleanroom cleaning, it can better concentrate on its core competency. Regardless of the reason, it's important for your company to keep its focus when comparing incoming proposals.

Time for the request for proposal (RFP)

The RFP is designed to ask suppliers for a proposal that fits your exact need. Remember, it's the cleanroom owner's obligation to the supplier to give a general overview of the current program, as well as the specifics of areas that will be serviced; in turn, the supplier will be able to present qualified information back to the owner.

An effective proposal is presented in two sections. The first should cover the suppliers **service programs**; list all the requirements, and determine weighted values for scoring. The second should review **pricing information**. Most decisions are cost-driven, as in the bottom line; however, look for *value*, not cost.

Therein lies the reasoning for splitting the proposal into two criteria; don't even consider the costs until you have chosen the two or three best values available. After the values have been established, you can compare what in-house costs would be versus outside costs while considering your objectives for contracting an outside service provider.

Under the first section of the RFP (service programs), list sections that will need to be explained; such as the supplier's management structure, site manager qualifications, safety data and training programs. The supplier should be asked for information on specific cleaning programs, such as ISO Class 5 and ISO Class 8 support rooms, and how they clean—especialty flooring and machinery.

Productivity standards and cleaning materials should also be noted in your RFP, since these will be part of the overall cost. You can determine right away if a supplier knows what it's doing based on how it proposes to clean, compatibility of methods, and cleaning materials used.

This section should also include a reference listing of current and past clients. It would be good to know how well a vendor maintains relationships with previous customers. Ask for a summary section that details labor and supervisory support to determine estimated productivity standards and ratio of non-working supervisors to technicians.

Send out the RFP with timelines

Chances are high that there are numerous custodial services in the area, so the key is to narrow the field. Try calling several companies or go with recommendations from professional associates. How many is enough? Consider how much time you have to review their proposals. Five or six should complete the first pass list.

You may miss one or two qualified suppliers, but the professional ones will know your company is in the bidding process. Make sure to have specified in the RFP the timelines of each event, including closing dates of receipt of proposals, interview of finalists, award date and initiation of contract dates.

Evaluation of proposals

Once the submission date has arrived, be ready to pare down the list to three finalists. Check for complete information as requested as well as thoroughness, typos and overall communication skills. If a proposal is inadequate, what service level can you expect when the real work begins?

Pricing information should be reviewed, but not necessarily used to eliminate contenders. Instead, pricing should be used in the scoring process/weighted value to determine whether a proposal is feasible and within budget. Review the pricing information and crosscheck the proposals to be sure that the math is correct on staffing, equipment, pricing and

continued on page 32









































FOLLOWING THE CALIFORNIA ENERGY CRUNCH, LEANROOM OPERATORS ARE RALLYING TO TA HE HVAC BEAST. IT'S TIME TO JOIN THE FIGHT

BY CHRIS ANDERSON

The California energy shortage of a few years ago opened the eyes of many in the business of running cleanrooms. Today, a small but growing cadre of cleanroom managers, as well as an application research team from the Lawrence Berkeley Laboratory, is working on ways to increase energy efficiency within cleanrooms that specifically targets HVAC systems.

While lesser energy consumption can result in savings to a company, some of the drivers of this effort have nothing to do with money.

"If you don't pay attention to conserving energy, your penalty could be perhaps consuming twice as much energy of what a very efficient system would," says Ernie French, senior sales engineer with Norman S. Wright Mechanical Equipment, a San Francisco-based supplier of mechanical equipment systems to the cleanroom industry.

'So, it's not a real penalty to the manufacturer in terms of adding a huge amount to the cost of the product," continues French. "But we are getting to the point where every penny counts, and you can tell a good story to the public about what you are doing."

The bottom line, according to French: "There are other benefits to saving energy besides the costs of the energy itself."

That said, being a good corporate citizen only goes so far. There's evidence that, for some forward-looking companies, the need to become energy efficient now and to perpetuate that in the future is more visceral.

"Since the energy crisis has passed, to some extent, we still want to be a good corporate neighbor," says Gary Shamshoian, senior mechanical engineer with Genentech a bio-pharmaceutical company in South San Francisco, Calif. "But there's also a general concern of what the future may bring, which was accentuated during the energy crisis here in California in 2000 and a reliability concern that comes out of that."

Unfortunately, companies aggressively pursuing improved HVAC and air-handling efficiency are still few, and

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those willing to share their information and data to help build accepted best practices are even rarer.

The trick to collecting data

Today, the hub of information for running energy-efficient cleanrooms is California's Lawrence Berkeley Laboratory. Bill Tschudi, project manager of the Environmental Energy Technology Division, has worked on the issue for nearly four years, beginning with case studies and benchmarking funded by local utility Pacific Gas and Electric (PG&E).

"In 1999 and 2000, we were able to dig up some data from real cleanrooms, and we did a cleanroom programming guide to give owners and designers some information on decisions they could make early in a project that wouldn't lock them into bad energy decisions," says Tschudi. He admits, however, that the early work only scratched the surface and that the largest obstacle is persuading operators to share data about their specific operations. "It's certainly easier today to get companies to share their data than it was five years ago, before the energy crisis," Tschudi says. "But now, the big stumbling block is that a lot of companies don't want to have the results public for competitive reasons."

To leap this hurdle, Lawrence Berkeley has worked out an anonymous reporting method for companies to share their data. Further, researchers from the lab have been able to assure companies that they won't be collecting information on the process of individual manufacturers, but working merely on the amount of energy used. "CFM per KW is the metric we are using, so it is merely a measure of how much air continued on page 14

FFU is unique

construction tech-

Huntair, GE attempt to turn the tables on FFU thinking

corvalis, ore.—If the future of fan filter units (FFU) is one that includes much greater energy efficiency, then two companies appear to be on the right path. Huntair and GE Industrial Systems recently unveiled what they dub the "next generation fan filter unit system" in a 750-sqaure-foot cleanroom at Oregon State University's College of Oceanic and Atmospheric Sciences.

According to the companies, this system can provide 70 percent energy savings as compared to FFUs currently on the market.

Oregon-based Huntair, Inc., a manufacturer of cleanroom components and industrial air handlers, designed the cleanroom and produced the 31 ceiling-mounted AF 300 FFUs used to maintain positive airflow. Each FFU is powered by a high-efficiency, variable-speed GE ECM 2.3 series motor.

GE Fanuc Automation provided the programmable-logic controllers and Cimplicity system software to run the units.

Performance

Performance
Contracting, Inc.
(PCI) built the interior envelope of the room and, like the other three com-

the other three companies, donated products and/or services to the project.

According to Huntair and GE Industrial Systems, the key to this

nique combined with fractional horsepower motors used to drive the fans. The differentiating design element was removing the baffle from inside the FFU. By using a backward curved air foil wheel without the baffle, Huntair greatly reduced the amount of resistance inside the FFU, which, in turn, produced a unit with an inherently greater efficiency profile.

This new design was then combined with a fractional horsepower GE ECM brushless-DC motor. According to GE, the ECM 2.3 has all of its speed and torque controls built in a microprocessor that allows the motor to be programmed at the factory or on site, and controlled remotely.

Both companies say that even greater efficiencies can be found in this FFU if it is used at lower flow rates.

For more information on the clean-room Oregon State University's Col-

of Oceanic and Atmospheric Sciences go to: http://wmkeck-icpms.coas.oregonstate.edu/



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you are using per watt of energy," Tschudi savs.

This subtle shift in strategy has brought wider participation, but researchers still need more data to validate their work. If more companies step forward to share their energy consumption data, Lawrence Berkeley plans to release a benchmarking document to the industry later this year or in early 2005.

Tschudi and research partner Dale Sartor, along with PG&E and other team members, will also present their current findings at a seminar entitled "Moving Towards Energy Efficient Cleanrooms & Standards" next month at CleanRooms East 2004, in Orlan-

do, Fla.

Against the grain?

Innovations to help squeeze energy savings out of cleanroom operations take many forms; from simply seeking HEPA filters

with lower pressure drop and choosing air-handling equipment that is more efficient and sized to the specific job, to adjusting how air is moved in and out of the cleanroom and at what volumes.

the expected result.

Some of the results may go against the grain of how some people have operated their cleanrooms for years. "The initial reaction of what to do when a room isn't as clean as it should be is to go for more velocity," says Shamshoian.

This increase in velocity ups a company's energy consumption—and it may all be for naught. "We're coming to the realization that we are possibly sacrificing HEPA efficiency because they weren't designed to have that much air moved through them," Shamshoian adds. "So, part of the effort to do more intelligent design is to realize that more air is not always better. In fact, more can be worse at some point."

Getting more cleanroom managers to take a hard look at their air flow is difficult, because of what Tschudi calls "process phobia"— the fear of changing an accepted process, no matter the energy consumption, because the cleanroom is producing

> Tschudi says this jibes with information he has collected. "There is no data that says more is better," he says. "We went back and researched how the industry accepted 90 feet per minute and found it was some ran-

dom decision made by some guy sitting around at Sandia."

The push to more efficient operations has engineers working to establish, with a scientific basis, the balance between moving enough air to maintain prescribed contamination controls while reaching peak energy savings.

But getting more cleanroom managers to take a hard look at their air flow is difficult, because of what Tschudi calls "process phobia"—the fear of changing an accepted process, no matter the energy consumption, because the cleanroom is producing the expected result.

Further, companies are all over the map

when it comes to which cleanroom classification they are operating, often choosing more clean over less clean (hence, higher energy consumption) without any scientific basis.

"We have often

asked the naïve question of why company A picked Class 100 [ISO Class 5] for a particular room, and there was never a good answer for why it was needed for that particular process," Tschudi says. "Then we'd go to another company performing the same process and the same operations in a Class 1000 [ISO Class 6] cleanroom and it's working just fine."

But beyond the big leap of changing air flow, which opens up questions of proper percentages of make-up air, recirculated air and the like, managers can make very basic changes to incrementally reduce HVAC energy consumption.

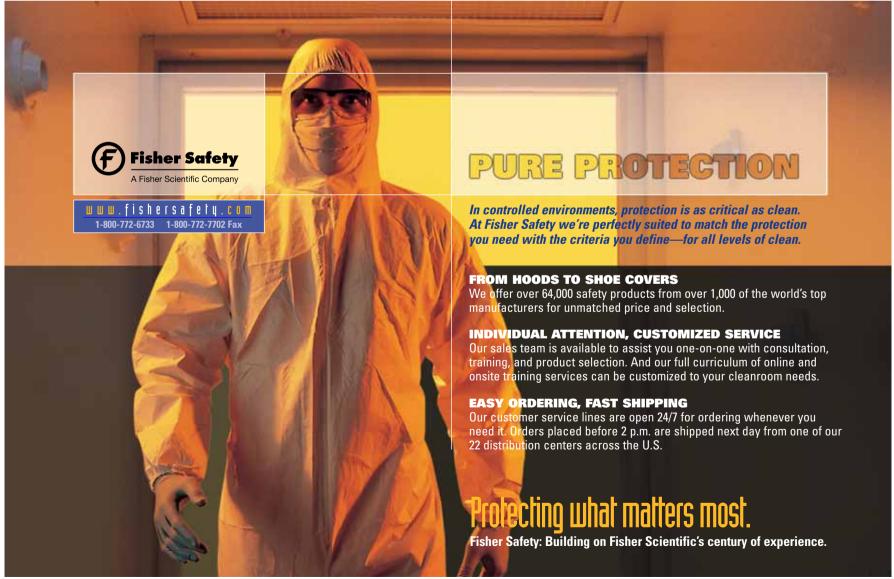
First on the list is to simply look for different HEPA filters.

"Generally, putting more HEPA media in the filter is going to lower pressure drop, so that alone requires less energy," says French. "There are different filter products and there are manufacturers that will vary the density of the HEPA media. And there are others that have developed a different kind of media."

In many cases, the only change required here is to slide out the old filters and slip in the new. An added bonus of using denser HEPA filters is fewer change outs because the filter can take a larger load.

At Bayer HealthCare in Berkeley, Calif., principal project engineer Dennis Leung has gone one step farther in an effort to reduce the amount of air leakage around the

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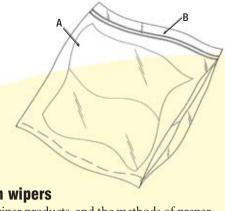


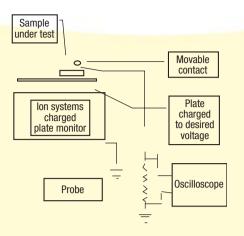






Inventor's Corner





ESD-dissipative ceramics

This invention relates to a dense ceramics having ESD-dissipative characteristics, tunable volume and surface resistivities in semi-insulative range (10.sup.3 -10.sup.11 Ohm-cm).

The ceramics are substantially pore free, of high flexural strength and light in colors for desired ESD dissipation characteristics, structural reliability, high vision recognition, low wear and particulate contamination.

They can be used as ESD dissipating tools, fixtures, load-bearing elements, work surfaces, containers in manufacturing, and assembling electrostatically sensitive microelectronic, electromagnetic, electro-optic components, devices and systems.

Patent number: 6,669,871 B2 Date granted: Dec. 30, 2003

Inventors: Oh-Hun Kwon, Matthew A. Simpson and Roger K. Lin. of Saint-Gobain Ceramics & Plastics (Worcester, Mass.)

Cleanroom wipers

Cleanroom wiper products, and the methods of preparing and using them are described in this patent. The cleanroom wipers are intended for use in cleaning up alkaline contaminants.

The wipers contain impregnated acidic solutions (e.g., solutions of organic acids and optionally solvents),

which are intended to reduce or eliminate the possibility of spontaneous combustion when used to contain spills of alkaline products such as hydroxylamine-based products and other caustic-based formulations.

The wipe (A) can be made of knitted, woven or nonwoven fabrics and preferably packaged in a liquid- and air-tight sealed bag (B).

Patent number: 6,645,930 B1 Date granted: Nov. 11, 2003

Inventors: Danny L. Wallis and Robert J. Small, of EKC Technology Inc. (Hayward, Calif.)

Track assembly

The cleanroom wall system uses a universal stud design that allows a variety of wall configurations to be assembled.

The stud (A) is preferably made of extruded aluminum,

is rectangular in cross-section, and includes outer walls (B,C,D and E), which are sized to define wide and narrow sides (F).

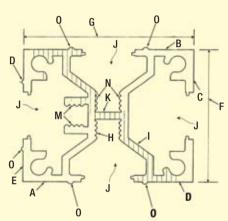
Slots (G) extend along the length of the stud to interrupt each of the four outer stud walls. Inside each slot, inner walls (H,I) are shaped to form chambers (J), which run continuous with the slots in the opposing wide-sidewalls and taper toward the stud. There, the inner walls are joined at the center of the stud by a web (K) that runs parallel with the wide sides.

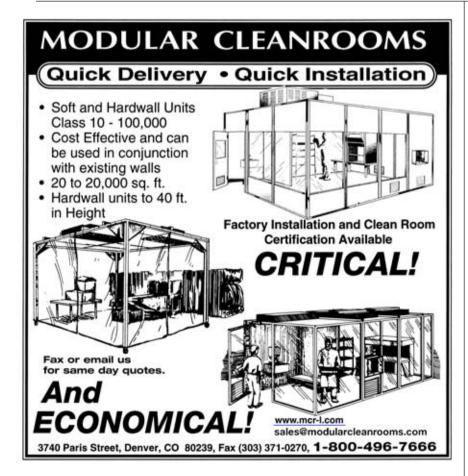
That web combined with corrugated surfaces (M,N) and ridges (O) allows the system to use a connector block (not shown) for joining perpendicularly oriented

> studs, or for splicing together axially aligned studs. A corner stud is also included, as well as a deflection track for connecting the top track of a wall panel to a conventional ceiling grid, allowing deflection of the grid relative to the wall and facilitating easy access to the portion of the ceiling immediately above the wall panel.

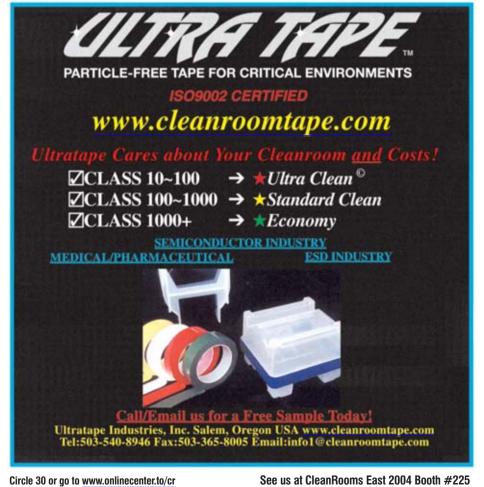
Patent number: 6,634,149 B2 Date granted: Oct. 21, 2003

Inventors: Dennis O. Cates, of Tualatin. Ore., and Roger K. Crawford, (Salem, Ore.)





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Where there's smoke...there's cleanroom disruption

With the introduction of higher insurance premiums and deductibles, high-tech manufacturers are on the prowl for the latest in fire suppression systems

BY LAURENCE GRODSKY

By their very nature, cleanrooms are very difficult environments in which to combat fire. The latest technologies, however, can help prevent a fire from even starting, let alone spreading.

From the outset, it must be understood that fire protection is a multistage process in which fire protection equipment must be deployed; but remember, a strong prevention plan must be established. Protecting lives, property and your

business from fire requires planning, guidance and the full cooperation of all the building's inhabitants.

When it comes down to it, education is actually the most important task in fire prevention and protection, as all the fire prevention techniques and planning simply can't insulate an organization from a fire incident. Even though fires are rare incidents, they do occur and can be extremely devastating to the operations and profitability of an organiza-

tion-especially in today's global manufacturing environment.

On top of globalization, businesses have also been experiencing increases in insurance premium costs and higher deductibles. With both of these issues creating new challenges and risk, there's never been a more important time to increase prevention and suppression techniques.

Equipment damages or losses that were routinely replaced through fire insurance coverage in previous years may now be the responsibility of the victim company. With this in mind, high-tech manufacturers are attempting to search for new products and methods that will limit or mitigate their exposure to this new insurance risk more than ever before.

How a fire develops

The combustion process begins before you see smoke or fire or feel intense heat. The initial development of a potential fire will emit the colorless, odorless by-products of initial combustion.

Once these particles are present, the fire is said to be in its "incipient" stage of development. This stage will eventually transform into the smoke, followed by the flame stage and finally the intense heat stage. The "incipient" stage causes no damage to any equipment and is not a danger to any inhabitants and the environment.

In fact, the impending damage that will occur in the subsequent development stages of a fire can be prevented by removing the source of the combustion either through the removal of power or heat from the overheating source of ignition. Actually, you can turn a potentially developing fireinto a maintenance issue—no loss of equipment, no danger to the inhabitants, no business interruption, no insurance losses, and no lost revenues. This technology will be addressed later.

"Must haves" for protecting your investment

Fire protection systems encompass two functions: the detection/notification of a fire, and the subsequent suppression of that fire. Detection systems rely on various types of detectors to sense problematic conditions, either being smoke, flame, heat or the presence of products of combustion.

Each type of detection device is used for specified conditions. Semiconductor manufacturing facilities present a unique environment for fire protection. The airflow tends to inhibit the function of standard spot smoke and thermal detection devices due to the resulting smoke movement.

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In semiconductor fabs, smoke will follow the laminar airflow rather than the traditional movement towards the ceiling, whether with little or no airflow conditions. Combined with the passive function and sensitivity of a standard spot detector, all types of ceiling detection will provide limited protection for the cleanroom facility.

Proper protection of cleanrooms typically found in semiconductor fabs calls for locating a detection device within the airflow where the entire room can be monitored properly. An appropriate location is typically within the airflow immediately before the air-handling unit where the dilution of the air occurs, as well as at the exit of both the air-handling and re-circulation handling units.

The detectors can provide passive or active detection but are required to provide a minimum sensitivity level of .03 per foot obscuration. The National Fire Protection Association (NFPA) has published Standard 318, "Protection of Semiconductor Manufacturing Facilities," which specifically indicates the location of approved detection devices as well as sensitivity and other characteristic requirements.

Potential detection devices in addition to smoke detection may include optical flame detection and gas detection as indicated by NFPA Standard 318. For highly-advanced manufacturing sites, water sprinklers have proven to be an effective life safety suppression agent, and are required in accordance with NFPA Standard 318. For minimum protection, sprinkler head locations should include the room as well as exhaust ductwork, plenum, and interstitial spaces above the room only if they are constructed of materials that are combustible.

Still, assets that reside within that facility are at risk. Water, by nature, can damage sensitive electronic circuitry, and sprinkler systems have potentially high clean-up costs.

To mitigate potential damage and losses, a clean gaseous agent can be considered as a supplemental (but not replacement) protection system to a sprinkler system.

By discharging a clean agent system before a sprinkler system engages, the agent, in most cases, will suppress a fire without injuring the inhabitants and will spare sensitive electronic equipment.

The clean agent systems, in most cases, will require deactivation of air-handling units. If this doesn't occur, the clean agent system may not successfully suppress the fire, in which case the standard sprinkler system can be employed to protect the facility and any workers who are still in the room. Remember, if the sprinkler system is employed, the assets within the protected structure will be either damaged or lost.

How HFC227ea works

Clean gaseous agents are safe for humans and will not damage sensitive electronic equipment; however, selection of preferred gaseous agents vary from country to country.

Fire-suppressing gaseous agents are typically an alternative to water for the protection of electronic equipment. Historically, Halon 1301 was the gaseous agent of choice

for the applications discussed in this article; however, the Montreal Protocol, ratified globally more than ten years ago, placed a moratorium upon the production of Halon 1301 in the majority of nations due to its

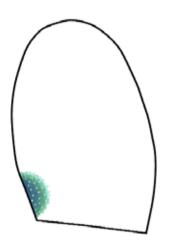
The interruption of the combustion process during the incipient stage of a fire will prevent any equipment damage and will not affect inhabitants or the environment.

ozone depleting characteristics. Since then, the U.S. and Europe have taken a different approach to suppression.

In the U.S., the Environmental Protection Agency (EPA) accepts the use of the next-generation halocarbon (HFCs) HFC227ea, a product that has no ozone depletion effects and makes a limited contribution to the greenhouse effect. Commonly employed across the U.S., the gas is

continued on page 18







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safe to inhale at design concentration levels and extinguishes fires without damaging sensitive electronic equipment and other materials.

In Europe, inert gases, including carbon dioxide, nitrogen and argon, are widely used as suppressants. Since they are derived from the atmosphere, they have arguably no overall effect on the environment; however, they are required in much larger quantities and must be stored under much higher pressure than HFCs such as HFC227ea.

Typically, an inert gas suppression system

will need five to 10 times more cylinders of gaseous agent at 2,000 psi than HFC-227ea at 360 psi. Also, inert gas delivery systems have to be built to high-pressure specifications, and higher levels of concentration are required for suppression.

Typically, a seven-percent concentration for HFC227ea will suppress a fire while inert gases will need 35 to 50 percent concentrations. HFC227ea is also stored as a liquid and releases into the air as a gas. Inert gases are always stored in the gaseous phase, which is why much larger volumes, logistical effort

and greater storage capability are required.

A high-tech approach

As discussed earlier, the interruption of the combustion process during the incipient stage of a fire will prevent any equipment damage and will not effect inhabitants or the environment. Recent technology advancements are available to provide such detection.

For example, Siemens employs the use of Very Early Smoke Detection (VESDA) with its core fire alarm panel products. VESDA is an aspiration detection system

that draws in air and examines it with laser particle detectors

Units can indicate a possible fire before smoke can be smelled or flames seen. By identifying a fire at the incipient stage, noti-

With incipient fire detectors, a system can detect overheating wire in an electrical installation before it reaches flash point.

fication allows damage, if any, to be limited and personal injury to be prevented.

With incipient fire detectors, a system can detect overheating wire in an electrical installation before it reaches flash point. In this case, there is no need to deploy the suppression system, because the circuit can be identified and simply switched off. The fire has not yet occurred.

Such intelligent systems are the future of fire detection and can save lives and investments. And with increasing insurance premiums and higher deductibles, the use of VESDA systems and FM-200, along with required sprinkler systems and a state-of-theart fire alarm system, can be your best insurance policy for your critical assets. III

LAURENCE GRODSKY is business manager for Siemens Fire Safety. Grodsky can be reached at: fiswebmaster@sbt.siemens.com



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- Six size ranges measured simultaneously - 0.3, 0.5, 0.7, 1.0, 5.0, and 10.0 µm
- 1 cubic foot per minute flow rate (28.3 L/min)
- Total particles and three concentration modes particles/m³, particles/L, and particles/ft3
- User friendly LCD touchscreen control panel
- Can be programmed from a personal computer
- Performs ISO 14644 and FS 209E calculations
- Optional sensors to monitor temperature, relative humidity, differential pressure, and air velocity

Microbiology Laboratory

- Provides quantitative and qualitative analyses
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 "Perfect Score" participant in
- the EMPAT Program

APC & APC Plus Airborne Particle Counters

- Measures two or four particle size ranges
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- 0.3, 0.5, 1.0, and 5.0 µm for the APC Plus Meets JIS for counting
- efficiency Two concentration modes -
- particles/ft³ and particles/L Temperature and RH
- sensors built-in Easy to use software
- included Remote and facility monitoring software

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www.cleanrooms.com

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- Programmable through the isolator controller
- Air circulation within the

RCS High Flow

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- Air direction flanges maintain unidirectional airflow in critical environments
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- Infrared remote control included

RCS PLUS

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- Exhaust port flances minimize air turbulence to maintain unidirectional airflow in critical areas
- Explosion-proof model available: RCS PLUS EX

Standard RCS

- Lightweight, compact design provides portability and ease of use
- Reproducible results due to accurate electronic control
- Economical

RCS Agar Strips

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- Ensures accurate and reproducible results
- Gamma-irradiated and selective media available

HYCON Contact Slides

- Standardized contact area of 25 cm² meets USP and
- Individual packaging prevents potential contamination
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- Gamma-irradiated and selective media available
- Ideal for use in isolators

Dip Slides

- For microbial analysis
- Selective media available



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February 2004

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Trouble-shooting parenterals via particle identification

Identification of visible product particles, like protein aggregates, can form the foundation of an effective, in-process contamination control program

BY DR. OLIVER K. VALET

Parenterals are subject to high requirements in regards to purity. These solutions are regulated by United States Pharmacopoeia (USP) and have to be free of any visible particles (less than 50 µm). The limit values for non-visible particles are to be followed, while intense efforts in production and quality assurance are required to ensure that they are.

Depending on the process, 0.2 to 3.0 percent of waste due to particles is accrued. If the cost of waste exceeds a significant amount, the source of the impurification certainly needs to be sought. The simple identification of the particles facilitates the detection and elimination of the source; and, in turn, the cost of this waste and the empirical attempts to solve the problem are reduced.

Simple contamination information

A system has been developed for the automatic chemical analysis of particles on the basis of RAMAN spectroscopy. ¹ The measuring device identifies all particles of organic and inorganic nature larger than 2 µm.

The key design piece that makes this possible is the metalized polymer membrane (top, page 20) through which the product is passed. The size of the nuclear pore is based on the solution's viscosity and size of the particles to be examined. The contrast between particles and membrane is optimized for particle recognition through automatic image analysis.

The membrane, once coated with particles, can be analyzed using a Liquid Particle Explorer, which was developed for the identification of particles according to the standards of measuring devices in a cGMP-controlled surrounding. ²

Similar to the method of membrane evaluation described in the USP, microscopic images (page 20) of the entire membrane surface covered with particles are automatically recorded and evaluated. I

The position, length and width of the particles is determined exactly, to the micrometer. The device carries out RAMAN spectroscopic examinations on the particles, and resulting spectra are automatically identified on the basis of the pharmaceutical and customer-specific database.

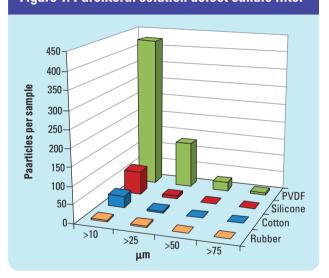
The database was created with RAMAN spectra of material samples. The system can, therefore, also clearly recognize mixtures of materials, such as rubber stoppers or dyed polymers, due to their characteristic spectra. An automatically created report provides the size, identification and spectrum quality as well as the result for each individual particle.

Particle sources at the production level

The search for the source of the impurification begins when a process exceeds the specification of the acceptance quality level. Currently, most end users responsible for production rely on their experiences. They have known their process for years and can, therefore, eliminate the contaminating source with a few trials and errors. For example, filter candles are replaced or stoppers are checked in regards to their particle load. This method may suffice; however, it often takes days, and some errors can't be contained and may disappear after some time.

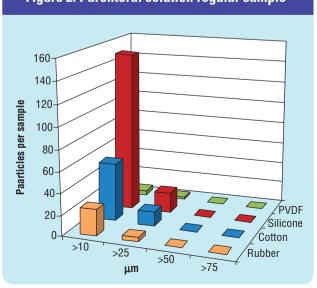
Only a full analysis can provide information on the effect of the measures. External laboratories are rarely consulted due to the long time period between test and result, and because of the small statistical relevancy of a particle's

Figure 1: Parenteral solution defect candle filter



Resulting table of parenteral solutions, main source PVDF, and historical particle spectrum.

Figure 2: Parenteral solution regular sample



single spectroscopic examination.

Identification of foreign particles from parenteral solutions supplies direct information regarding the impurification source. ^{3, 4} Different sources during the production process are all considered—personnel, clothing, containers and caps. The established database contains 500 RAMAN spectra of substances, and end users may add new material samples to the database within minutes.

Examinations completed with the Liquid Particle Explorer enable a statistically relevant and comparable conclusion about the particles' chemical composition in a relatively short time. The main impurification sources can be detected on the basis of the particle spectrum of a product

Figures 1 and 2 show the results of the measurements of a product of two different batches. The main contamination source of batch A is polyvinylidenfluoride (PVDF). In a secondary database, PVDF was identified as part of the membrane of a candle filter. A significant increase of the yield was achieved through the removal of the candle filter (a typical sample is shown in Figure 2).

Continous identification = clean intellingence

Continuous monitoring of particle composition is preventative quality assurance which, in turn, increases product safety.

To guarantee permanent protection, additional samples and rejects of this product and current batches were continuously examined. In the beginning, less noticeable impurification sources were detected and minimized.

Subsequently, some particles remained in the non-visible area and were assigned to this process. The specification of the product was extended through the historical as well as through the product- and process-specific particle ID distribution.

Deviations from the historical particle profile can, therefore, be quickly detected. Total particle load count can be constant using a particle counter, but the composition of the particles may vary significantly. The identification of a new particle type makes latent impurification sources visible before the damage is done.

The FDA also recommends characterization of foreign particles for the rapidly growing number of inhalers. Analysis of the particle composition can prove that no contaminating particles are present in these products.

Another application field is the analysis of particular drug delivery systems. For quality assurance purposes, analysis of the particles' material composition is exact to less than a micrometer and provides exact information about the particles and the production processes.

continued on page 20

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membrane with nuclear pores, ranging from 0.2 to 8 μ m, is metalized and set

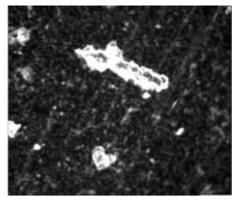
Based on determination of layerthikness parameters, release time of the active substances are reliably determined. Further, RAMAN examinations provide reliable information about the potency of such samples, especially after calibration to the active substance.

Effective downtime reduction

Through the statistically relevant result of particle measurements, the main impurification sources can be reliably detected within minutes. The source can then be removed quickly through cooperation between the quality assurance and production departments.

Liquid Particle Explorer technology can be used directly in production, reducing the time required for transport of samples and subsequent results. Establishing a customer-specific, secondary database will quickly provide information about the materials used in the process.

After the result of the identification (for example, of 50 particles, > 25 µm of blue polypropylene), only the blue screw caps made of this material are considered. Even if the result during the detection of cellulose fibers points to several sources—such as paper, cardboard and wipes—the number of possibilities is drastically reduced.



Microscopic images of the membrane with particles (white); below, the same picture after image recognition.



Process knowledge

Through continuous monitoring of particle composition, latent particle sources can be detected before serious damage occurs, increasing product safety and reducing the number of batches restricted for approval.

This process is especially profitable for the production of drugs made of valuable active substances that can only be processed with great difficulty. In the long run, each particle-sensitive production profits from monitoring the particle identification.

The execution of particle composition measurements provides the drug manufacturer with a good starting basis for discussions with the authorities. Additional examinations of the particle composition are not mandatory, but authorities honor the fact that the manufacturer is seriously interested in an explanation of an occurred "out of specification" and has taken the appropriate initiative.

The secure identification of visible product particles, like protein aggregates, can form the foundation for the release of a rejected batch as deviation report. High values can be released directly and, therefore, reduce costs. III

DR. OLIVER K. VALET is senior scientist at rap.ID Particle Systems, Berlin, Germany. Dr. Valet can be reached at: oliver.valet@rap-id.com

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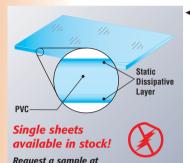
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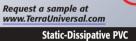
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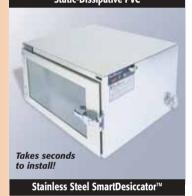
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CleanRooms East Conference: March 8-10, 2004
PDA SciTech Summit™: March 8-11, 2004

Exhibition: March 9-11, 2004

PDA Training and Research Institute Courses: March 10-12, 2004
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This March, CleanRooms Group and PDA are teaming to bring the pharmaceutical manufacturing and contamination control communities the science, technology and regulatory event of the year!

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- EH&S Focus: Cleanroom Facility Decontamination/Decommissioning
- Modular Cleanroom Construction for cGMP Facilities
- Water System Design for Clean Scientific Laboratory Facilities
- New Technology: Higher Parenteral Productivity through Particle Identification
- Cleanroom Design/Construction: Where Does the Money Go?
- Beyond HEPAs: Chemical Filtration for Cleanroom Applications
- Introducing Components to Aseptic Processing Areas
- Determining the Dynamic Wiping Efficiency and Particle Removal Ability of Cleanroom Wipers
- The Growing Impact of Cleanroom Flooring
- Open Forum: Isolators/Gloveboxes Issues and Answers
- Unitizing Manpower to Maintain and Improve Cleanroom Operations
- OSD Manufacturing: Containment in High Potent Compound Processing
- Moving Towards Energy Efficient Cleanrooms and Standard Methods of Testing and Reporting Performance—the LABS 21 Approach
- The Evolution of the Gravity-Free Cleanroom

For a complete agenda including conference descriptions, speakers, times and a list of exhibitors, visit us online at www.cleanrooms.com.

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Venue

2004 CleanRooms East Exhibition / PDA SciTech Summit™ Exhibition Orange County Convention Center 9800 International Drive—Orlando, Florida

Exhibition Hours:

Tuesday, March 9 10:00 am - 4:00 pm Wednesday, March 10 10:00 am - 4:00 pm Thursday, March 11 10:00 am - 12:00 pm

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Wednesday, March 10 6:00 pm - 9:00 pm

Universal Studios

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There's something for everyone at CityWalk! 2004 CleanRooms East / PDA SciTech Summit™ is pleased to bring attendees, exhibitors, speakers and guests to Universal CityWalk, Orlando's hottest spot for entertainment—a dazzling 30-acre entertainment complex where you can experience the best of the best in live music! Offering an updated array of live music and dance clubs, this uniquely original entertainment complex will be complemented by a cornucopia of delectably themed specialty restaurants, bars, and cafes. No matter what kind of entertainment you're in the mood for, CityWalk has it all!

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Anticon by Milliken's cleanroom wipers and mops are billed as the cleanest and most absorbent products of their kind, according to the manufacturer. Sterilization for use in the pharmaceutical, medical device and biotech industries is available, as well as pre-saturated wipers with various cleaning solutions. Knit brands include the Gold and Anticon series, while new nonwoven wipers include the Matrix and Captura brands.

Anticon by Milliken LaGrange, GA

www.milliken.com

Circle No. 203

Online system measures endotoxin

Cambrex Bio Science will preview a new online endotoxin detection system that will allow in-process monitoring of fever-causing, gram-negative bacterial endotoxin in water-for-injection (WFI) systems used for production of injectable drugs, medical devices, and other therapeutic products. The PyroSense system automatically and continuosly monitors endotoxin levels in WFI and high-purity water systems. 21 CFR Part 11-compliant host software stores raw data and test results, provides immediate feedback on water quality across a company network, and pro-



vides what the manufacturer claims is an efficient tool for trending endotoxin levels. The company says the new technology moves endotoxin testing from the lab bench to the water loop, and replaces manual collection and testing of samples with an automated process. Consistent testing techniques are achieved using robotics and a snap-in reagent cartridge for replenishing supplies.

Cambrex Bio Science Walkersville, MD www.cambrex.com

Circle No. 201

Portable airborne particle counter



Portable APC airborne particle counters are used for the detection of particulate contamination in controlled environments, or anywhere particulate contamination is a concern. Features include 0.2-micrometer particle sensitivity, ability to measure six size ranges simultaneously, 1 cfm flow rate, and three concentration modes (total particles, particles/m³, particles/L and particles/ft³.

Biotest Diagnostics Corp.

Denville, NJ

www.BiotestUSA.com

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The 2H digital photometer replaces the company's TDA-2G device and offers new features such as flow and optics sensors, integrated HEPA filter on the vacuum pump

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Dupont Contamination Control

Wilmington, DE www.usa.dupont.com Circle No. 206

Battery-operated particle counter

The SOLAIR 5100+ line of laser particle counters use the latest in optical particle counting technology. Devices offer a sensitivity of 0.5 μm and a flow rate of 1 cfm (28.3

> LPM), with a wide dynamic range up to 25 μm. Featuring

a 5.7-inch color backlit touchscreen interface, the SO-LAIR 5100+ is designed to store a large amount of particle count data

from six channels, and data from up to four environmental sensors. Data can be downloaded to a computer or sent to its built-in printer. It can be used as a portable instrument or integrated into a larger facility-monitoring or management system.

Lighthouse Worldwide Solutions

Milpitas, CA www.golighthouse.com Circle No. 207

Bucketless floor mop

The EastSat bucketless floor mop is designed specifically for the cleanroom, and its built-in 52-ounce solution tank

eliminates the need for a bucket and wringer. A trigger mechanism flow control releases cleaning solution on demand or continuously for cleaning up to 5,000 square feet. The mop head is constructed of a durable polyester fabric that is laser-cut and laminated to clean ester foam without the use of glues or adhesives. The angled head cleans hard-to-reach areas, and be attached and removed eas-



ily. Mop head choices include textured for more abrasive action, or flat for standard floor cleaning.

Contec Inc. Spartanburg, SC

wipers@contecinc.com

Circle No. 208

Microbial system

The RiboPrinter microbial characterization system uses genetic information to provide a snapshot for automated identification and strain-level tracking in less than eight hours. RiboPrint patterns characterize environmental isolates, pathogens, control strains, or any bacteria important to the pharmaceutical, personal care and food safety industries.

Dupont Qualicon

Wilmington, DE www.usa.dupont.com

Circle No. 209

Class 10K workstation

The new Class 10K workstation is designed to provide limited HEPA-filtered airflow across double-sided work areas to reduce FM contamination. The product was designed specifically for medical device assembly work, and the

manufacturer claims its workstation is more cost-effect than typical laminar flow benches since it allows for two or four workers per station. Options include electrical outlets, storage cabinets and pneumatic connections.

Gerbig Engineering Co.

New Brighton, MN www.gerbig.com

Lymtech Scientific

www.lymtech.com

Chicopee, MA

Circle No. 213

Validated sterile wipes

Circle No. 210

Facility monitoring software

CIMScan facility monitoring software is designed for simplified monitoring of particle counter instrumentation and

key parameters in critical areas of a facility. The software provides a complete environmental monitoring solution and, according to the company, typically requires no special train-



ing for configuration and use. Parameters monitored include particle counts, filter conditions, airflow rates, electrostatic discharge, temperature, relative humidity and differential pressure. Collected data can be analyzed in real time or linked to an ODBC database or Microsoft Excel program.

Hach Ultra Analytics Grants Pass, OR www.hachultra.com Circle No. 211

Garment tracking system

The GTS Bar Code System, developed in coordination with the company's customers, provides a complete account history report for each garment, from installation to any repairs. It also tracks usage analysis by wearer, department



and distribution point. The system identifies: type of fabric, customer name, when installed, style and size of garment, and history. Reports include: soiled count pick up, inventory usage, package/delivery slip, cancelled items, repairs, and monthly accountability.

Prudential Cleanroom Services

Irvine, CA

www.pcs-clean.com

Circle No. 212

continued on page 26







designed for easy use with a gloved hand.



The company's validated sterile wipes are gamma-irradiat-

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cordance with procedures outlined in Standard AAMI/ISO

11137-Method 1. Each shipment is accompanied by Cer-

tificates of Processing and Sterility. Linear-tear packaging is









www.cleanrooms.com

Benchtop crossflow system

The Sartoflow Slice 200 Benchtop Crossflow (TFF) System is designed around the Sartocon Slice 200 (200 cm2) Cassette. The system includes a Sartorius precision balance, stainless steel Sartocon Slice 200 cassette holder, 500 ml reservoir and integrated magnetic stir plate, disposable pressure transducers, fittings, tubing, valves and SartoWedge PC data acquisition software.

Rooms

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Stainless steel models

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• Cleanroom-packaged vacs

models & attachments



The software collects and provides automatic graphic profiles. The system monitors and automatically controls and records flow rates and pressures, and is designed for scale-up and scale-down process development. Slice 200 cassettes are available in a variety of MWCOs, from 1000 kD to 0.45 µm in PES and 1N NaOH stable non-fouling Hydrosart (stabilized regenerated cellulose). The TFF system's pump has flow rates up

to 2,200 ml/min, making it possible to integrate standard Sartocon Slice cassettes (1000 cm²) or Sartocon Slice Disposable cassettes for seamless linear scale-up work.

Sartorious Corp.

Edgewood, NY

www.sartorius.com

Circle No. 214

Disposable HEPA-filtered collection container



SafePak is billed as the first disposable HEPAfiltered vacuum cleaner collection container designed for potent compound pharmaceutical applications. SafePak lets manufacturers safely collect, handle and dispose of potent compounds

When integrated with the company's CFM 3156 or 3306 vacuum cleaners, SafePak lets users continuously collect materials that are then retained with the HEPA-filtered unit. When full, users simply dispose of the entire container, avoiding potential contamination and exposure.

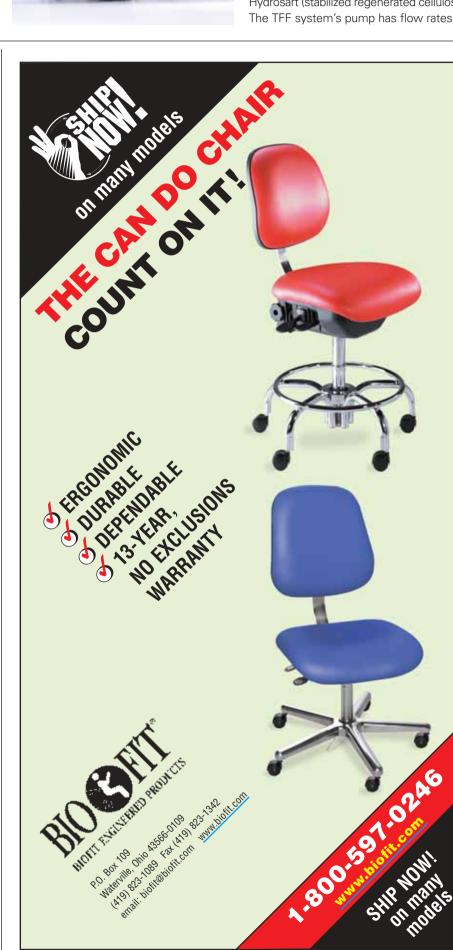
Nilfisk-Advance America Malvern, PA www.nilfisk-advance.com

Sterile alcohols

Circle No. 215



TexShield Sterile 70% Isopropyl Alcohol and Sterile 70% Isopropyl Alcohol with WFI were created to maintain their sterility assurance level throughout prolonged normal use. One-liter and five-liter bottles are recyclable, and the contents can be completely dispensed. Products are packaged under the patent-pending SteriShield Delivery System, which holds the liquid inside an ultra-clean, medical-grade polyolefin bag that does not allow air to be drawn back into the bag when the trigger spray mechanism is



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cfm

26

operated. Testing shows the contents remain sterile for three months after first use.

ITW Texwipe

Upper Saddle River, NJ www.texwipe.com

Circle No. 216

Woven reusables



The WK 3000 reusable protective apparel is woven from 100-percent filament polyester yarn with carbon filters laced into a stripe throughout the material. The durable fabric is designed to repel fluids, prevent particulation, and dissipate static electricity

White Knight Engineered Products Charlotte, NC

www.wkep.com Circle No. 217

Aerosol particle sensors

IsoAir Plus sensors are designed to be compact, rugged and simple to install for troublefree aerosol monitoring. Sensors. say the company, are built to provide outstanding performance in a chemically-resistant, easy-to-disin-



fect stainless steel box. The quiet internal pump makes IsoAir Plus suitable for cleanroom and isolator applications. IsoAir Plus feature 0.5 and 5.0-µm channels for GMP, and has Ethernet as well as 4-20 mA output that exceeds 21 CFR Part 11 regulations. It interfaces with Pharmaceutical Net software to provide advanced reporting features as well as alarm paging for instant responses to particle events. System validation documenting is available.

Particle Measuring Systems

Boulder, CO

www.pmeasuring.com

Circle No. 218

Vaporized BIER

The VhyPer Vaporized H₂0₂ BIER (biological indicator evaluator resistometer) Vessel features multiple VHP and relative humidity set point operating parameters centered on current industry practice, and exposure kill times adjustable for D-value and survival-kill testing. Data can be saved to a network disk via corporate



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Mundelin, IL

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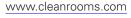


























continued from page 14

filter. While he estimated the leakage amounted to between one to two percent of the air moving through the system, it was energy wasted—and also contributed to contamination buildup downstream in the company's duct work.

To tackle this, Leung found a local supplier, Total Filtration Systems (TFS), to solve the problem. "We wanted to look for opportunities to reduce the bypass leakage around the filters," Leung notes. "One idea was to look at other filter frames and we

discovered TFS, which has a filter frame with an interlocking gasket, and there is virtually no leakage around the frame."

Efficient fans emerge

Another easy fix for cleanroom engineers is to use energy-efficient fans and air-handling equipment. Sounds like a no-brainer, but figuring out which fan is most efficient for a need can be a real chore.

Choosing a fan that is more efficient should be as easy as picking which one

uses the least energy when moving the same unit of air against the same static pressure. The problem is, manufacturers perform their own efficiency tests using a wide range of test conditions.

"Many companies are using fan filter units, and it turns out they are not very efficient as in a big open space above the cleanroom plenum system with big fans feeding it," says Tschudi. "In general, the fan filter units were way down in the efficiency; and one of the things we want to see in this next go 'round is whether any of them are getting close to the efficiencies of the large system."

Something that would help cleanroom managers make better decisions about FFUs would be efficiency numbers that can be compared easily. For that reason, the IEST is forming a working group whose task will be to create testing standards for these units.

"Some of the data out there is extremely hard to justify and it is hard to duplicate," says Monroe Britt, manager of research and technology for Clarcor Air Filtration Products, who will chair the working group. "So, the idea was to have a common test standard that everyone could reference and compare the claims of each of the fan filter unit manufacturers."

The informal effort started a couple of years ago with the recognition that an apples to apples comparison of FFUs was needed by cleanroom managers to let them make more informed product decisions.

The next meeting of the group is scheduled to take place in late April in Las Vegas at ESTECH. Britt hopes to create a committee that includes participants from end users and cleanroom engineers to product manufacturers and consultants.

The group hopes to iron out standard test conditions that include air flow (in CFM), energy consumption, noise, air flow uniformity and vibration. Realistically, the standard may take two years to complete, though Britt hopes to draw a cross-section of the industry to aid in creating a meaningful standard.

Tschudi, a member of the IEST working group, sees the standard as one more player that can widen the amount of solid, tested, verified information about creating energy efficiency in cleanroom HVAC systems.

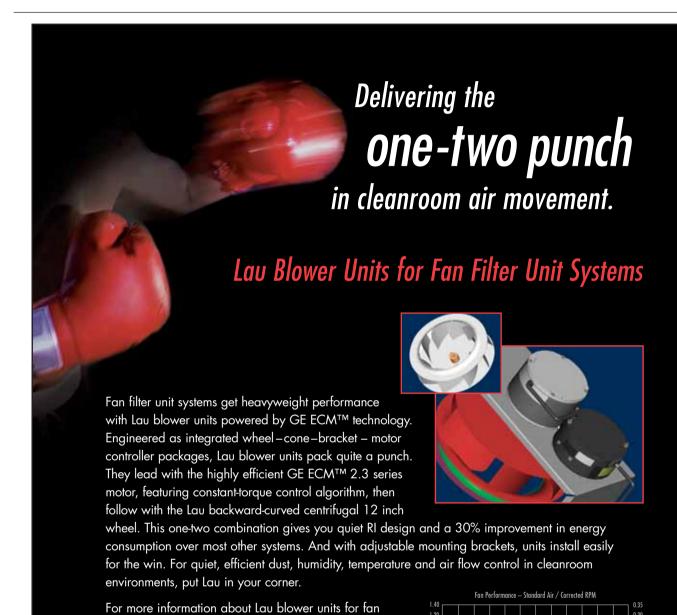
Meanwhile, he and the other researchers at Lawrence Berkeley continue the search for more companies willing to share data about their cleanroom energy consumption and to share what Lawrence Berkeley learns with other interested parties.

"To our knowledge, there is no other data like this available, either on an industry basis or a national basis," says Tschudi. "When people see the range of results we have, they begin to wonder where they fit in. This is how we get their interest—to have us come through their operation and do the benchmarking."

It's the kind of win-win situation Tschudi hopes more and more companies will take advantage of in the coming years.

If you or your company would like to contact Bill Tschudi to add data to LBL's benchmarking project, contact him at: wftschudi@lbl.gov.

CHRIS ANDERSON is a special correspondent to CleanRooms magazine based in Portland, Maine. Anderson can be contacted at: canders1@maine.rr.com





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eye on Asia

continued from page 5

Consumer and business confidence was shaken by the outbreak of SARS and the uncertainty surrounding the war in Iraq during the first half of last year. A slump in private investment and consumption last year hampered the nation's economy, as measured by GDP growth, said Lin Jin-lung, a research fellow at Academia Sinica.

The SARS outbreak kept most consumers at home and resulted in negative economic growth of 0.08 percent during the April to June period, according to Directorate General of Budget, Accounting and Statistics' (DGBAS) data. But the nation's economy began to regain its footing in the second half, following the recovery of the world economy, and especially the solid recovery in the U.S. As a result, investment by both local companies and multinational firms in Taiwan amounted to some \$21.3 billion for the whole of last year, after local businesses felt confident about investing in new plants and equipment.

Matsushita throws down \$1.2 billion for new fab

UOZU, Japan—Matsushita Electric Industrial Co. Ltd., best known for its Panasonic brand, is investing \$1.2 billion to build a new semiconductor facility aimed at making chips for DVDs, digital TVs, mobile communications equipment, memory cards and network-related equipment.

Officials say that construction is set to begin in May with production aimed for the end of 2005. The new facility will be located at its Uozu plant in the Toyama Prefecture of Japan, the

The facility will be equipped with a 90-nm production process for 300-mm wafers, with plans to eventually upgrade the production processes to 65-nm. The latter number refers to the smallest gap or feature that can be created on a chip. While most commercial semiconductor plants currently use advanced 90-nm processing, by upgrading to 65-nm processes, the company will be able to make the chips physically smaller. This allows more chips to be made from each wafer, increasing production efficiency. Additionally, smaller chips meet demand for smaller electronic

The facility will eventually have a capacity of 7,500 wafers a month, Matsushita said. Investment in the expanded production of advanced system LSI (large scale integrated circuit) chips meets with its goal of targeting the digital home electronics market, the company said.

REPORT: '04 will be banner year for China chip making

SHANGHAl—Driven by the recovery of the global semiconductor market and soaring demand from domestic electronics manufacturers, China's semiconductor foundry industry grew rapidly in 2003, setting the stage for the country to play a bigger role in the global chip-making business this year and beyond.

China's semiconductor foundries achieved a total monthly production capacity of more than 100,000 wafers in 2003. Four Chinese foundries are now making products on 8-inch wafers, with two others planning to start this year. The combined capacity of these fabs will exceed 170,000 wafers per month by the end of the year, according to a report from iSuppli, a research marketing firm based in El Segundo, Calif.

The expansion of the global wafer industry is dominated by growth in Asia, and China is the fastest growing country in the region. China's share of worldwide wafer capacity will grow to 9 percent in 2007, up from 4 percent in 2003, iSuppli predicts.

The major factor behind the rise of China's foundries is the unfolding recovery in the worldwide semiconductor industry. Following estimated growth of 13.9 percent in 2003, global semiconductor revenue will rise to \$208.8 billion in 2004, up 17 percent from \$178.4 billion in 2003, according to iSuppli.

Meanwhile, the amount of semiconductor manufacturing that integrated device manufacturers (IDMs) outsource to foundry providers will continue to rise this year. iSuppli predicts the worldwide foundry business will swell to \$14 billion this year, up 22 percent from 2003.

Chinese foundries still cannot compete effectively with their leading international competitors, either in production volume or manufacturing technology. But the immense potential domestic market is a major enticement for IDMs to outsource portions of their manufacturing to Chinese foundries

China's foundry growth this year will be propelled by orders for chips used in mobile phones, PCs and automotive electronics. Production of all these products is booming in China.

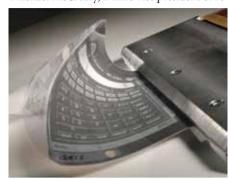
Growth in China's foundry market is being led by the country's major 8-inch wafer manufacturers, all of which plan to increase their production capacity this year. Semiconductor Manufacturing International Corp. (SMIC) operates three 8-inch fabs in Shanghai that have a combined production capacity of 60,000 wafers per month. SMIC expects production capacity at its Shanghai facilities to reach 85,000 wafers per month by the fourth quarter.

In December, SMIC acquired Motorola's 8-inch fab in Tianjin. SMIC intends to transfer its older CMOS technology to the Motorola fab, while focusing its Fab 1 and Fab 2 facilities in Shanghai on advanced technologies.

Paperless era from page 1

of E Ink Corp., a privately-held company based in Cambridge, Mass.

"Philips is our manufacturing partner," says Michael McCreary, E Ink's vice president of re-



The flexible active-matrix display uses Philips Electronics' utlra-thin backplane with organics-based think film transistors combined with F Ink's electronics ink front plane.

search and development. "We've been working on this with them for some time, and from a cleanroom standpoint, all of the existing equipment is based on rigid infrastructure. But this will spawn the introduction of flexible, organic transistors. This will enable new manufacturing applications."

The cleanliness level, McCreary says, will not be any different than it is for a semiconductor operation. "The only issues are temperature because too much heat will melt, burn or deform the plastic," he adds. "So, you need low temperature processes, and you're getting away from doping silicon."

The display—the next generation of an existing E Ink technology—consists of a front portion that switches according to electronic signals and a back component circuit made of transistors that control each individual pixel that composes the display.

To function, each pixel needs a circuit behind it, made of transistors. To make electronic paper, the transistors have to be made on a very thin and flexible substrate.

The first generation was a thin-film transistor with a traditional glass backing, which is rigid, McCreary explains. That display is made with a metal foil back pane, which is about three-tenths of a millimeter, or five to 10 times thinner than a traditional LCD.

The other integral part of the display, he says, is the electronic ink, which is made up of millions of tiny microcapsules about the diameter of a human hair. Each microcapsule contains positively charged white particles and negatively charged black particles, which are suspended in a clear fluid.

When a negative electric field is applied, white particles move to the top of the microcapsule where they become visible. This makes the surface appear white at that spot. An opposite electric field pulls the black particles to the bottom of the microcapsules where they are hidden. By reversing this process, the black particles appear at the top of the capsule, making the surface appear dark at that spot.

Philips, Europe's largest maker of consumer electronics and lighting, has already shown prototypes of a glass-based E Ink display, which it says will be in stores later this year. The price has not yet been set, but Philips said it would be in the range of current thin glass models. The new range will use much of the manufacturing technology already being used to make glass-based thin screens, but is more adaptable to different surfaces, such as the dashboard of a car. III



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Your wiper purchase is one to take seriously, since microbial and particle contamination can lead to expensive loss of product. But no one wiper is right for all cleanroom applications. Choose one that is suitable for use in the ISO Class specification of your work environment, and one that has the properties and features essential to your cleanroom applications. Here's a sampling of the latest wipers available.

Low-cost polyester

The Novation line of private-label supplies includes a low-cost, high-quality 9x9-inch polyester wiper. The product is laser cut, laundered, doublebagged, and available in various quantities. The company's catalog also offers a diverse mix of



wipers from other leading manufacturers.

Cintas Cleanroom Resources

Cincinnati OH

www.CintasCleanroom.com

Circle No. 220

Sterile polyester/cellulose

Comprised of durable hydroentangled polyester/ceullu-



lose, and sterilized using gamma irradiation, Sterile-Sorb nonwoven wipers are designed for general purpose cleanin sterile environments.

The extra-absorbent fabric features low levels of particles and extractables. Wipers, available in 9x9-inch and 12x12-inch sizes.

are packaged in peelable outer bags and linear tear inner bags. Embossed lot numbers on both bags ensure lot traceability, and sterile validation reports are available upon request.

Contec

Spartanburg, SC www.contecinc.com

Circle No. 221

Nonwoven additions

Anticon by Milliken has added nonwoven wipers to its portfolio, including the Matrix and Captura brands. Matrix



is designed to provide what the manufacturer calls "unparalleled" wiping performance, while the Captura family are billed as the most sorbent nonwovens available.

Anticon by Milliken

LaGrange, GA www.milliken.com

Circle No. 222

Thermally-sealed wipers

ThermaSeal 60 hot-cut polyester wipers are for all-purpose cleaning in critical environments. Thermally-sealed edges provide fiber control. Products are available in

9x9-inch and 4x4inch sizes, and feature what the manufacturer claims is good absorbency, wiping efficiency and abrasion resistance. Recommended for ISO Class 3-5 cleanrooms where fiber control is essential, ThermaSeal wipers are produced



and packaged in an ISO Class 4 cleanroom laundry. Double-knit construction is designed for durability and allowing for rigorous wiping with minimal release of particles and fibers.

ITW Texwipe

Upper Saddle River, NJ info@texwipe.com

Circle No. 223

Validated wipes

Validated sterile wipes are gamma irradiated with Cobalt-60 to a sterility assurance level of 10⁻⁶ in accordance



with procedures outlined Standard AAMI/ISO 11137-Method 1. Each shipment is lottraceable and accompanied

by Certificates of Processing and Sterility. Linear-tear packaging is designed for easy use while wearing gloves.

Lymtech Scientific Chicopee, MA www.lymtech.com

Circle No. 224

Testing for quality assurance

The line of cleanroom wipers from Berkshire is subjected to test properties that contamination-control professionals identify as most critical. To ensure cleanliness, a tested wiper is "washed" in water using a biaxial shak-

er for five minutes. Particles released into the water are counted by a liquidborne particle counter. By dividing the total number of particles released by the area of the wiper, results are expressed as particles ≤0.5 µm per square centimeter of wiper. Special tests are also conducted for



absorbency, specific absorbency, and time to half-sorption. Purity testing includes extractables and metallic

Berkshire Corporation Great Barrington, MA www.berkshire.com



Circle No. 225



February 2004

















Cleanroom experts from page 1

results of a computational fluid dynamics simulations of IBM cleanrooms where two plaintiffs, Alida Hernandez and James Moore, worked. Both were employed at IBM's disk drive and printed circuit board manufacturing facility in San Jose starting in the late 1960s and into theearly 1970s. Hernandez and Moore allege that exposure to chemicals at IBM later caused their cancers.

"We are going to bring the focus of the case back to where it belongs: on these two specific plaintiffs," IBM attorney Robert Weber told the Mercury News of San Jose. "We will demonstrate the total lack of merit to any claim that the doctors and nurses of IBM committed fraud on their fellow employees."

The elimination of the cleanroom simulation accounts may be a small, but significant victory for IBM, as its attorneys put plaintiff witness Robert Morris through six days of tedious cross-examination in an effort to minimize the data, saving it did not accurately represent the IBM cleanrooms in which Hernandez and Moore worked.

Morris, a cleanroom ventilation expert who testified that IBM did not supply cleanrooms with fresh air, was hired by the plaintiffs to help create virtual reality models of cleanrooms to simulate airflow and working conditions.

Another witness for the plaintiffs, Scott Reynolds, an expert in computational fluid dynamics, would have also endured relentless cross-examination. Defense attorneys, however, agreed to not bring in their experts to refute the virtual reality models on the condition that the lawyers for the plaintiffs did not present what would have been rather damaging testimony.

"This is a very political thing," says Reynolds, an engineer at Binghamton, N.Y.based Computer Aided Engineering Solutions. "They put an awful lot of effort in trying to keep me off the stand."

Reynolds and Morris were also going to provide testimony on wafer spinners in cleanrooms. The machine spins substrates at high revolutions to evenly coat such noxious chemicals as isophorone, acetone, formaldehyde, xylene, ethyl, and amyl ketone on wafer surfaces. But because exhaust ports are on the outer edge of the wafer spinner, fumes are not completely evacuated from the chamber, and Morris and Reynolds concluded that fumes—trapped in the vortex created by the spinning wafer—flow upward of right into a worker's breathing space. [See related story, page 1]

That kind of testimony, Morris says, "scared IBM. They have been trying to block that from coming in, so lawyers from both sides negotiated," says Morris, president of Flow Safe Inc., a Denville, N.J.-based manufacturer of airflow and control systems. "But what really happened is they threatened to drag it out. They said 'Hey remember what we did to Morris for six days? We'll drag it out with Reynolds even longer.' And that would have bored and confused the jury."

Still, according to reports, IBM has conceded some key points to the plaintiffs.

The company has acknowledged it recorded early health complaints, including abnormal liver tests in Hernandez's case and 'profuse nasal discharge" in Moore's. IBM data sheets indicate that overexposure to acetone causes systemic liver damage. Hernandez testified she sometimes used more than a gallon of acetone a day. A note in Moore's medical record specifically links his condition to chemical solvents.

Years after the complaints were logged, Hernandez developed breast cancer and Moore developed non-Hodgkin's lymphoma. The plaintiffs argue that IBM covered up the their health condition causes. Furthermore, they contend that by sending them back to work with cancer-causing chemicals, IBM caused them to become sicker: a violation of state labor law punishable by punitive damages.

IBM has admitted it did not warn Moore or Hernandez that their health problems were linked to workplace chemicals. But the company's attorneys have maintained such warnings would have been misleading because their health problems were caused by other factors. These admissions mean that the crux of the plaintiffs' case has revolved around persuading the predominantly female jury—only one of the 12 jurors is male—that IBM must have known Hernandez and Moore were suffering from systemic chemical poisoning when they worked at the Cottle Road plant.

Unfiltered from page 38

neutralized? These lab details must be understood before the correct waste system can be selected.

Installing a separate waste system is much more costly, involving digging up an existing floor and installing an additional plumbing system.

Sharing space

In programming for a new lab, the amount of material that needs to be stored is always carefully examined. Various future users of the new lab often name the same items, creating numerous redundancies. When these are identified, shared storage space can be created between different labs. The result greatly increases space efficiencies.

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LEAFORD BLEVINS is a senior laboratory planner with HDR in San Diego. He can be contacted at: lblevins@hdrinc.com



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References and decision-making

This is also a good time to check references

for your three finalists before you narrow the field, in case one of them may need to be replaced. If your homework is done properly and thoroughly, this step can save von future grief

Have a list of prepared questions ready to interview the references. Keep in mind that since the references were given by the supplier, you should expect good reviews; this is time to read between the lines and use open-ended questions.

You'll need to assemble an internal review team that can decide on the finalists and the ultimate winner. There are several qualifications required of the team collectively and individually. Collectively, members should have a range of minimal to expert knowledge and experience with cleaning and contracting, and have the time available to review, meet and make recommendations.

Each member should be able to com-

mit to 40 to 80 hours over a two-month course. Remember, you're operating under a timeline; you want to hire a professional service; you need to perform as one in a timely manner

Individually, members don't necessarily need to be experienced so long as one or two members are. In fact, the team may want someone completely inexperienced to ask the simple questions that others on the team may take for granted, or are too embarrassed to ask. This inexperienced person could be the objective voice that determines whether the finalists have the same management chemistry as your company.

Options give you the ability to review/continue with the new vendor or opt out after a given period of time. If you're satisfied, you won't have to go through this rigorous process again for several years.

After references have been checked, narrow the selection to two or three finalists and arrange interviews. Ideally, arrange the interviews at the contractor's site; and while the team is there, speak with the office and support staff. Look over the supplier's warehouse, training facility and building in general. The team will see and hear quite a bit about the company before the interview.

Compile all the proposals, interviews and team notes. Meet as a team to finalize an agreement or discuss concerns. Remember that typically, the contract will be at least for one year and possibly more. It's a very expensive process to select and hire your choice, and it's almost double that cost to have to re-do the work if not done properly.

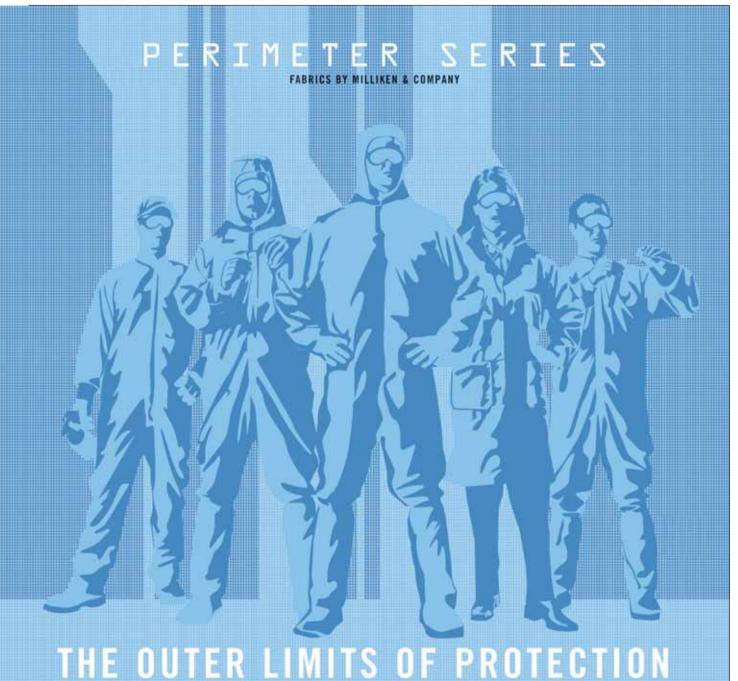
Awarding the contract

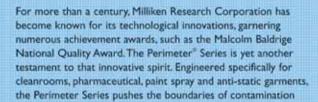
Once the decision has been made, it is time to award the contract. Your team may have decided on a one-year or multiple year award, with or without options for renewal.

Options give you the ability to review/continue with the new vendor or opt out after a given period of time. If you're satisfied, you won't have to go through this rigorous process again for several years.

Implement the contract

At the implementation stage, you may be turning over the project management to





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Checking it twice

Before setting off on the search for the perfect cleaning supplier for your cleanroom, you must "know thyself." Use the following checklist to capture all the information that will be critical to creating a completely thorough RFP. When this checklist is used properly, it will capture the broader picture for the team responsible for all the cleanroom areas involved:

A. Controlled areas

Square footage Classifications Entry/Exit (airlocks, behavior, personnel load) Gowning requirements Cleaning materials and equipment requirements Cleaning methods (Expertise required) Testing methods

B. Budgets

Past three years **Supplies** (cleaning, equipment, what is and isn't included) Gowns Labor Support staff/ Supervision/ Management Bonuses/ Incentives

C. Policies and procedures

Appendix requirements Routine monitoring Qualification (media fills, gowning, technique) **Exception reporting** and corrective action

the Operations or Facilities departments; but the overall success will depend on the performance on both sides over an

Make sure all processes have been determined, documented and, most importantly, supported by all involved. The three basics steps are orientation, turnover of operations and performance review.

Orientation. New staff (technicians, supervisors, management) includes internal and external employees. Make sure all introductions have been made, in person, and a contact list is given to everyone involved in the project.

This list should provide the primary and back-up personnel for routine and emergency situations. The best assurance and validation of your selection will come in emergency situations. The best way to prepare for emergencies is to have a documented program for both groups-internal and external. Keep in mind people take vacations and other leave time—but systems do not. Have qualified back-ups that know the systems in place.

Turnover from current staff to contractor. Make sure all internal staff is in support of turning over the keys and responsibilities to an outside service. This will not guarantee success, but will sup-

Orientation is the time to ask questions, such as, "who does what and when?" Play out scenarios, review inspection logs and documentation requirements one more time. It's difficult and expensive making and receiving phone calls at 7 a.m. when a team member is looking to correct incomplete documentation that's keeping a production line from starting.

Check in daily the first week and week-

ly the first month to work out any bugs or misunderstandings. Correcting simple issues early on is a grand investment in future success.

Performance review

Assure that mutually understood inspections, expectations and reviews are in place. The team is responsible for the operation and success of this project; you write the rules, roles and responsibilities and there should be no surprises at this

Daily logs and records should be measured in terms of completeness, and room inspection reports should be a part of this review. A weekly tally should be forwarded to the person in charge along with the cleaning supplier, and then reviewed.

After a month or so, reduce this review to monthly and then quarterly. Many companies make the mistake of completely turning over the responsibility to the vendor. While competent, outside service providers need to know your expectations on a regular basis to support your objectives. This includes budget reviews, overall performance as well as anticipated changes to the program.

If you have a desire to contract an outside cleaning service, now you know how much work is involved. But when all is said and done, the selection process is the easy part. The management/partnership, as in all relationships, is the hard part. **...**

GREG JONES has been involved in pharmaceutical and medical device operations, including several start-ups, for 25 years. He works for Porter Industries Inc., based in Ft. Collins, Colo., and can be reached at: gjones@Porterindustries.com

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Spin coat design from page 8

problems start to arise, Reynolds says.

"There is a trap around the perimeter that catches the fluid that flies off the disc," he explains. "This clogs the drain lines, and workers would have to push a wooden dowel to push the gunk out of the lines. Then there is an outer tray that serves as an exhaust plenum. That outer tray is designed to capture the fumes, but some of that gunk flies off, blocks that up. It was a very bad design,

and there did not appear to be any effort to isolate the product and the chemicals being applied to the product from the people."

The most alarming aspect of the design, Morris adds, was the unavoidable law of

"Fumes are trapped within the spinning substrate, and air is spinning with it and creates a vortex. It was like a tornado," he explains. "At that kind of RPM, the fumes get caught in the eye of the storm, but as soon as that machine is shut down, the fumes are released into the breathing zone of the worker."

And the complaints about the fumes in cleanrooms alone should have sparked IBM officials to take actions, Morris says, citing specific Occupational Safety and Health Administration (OSHA) regulations. Morris says he regularly corresponds with OSHA, and in a letter dated April 4, 2001, Richard E. Fairfax, director of compliance programs for OSHA, told Morris that employers are responsible for ensuring that fume hoods are functioning properly and implementing feasible control

measures to reduce employee exposures.

"If an employer discovers, through routine monitoring and/or employee feedback, that fume hoods are not effectively reducing employee exposures, it is the employer's responsibility to adjust controls or replace hoods as necessary," Fairfax wrote, adding that OSHA does not "promulgate specific fume hood testing."

Fairfax continued, "If an employee believes that he or she is routinely overexposed to hazardous substances while work-

'Magical' wafer from page 5

track slightly in the desired direction.

Calculations are simplified by using a vibrating foil on top of the solid unit, instead of vibrating the entire base unit. Wafers can remain floating in buffer storage in cassettes of stacked flexible vibrators, or loaded and unloaded from standard cassettes with a non-contact gripper. The gripper picks them up without touching their surface by a counterbalancing combination of vacuum and ultrasonic forces.

But the gripper does touch the edge of the wafer, as do the side barriers, which are the simplest means to keep the wafer centered on the track. Researchers point out that the contacts serve only to center and guide the floating wafer in the desired direction, so they only touch the outer edge very lightly, leaving very few particles.

"If you need higher precision, wafers have to be aligned by touching the edges very slightly, only to move the wafer on the frictionless surface," Schilp says. "Compared to edge-gripping technologies, the whole wafer surface is supported. Also, in most applications, particle generation is reduced."

Schilp says the system has the advantage of being able to apply even support under an entire ultra-thin 300-mm wafer so it does not sag. Because they are so thin, 300mm wafers can actually wrinkle up, and may have to be flattened back out by another layer of ultrasonic vibration pushing down from the top. The system also cannot be operated at the natural frequency of any of the materials on the wafer.

"It is possible to transport wafers over long distances and store them without any [human] contact," Schilp says. "Wafer cassettes, and the bound capital inside them, can be avoided. Also, people carrying these cassettes are not necessary anymore. Process stations can be connected in a manner that the wafer is not leaving the local environment at all."

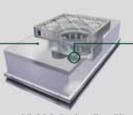
At press time, the Technical University was seeking partners to test and assist in the further development of the technology. "As we are not originally from the semiconductor industry...we do not know all the requirements of the different processes," says Schilp. "The technology is at a state now where we need to find applications and develop specific prototypes for special processes."



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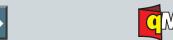












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ing in or around fume hoods, he or she may want to file a formal complaint to the local OSHA area office."

Morris and Reynolds claim IBM cleanroom workers, like Hernandez and Moore, were denied the rights outlined in the OSHA regulations. "We know that the chemicals did get in the room because all the workers I talked with mentioned the odors," Reynolds says. "IBM's objective was to keep the product safe. Employee health was not part of the equation at all."

A semiconductor equipment design engineer who spoke with CleanRooms, on the condition of anonymity, says it has been a wellknown fact for many years that filtration and exhaust systems of spin coaters are ineffective. The devices, he says, are built with one goal in mind: To protect the product.

"It's all specked, but there is no pollution abatement," he says. "There is a complete lack of participation on the management's part in the health of their workers. It is a lack of attention to detail, and due diligence. It's negligence."

When it comes to spin coaters, says the design engineer, the laminar flow theory does not work, and the belief that it does is just another example of the "legend and mythology that goes into manufacturing these machines."

He also says that while there are a lot of spin coaters in the industry that are clean because the process demands it, there are still many machines in operation worldwide that continue to put cleanroom workers as risk.

"We have all these laws on the books to stop stuff like this from happening, but how do these get enforced?," the design engineer asks. "Employers, by law, are supposed to instruct their employees about the chemicals and inform them that they may also call OSHA to file a complaint. So, then you have the whistleblower phenomenon, and they suffer egregiously because of their actions, even though they were encouraged by OSHA. It's a Catch-22, and this is a wake-up call, or at least, it ought to be." III

Mad cow from page 6

- Specified risk material: USDA will enhance its regulations by declaring as specified risk materials skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age, and the small intestine of cattle of all ages, thus prohibiting their use in the human food supply.
- · Advanced meat recovery (AMR): The industrial technology removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material. AMR product can be labeled as "meat."
- · Air-injection stunning: To ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process, FSIS is issuing a regulation to ban the practice of air-injection stunning.
- Mechanically separated meat. USDA will prohibit use of mechanically separated meat in human food.

"Our aggressive response has helped to protect food safety and public health and to help maintain consumer confidence," said Ann M. Veneman, secretary of agriculture, during a recent press conference, flanked by Canadian and Mexican agriculture officials.

And the guidance could not have come at a better time, as more than 30 countries, including Japan—the single largest market

"Our aggressive response has helped to protect food safety and public health"

for U.S. beef—banned the import of U.S. beef products after the mad cow announcement. That ban left 10 percent of U.S. beef without a market.

"It is also critical that we have a consistent trade environment on this continent," Veneman adds. "We have already begun a process to enhance coordination of our approach to BSE. This summer Mexico, Canada and the U.S. worked together to encourage the World Organization for Animal Health—what we commonly refer to as the OIE—to develop a practical risk-based guidance on BSE issues that impact international trade." III

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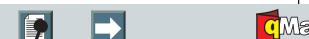
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Designing better clean labs for exact usage

BY LEAFORD BLEVINS

When you're moving forward in the design for a new construction or retrofit of a biotechnology lab, the key to success is fully understanding the exact usages that lab is going to have during its lifespan. Once that's in place, the selection of the most appropriate design resources should be elementary.

Major cost savings are achieved when this thorough understanding of lab usage is applied to six key design areas:

- Floor plan layout;
- Space volume;
- Finishes and furnishings;
- · Control room placement;
- · Waste systems;
- · Shared spaces.

Achieving efficient space

The most economic floor plan layout is a modular design. Biotech labs often work best when designed in a regular grid pattern, with each module about 10 to 12 feet in width. Understanding the lab technicians' exact needs will determine whether this size is appropriate.

The lab should be about three modules deep, or about 30 feet from the entrance to the room's far side. A lab that approaches 35 feet in depth has the greatest design efficiency, allowing for a 20-foot bench with double-loaded end passages at either end of the island.

Reducing space volume

Volumetric economy in a lab is reached when spaces are designed to the lowest height possible. Taller, higher spaces are more costly because the overall area for painting is increased; and, in the long run, the larger volume of air requires more changes.

Early understanding of which piece of equipment will be needed and where it will be located allows the floor-to-ceiling height of certain areas to be minimized. A lower ceiling (a minimum of nine feet) can be placed over areas where no equipment will be located, as well as over aisles and corridors.

Designing the lab spaces to be as small as possible lowers the total volume of space that needs to be conditioned and illuminated. Overall construction and operations can be reduced significantly. Again, knowing which functional areas can be reduced requires a clear picture early in the design as to how the spaces will be used.

If a multi-story building is being retrofitted for lab spaces, keep in mind that upper floors do not have the same floor load-bearing capability as do lower floors. Activities requiring heavier loads should be placed on the lowest floors to avoid costly structural changes. Knowing which biotech functions in the lab will necessitate the heaviest equipment is critical to this decision.

Editor's note: With CleanRooms East 2004/PDA SciTech Summit taking place next month in Orlando, Fla. (March 8-12), much of our editorial concentration has been geared toward contamination control in life sciences facilities. A majority of our technical coverage has been geared toward production and manufacturing areas, with little emphasis placed on the importance of the clean laboratory space; specifically, in the biotechnology arena. Fully understanding the laboratory's evolving role in biotech's growth, HDR's Leaford Blevins offers a few guidelines for getting the clean lab that suits your facility's specific need.

Selecting finishes and furniture

Appropriate finish and furniture selections in lab design include flooring, caseworks, lab tops and fixed equipment. Each has several options from which to choose. The final specification relies on the precise level of durability and cleanliness needed in the new lab.

Flooring. In lab design, the typical selections are from vinyl, VCT or epoxy flooring. VCT is the least expensive, seamless vinyl is the next costly, and epoxy the most expensive. It's important to avoid over-specifying flooring and wind up buying a more expensive flooring product than needed. Unless a very high level of cleanliness is required, VCT flooring is totally acceptable and much easier to maintain and repair.

Casework. Possible selections for cabinetry include plastic laminate (the least expensive), metal, or custom wood products (the most expensive). Because frequent changes are made to its floor plan layout, the typical commercial lab's life span is usually not long enough to justify more than plastic laminate caseworks.

If it's known early on that the lab's floor plan needs to be flexible, metal can be the best casework selection. Metal casework is more easily reconfigured, can be sent out for repair or repainting, and can be an economical selection depending on the need for longevity.

Wood casework can be the best selection for a lab in a campus setting, for example, where a warm-looking, attractive lab is appealing. Wood is also a good selection for labs in which the same group of scientists and technicians will be working for long periods of time. Wood, however, is relatively difficult to repair compared to plastic laminate and metal, so it may not be the right selection depending on your level of use and abuse.

Lab tops. Plastic laminate, epoxy and stainless steel are the selections for laboratory tops. While plastic laminate is not as chemical-resistant, it may be the best and most economical selection for a microscopic lab that does not heavily use chemicals. Epoxy is available in a range of thickness; it's important to know that a 3/4-inch epoxy is just as durable but less expensive than custom metal.

In cleaner spaces, stainless tops are often the best choice, with the 304 stainless being the most common selection. Unless there is need for high resistance to acid materials, it's unnecessary to specify the more expensive 316 stainless.

Fixed equipment. Fume hoods may be composed of metal or fiberglass. The latter is much less expensive, but if fume hoods are subject to high abuse and expected to have a long life span, fiberglass is often not the best selection. If the lab, however, has lower usage or is occupied by a staff of highly trained technicians, fiberglass may be used. In a student lab, for example, where many different people are using the space, a higher grade, metal fume hood will have greater durability.

Lab sinks are generally either drop-in stainless steel or epoxy. Either can be fitted to any casework top; however, it's important to specify a high-usage product only when it's absolutely necessary. The stainless sink is offered in the less-resistant 304 or the more durable 316 versions. The 304, while less resistant, is also less expensive and may be appropriate if the new lab will not be using corrosive materials.

Use low-population areas

To avoid the re-rating of corridors, temperature control rooms are best placed in lab areas that will be sparsely populated. These rooms include freezers and walk-in incubators that can be built into a biotech lab. Various surface material choices are available for enclosure, but use stainless steel only if necessary for durability. Placing a cold room along a corridor that is heavily used may require a fire-rated door and special access doors, so this approach should be limited. Such rooms are better placed off corridors that don't require a rating, or in hallway areas with relatively low traffic.

Disnosina waste

Many labs have separate waste systems; however, in an existing building that's being converted, a neutralization tank at each sink, which allows lab waste to go into the normal waste system, may be suitable.

The question of how much space the tanks will require, and if you can afford it, must be examined. What is the nature of the material that will go into the system? Can it be

continued on page 31





















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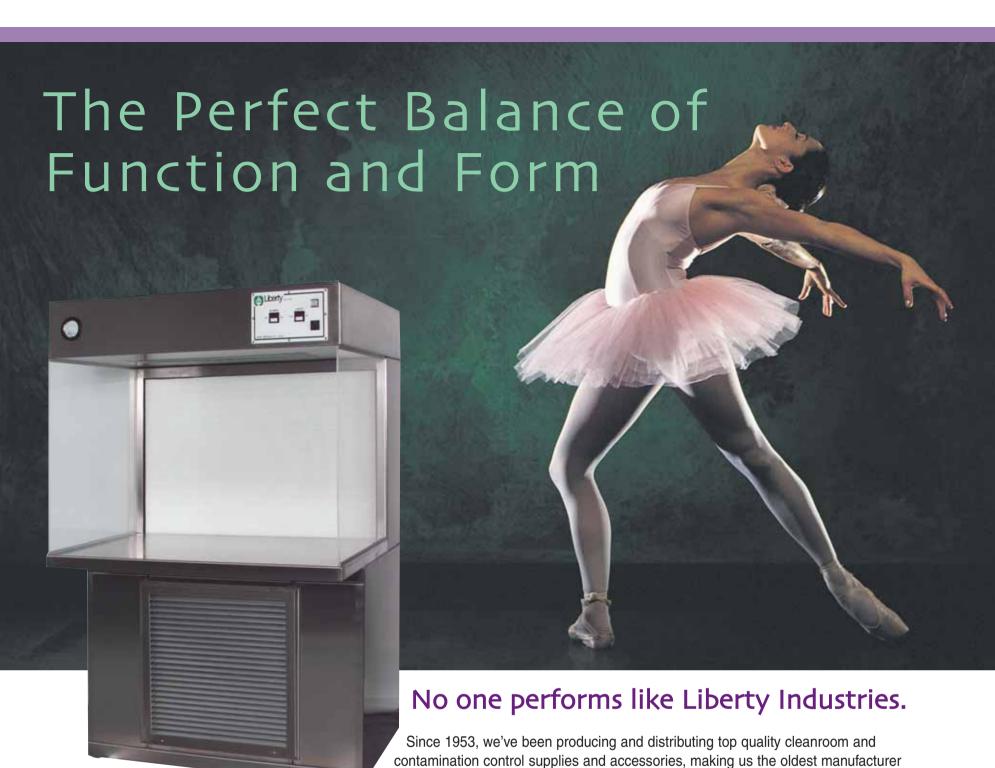








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