Editor's Note: This article was inspired by The Microbiology Webinar Series, "How to Automate Your Micro Lab." The event, held Nov. 8, featured Mark Carter, general manager of the Silliker Food Science Center, and Pascal Yvon, Pharm.D., MBA, CEO of AES-Chemunex Inc. To review the entire Webinar, visit www.foodquality.com, www.pharmaquality.com or www.aeschemunex.com.

AUTOMATION JUSTIFICATION

A PUSH OF A BUTTON CAN MEAN INCREASED PRODUCTIVITY, QUALITY RESULTS, SAFER LABS AND IMPROVED EFFICIENCY

COVER STORY BY **PASCAL YVON, PH.D., PHARM D.**

NOW MORE THAN EVER, THE FOCUS OF MICROBIOLOGY LABS is to continually find new ways to increase productivity, enhance the quality of test results, increase employee safety and, of course, minimize budget expenses. Automation is an option some labs are using to achieve all these objectives.

Basic microbiology lab tasks such as media preparation and dispensing, sample preparation and temperature monitoring are highly repetitive, time-intensive and tedious activities that could be completed easily by automated equipment. But in an era when microbiologists (and all corporate personnel) are pressured to do more with less, how can lab managers justify the purchase of automation equipment to top management?

The simple answer is to identify and evaluate all the potential benefits that such capital expenditure will deliver to the company's bottom line. Lab managers will want to consider numerous factors including how the purchase of lab equipment will increase employee productivity and safety, enhance the efficiency and standardization of lab procedures, and improve the quality and reliability of test results.

Some questions to consider include:

Increasing productivity and employee safety

- How much lab time will be freed up by automation, thereby allowing lab personnel to focus on higher-level activities?
- What business opportunities are lost by staying with manual methods?
- Where can automation improve workplace safety and reduce on-the-job injuries?

• How will it improve employee morale and job satisfaction?
• In what ways will automation help lab managers do more with the same number of people?

Enhancing the efficiency and standardization of lab procedures
• How will automation streamline lab practices and operations?
• How can automation standardize operations?
• In what areas can automation reduce waste and material expenses?
• Where can automation reduce or eliminate delays or bottlenecks?

Improving the quality and reliability of test results
• How much will automation enhance the speed and reliability of test results?
• How will automation improve traceability and data management in the microbiology lab?
• How will the availability of comprehensive statistics on lab activities help managers with trending and planning?

Next, lab managers will want to quantify these benefits in dollars. For example, if lab injuries from dispensing hot media or glass breakage are problematic, a lab manager would estimate measurable costs such as lost work time, medical expenses/rehabilitation, increased insurance premiums, long-term disability, temporary staffing, etc. Immeasurable factors such as employee safety and morale are critical considerations as well. Even if employees are not injured, do they feel safe? Will concerns about potential harm impact their productivity?

When evaluating the benefits and savings of automation, lab managers will need to consider the actual cost of the equipment, annual maintenance and calibration, training, etc. In general, the lab equipment should show a positive return on investment within two to three years and offer a lifespan of five or more years if properly used and maintained.

As mentioned, there are three areas in most labs that should be evaluated for possible automation: media preparation and dispensing, sample preparation and temperature monitoring.

CRITICAL POINTS: MEDIA PREPARATION

When considering media preparation for the microbiology lab, evaluate how automation can positively impact:
• **STERILITY:** System provides sufficient temperature to sterilize the media (Example: 121°C 15mn., 110°C 20mn.);
• **FERTILITY:** Temperature is maintained so media is not destroyed (i.e. does not destroy the sugar, the peptone, greater than 122°C);
• **HOMOGENEITY:** Prepares the same quality of media for each batch;
• **STANDARDIZATION:** System is operator-independent; prepares media the same way no matter who is operating the unit;
• **PRODUCTIVITY:** Prepares media in the shortest time possible, is easy to install and implement, is a walk-away system;
• **TRACEABILITY:** Documents that the media is sterile (and fertility is not compromised. (Printed report of cycle curve shows highest temperature reached and how long it was sustained).

CASE STUDY: MEDIA PREPARATION

Syed Rehan, president and chief scientific officer for Growcells.com, has based his media business on reliable automation. The Irvine, Calif.-based molecular biology supply lab performs research and develops specialized media products for molecular biologists primarily involved with cloning using robotic colony pickers in high-throughput genome research.

Growcells.com produces more than 120 liters of agar-based media daily. One of the company's key services is the daily production of over 400 bioassay plates the size of notebooks (245mm x 245mm) each containing in excess of 300 ml of media.

> "Now, with temperature control, every batch is a flawless product. We also have printed reports that document the temperature levels reached by all media. The antibiotics are added at the optimal temperature, and we have validated this unit several times. This has become critical for our internal quality control and part of the documentation we provide our customers."
>
> –SYED REHAN, president and chief scientific officer for Growcells.com

"These bioassay trays have a large surface area, are designed for robotic colony picking, so they introduce different challenges than pouring agar in a more commonly used small 60mm or 100mm Petri dish. For the bioassay trays, the media has to be very consistent in temperature as it is being poured so it doesn't harden too quickly or unevenly," explains Rehan, whose customers typically use $200,000 lab robotic systems to handle the finished trays when conducting research.

"The media has to be extremely clear, perfectly leveled and dried before using the trays," says Rehan. "Otherwise a $20 tray might throw off the calibration of a robot and cause costly delays and expensive recalibration problems for our customers."

When considering media/agar sterilizers, Rehan was looking for equipment that was reliable, offered higher-throughput, was compact and easy to use. After trying media preparators from other companies, he selected a Masterclave 60.

"The unit is intuitively designed, making it seamless to incorporate in our production process," says Rehan. "The media dispensing port located at the bottom of the tank allows gravity flow (instead of air compressors) to move the media from the tank via a standard peristaltic pump during dispensing."

"It's our workhorse; we would not be in business without it," says Rehan, who has been using the unit every day for nearly three years. "Other media sterilizers didn't have user friendliness, easy-to-use controls, reliability or printout. When the media would

not reach the right sterilization temperature, our plates would develop contamination. This would cost us time, money and aggravation. There was a constant need to monitor the temperature to ensure that sterilization temperature was being achieved and for the appropriate time period."

"Now, with temperature control, every batch is a flawless product," says Rehan. "We also have printed reports that document the temperature levels reached by all media. The antibiotics are added at the optimal temperature, and we have validated this unit several times. This has become critical for our internal quality control and part of the documentation we provide our customers."

Autopreparators provide critical benefits compared to manual methods.

AUTOCLAVE vs. AUTOPREPARATOR
QUALITY, STERILITY & FERTILITY

AUTOCLAVE
- No core temperature probe
- No stirring paddle for media
- No cooling system
- Over-cooked media can reduce fertility

AUTOPREPARATOR
- Highly accurate core temperature probe
- Consistently homogeneous media with stirring paddle
- Rapid cooling device saves time
- Better control makes media fertility highly reliable

LABOR INTENSIVE
- Only uses small bottles (100 or 200 ml)
- 100 plates = 10 bottles = 40 minutes labor
- 1,000 plates = 100 bottles = 6.5 hours labor

REDUCED LABOR TIME
- Walk-away system processes big volumes (1 hour cycle)
- 750 plates/hour = 10 minutes of labor (when connected to automated pourer stacker)

REDUCED PRODUCTIVITY
- Accuracy = +/- 3° C
- Maintains high temperature 50° C
- Steam in plates
- Slow solidification

IMPROVED PRODUCTIVITY
- Accuracy = +/- 1° C guaranteed
- Dispensing at 42° C
- No steam in plates
- Quick solidification

CRITICAL POINTS: MEDIA DISPENSING

When considering media dispensing for the microbiology lab, evaluate how automated equipment can positively impact:

• **STERILITY:** System maintains sterility;
• **ACCURACY:** Dispenses an accurate volume for plates, tubes and bottles;
• **SIMPLICITY:** System is easy to use and quick (walk-away system), provides a cooling device and plate printer;
• **PRODUCTIVITY:** Automatically produces a high number of plates and tubes in the shortest time possible; cooling system makes plates available quicker and prevents condensation so plate quality is high;
• **VERSATILITY:** Uses different brands of Petri dishes;
• **STANDARDIZATION:** Always dispenses the same way independent of the operator.

CASE STUDY: MEDIA DISPENSING

As a result of public health emergencies like the Jack-in-the-Box *E. coli* outbreak in 1993 and the focus on homeland security resulting from 9/11, Mike McDowell, microbiologist IV and supervising microbiologist for the Washington State Department of Health, was able to get the support and funding to automate his laboratories.

During the Jack-in-the-Box outbreak, McDowell and his staff spent the better part of two weeks and many late nights manually pouring media so they had enough plates to test hundreds of specimens a day. Since 9/11, they have been doing a lot more testing for hospitals, local health departments, the U.S. Department of Justice, for mysterious white powders, botulism and unusual infections. Of course, this is in addition to their normal workload for their microbiology labs; virology, bacteriology, a special bacteriology lab for bioterrorism response, an enteric lab, group A strep, whooping cough (by the 100's), etc.

"When responding to public outbreaks, we realized we needed to be able to pour, streak, and inoculate large amounts of media quickly," says McDowell, who also has the Epidemiological Intelligence Service (EIS) from the CDC assigned to his facility. "We were borrowing people from everywhere to pour plates and streak plates, even taking microbiologists away from their work to deal with the bottlenecks."

"This was very labor intensive, we knew we had to streamline this process," says McDowell. "Our first order of business was to get automated."

McDowell purchased an automated pourer stacker (APS320) to pour media into plates, up to 750 per hour. To work with the APS320, he purchased a Vista Plate Streaker, which processes 180 plates an hour. In addition, to help us identify these agents, we have the Microbial Identification System, with "fast GC," which can identify organisms at two identifications every five minutes.

"Now we are able to respond more quickly and efficiently to public health outbreaks. Also, the equipment is always available to help make our routine work more effective," says McDowell, who has put the plate streaker on a cart to be shared among labs. "Automation saves us a ton of time on routine work so we are able to focus on more important activities."

CRITICAL POINTS: SAMPLE PREPARATION (DILUTION & BLENDING)

When considering automated sample preparation equipment for the microbiology lab, evaluate systems on:

• **ACCURACY:** of sample weighing (e.g. 25.0g+/- 0.1g), of the volume of diluent (225.0 ml), of the real dilution factor (+/- 1 percent);
• **SIMPLICITY:** System is easy to use, easy to clean and quick;
• **EFFICIENCY:** System blends even the most difficult samples

(beef, carrots), getting the best homogeneous sample;
• **QUIET:** Reduces lab noise substantially;
• **PRODUCTIVITY:** Helps lab do more with less (i.e., reduces operator time during dilution step);
• **STANDARDIZATION:** Is operator independent.

CASE STUDY: SAMPLE PREPARATION & BLENDING

Tom Hanks, microbiology supervisor, with the Wyoming Department of Agriculture, automated his lab's sample preparation with an EasyMix lab blender to comply with new FDA regulations. His lab primarily tests the microbiology of meat, dairy and water on a routine basis and responds to consumer complaints and public health emergencies.

"When the Food Safety Inspection Service (FSIS) changed its regulations, requiring us to increase the volume of our sample sizes and the number of samples we were preparing, we knew we had to make a change," says Hanks. His lab had been using a 1-liter metal blender similar to a kitchen blender to grind food samples. Meat tissue would bind up the blades making sample preparation difficult and time consuming.

"We needed a faster and easier way to process samples, especially for meat products, which are harder to blend," says Hanks. "We needed to reduce the labor-intensive part of processing samples."

EasyMix allows Hanks and his team to put samples in durable, yet disposal plastic bags (80 ml or 400 ml), which are then compacted in a stainless steel chamber.

"It takes us only 10 percent of the time it used to take," says Hanks, who points out that not having to clean the instrument in between samples is a big time saver. "It's easy to use, saves us time and provides consistently blended samples."

CRITICAL POINTS: TEMPERATURE MONITORING

When considering automated temperature monitoring equipment for the microbiology lab, evaluate systems on:

• **CONTINUOUS MONITORING & RECORDING:** Provides automatic 24-hour monitoring (temperature, humidity, CO2, etc.) of refrigerators, incubators, freezers, etc. from a central location;
• **ACCURACY:** Measures temperature etc., with the smallest standard deviation;
• **TRACEABILITY:** Maintains real-time and comprehensive readings in an electronic data base (system is 21 CFR Part 11 compliant), and data can be printed;
• **SIMPLICITY:** Wireless, easy-to-use, walk-away system with

RAPID RETURN ON INVESTMENT IN AUTOMATED CULTURE MEDIA PREP & DISPENSING

EXAMPLE: SAVE $16,160+ PER YEAR

- Making 514 plates (i.e., 9 liters of agar [17.5 ml/plate])

MANUAL LABORATORY COST

- 45 flasks of agar (200 ml) x 4 minutes per flask = 180 minutes (includes the preparation of dehydrated media, the distribution into the flasks, to close them, to handle in the autoclave and to wash, dry and use again)
- 514 plates x 4 seconds per plate = 34 minutes (includes the distribution of the agar from the flasks into the plates)

AUTOMATED LABORATORY COST

- 9 liters of agar in one batch with Masterclave 09 = 10 minute
  Plate preparation with APS320 = 10 minutes

RETURN ON INVESTMENT

- Manual - Automated = [214 - 20 minutes per day] = 194 minutes or 3.24 hours per day = 808 hours per year saved
- $20/hour labor = $16,160/year savings
- $30/hour labor = $24,250/year savings
- Making 514 plates (i.e., 9 liters of agar [17.5 ml/plate])

Note: This is one example on how to measure potential savings. Lab managers should use this as a guideline and adapt the example above to calculate the needs of their specific lab operations.

RAPID RETURN ON INVESTMENT IN AUTOMATED SAMPLE PREPARATION

EXAMPLE: SAVE $40,000+ PER YEAR

- (20.25 liters of diluent - 225 flasks - 90 samples)

MANUAL LABORATORY COST

- **Diluant Preparation (225 flasks):** 90 Samples x 4 minutes = 360 minutes (Includes time to prepare dehydrated media, distribute into flask, close, handle in autoclave; then wash, dry and use again.)
- **Sample Preparation:** 90 Samples x 3 minutes = 270 minutes (Includes time to cut, size and weight a sample.)

AUTOMATED LABORATORY COST

- Diluent Preparation (20.25 liters in one batch) = 15 minutes to prepare autopreparator
- **Sample Preparation (with Dilumat):** 90 Samples x 1.5 minutes = 135 minutes

RETURN ON INVESTMENT

- Manual - Automated = [630 - 150 minutes per day] = 480 minutes or 8 hours per day = 2,000 hours per year saved
- $20/hour labor = $40,000 per year
- $30/hour labor = $60,000 per year
- $40/hour labor = $80,000 per year

Note: This is one example on how to measure potential savings. Lab managers should use this as a guideline and adapt the example above to calculate the needs of their specific lab operations.

(Automation Justification Continued)

remote access and automatic alarm management;
• **PRODUCTIVITY:** System increases time available for higher-level functions and provides more comprehensive data for trending and planning;
• **STANDARDIZATION:** Is operator independent;
• **VERSATILITY:** the same system (software, receiver) can be used to monitor several parameters (temperature, humidity, pressure, etc.).

CASE STUDY: TEMPERATURE MONITORING

Larry Kent, quality manager at ETS Laboratories in Napa Valley, offers analytical services to the wine and beverage industries. His lab is one of the largest independent wine testing labs in the U.S., testing 400 to 700 samples per day and more during harvest.

ETS purchased an automated temperature monitoring system (LabGuard 2) to improve environmental monitoring as part of its ISO 17025-accreditation. Monitoring of stored samples and reagents went from a once-a-day reading manually written in a notebook to hourly readings logged automatically in a computerized data base.

"Once-a-day day testing is meaningless, it doesn't tell anyone anything," says Kent who uses automation to monitor refrigerators, incubators, freezers and deep freezers (-80° C) in his main lab and satellite labs. "Now if there's a problem, we can respond at

RAPID RETURN ON INVESTMENT IN AUTOMATED TEMPERATURE MONITORING

EXAMPLE: SAVE $4,078 TO $16,312+ PER YEAR

MANUAL LABORATORY COST

- 5 minutes/measuring point x 10 measuring points = 50 minutes/day or 208 hours/year to measure and log readings

AUTOMATED LABORATORY COST

- 0 minutes measuring temperatures or logging results = automatic with LabGuard 2
- 1 minute/day to review automatically generated results chart = 4.1 hours a year (however, not mandatory)

RETURN ON INVESTMENT

- Manual - Automated = [208 - 4.1 hours] = 203.9 hours per year saved
- $20/hour labor = $4,078/year (10 mp)
  $8,156/year (20 mp)
- $30/hour labor = $6,117/year (10 mp)
  $12,234/year (20 mp)
- $40/hour labor = $8,156/year (10 mp)
  $16,312/year (20 mp)

Note: MP = measuring points (refrigerators, freezers, incubators, etc.) This is one example on how to measure potential savings. Lab managers should use this as a guideline and adapt the example above to calculate the needs of their specific lab operations.

once," Kent points out.

"Round-the-clock monitoring gives us more control from a central location, greater standardization and more confidence in the way things are stored," he adds. "I can come in on Monday and check the log and know just how things went over the weekend. Now we're placing a greater emphasis on microbiology with our customers, so LabGuard 2 is helping us establish this line of business with confidence."

CONCLUSION

Automation can bring many benefits to the microbiology lab including: standardization, high productivity, accuracy, efficiency, traceability and security/safety. These benefits can provide significant savings to the organization. However, the need for automation and the parameters to justify the investment will need to be adapted for each microbiology lab. The guidelines above are meant to provide a substantial framework from which to start (please see the attached checklist to get started). Lab managers can prove their case with a thorough business assessment of how automated lab equipment will deliver measurable benefits to the company. Lab managers who provide this information are very likely to gain the interest and support of top management. *–FQ*

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