

President's Message



Dear ISPE Boston Area Chapter members, As the holiday season approaches and the end of 2004 is near, I would like to share a story I recently heard.

The story is about a retired teacher who decided to volunteer at a local children's hospital tutoring young patients. When she received her first call for duty, she was excited but a bit apprehensive - her assignment was for the burn unit.

The next morning, as she prepared the lesson for the fourth grader she was to visit, her thoughts of the children who were in this unit brought her visions of pain and suffering she did not want to face. However, she overcame her fears and walked slowly to the young burn victim's room.

Unfortunately, the boy's appearance was even worse than she had imagined. He looked at her and said, "Who are you?" She silently gasped and stated, "I am your teacher and today we are going to learn about nouns and pronouns. It is time to begin your lessons." Well, she made it through the lesson and went home.

Over the next few days, the teacher could not shake the experience and felt she might not be able to continue with this task. As evening approached, she received a call from the young boy's mother. When the teacher realized who it was, she apologized for the lesson. She told the mother that she understood if the mother didn't want her to continue to tutor her son. The mother interrupted and stated, "Ever since you came to teach my son, his recovery has improved dramatically. He has decided to fight for his life..."

The teacher was surprised and asked why. The mother told her, "He said that he knew that the doctors wouldn't send for someone to teach him about nouns and pronouns unless they thought he was going to get better." Simply put...the teacher's visit gave him hope.

Hope...it is one of the reasons, or perhaps the most significant reason we are in this profession. Every one of you helps in giving hope to a sick child, adult or elderly patient. While meeting your everyday challenges, your hard work, due diligence and caring encourages this hope to grow and helps to make miracles happen. I am proud to be a part of such a great community of professionals.

Since my last letter, the Boston Area Chapter held its 13th Annual Product Show. I would like to thank all the committees and participants who made this an outstanding event. Over 160 tabletop displays and 12 different seminars provided nearly 1,000 attendees with the latest in technological innovations.

Our keynote speakers, Tom Finneran, President of the Massachusetts Biotechnology Council, and Scott Sarazen of MassDevelopment, are looking forward to working with the ISPE Boston Area Chapter to make Massachusetts a better place for our industry.

During the show, we had a Student Chapter meeting with 25 student representatives from UMass Amherst, UMass Lowell, the University of New Hampshire and Tufts University. It was great to see our student members there and we look forward to their participation in other events.



Mike Denault-Board of Directors, Dave Novak-Chapter President, Scott Sarazen-Mass Development, and Tom Finneran-Massachusetts Biotechnology Council.

In fact, it is important for all members to know that you have the opportunity to have your voice heard in our Chapter. If you have any ideas, comments or questions about the Chapter and our activities, please contact me at dnovak@erland.com.



Show Floor at the 2004 Annual Pharma Product Show

We are looking forward to a great winter season, with several great facility tours, presentations and events.

On behalf of the Board of Directors, I would like to thank you all for your continuous support and look forward to seeing you at the next Chapter Event!

Best regards,
Dave Novak
President

See page 5 for more Product show photos.

Using Your Nose

Ben Wilbert, Product Manager, Cole-Parmer Instrument Company

While most scientists who study human brain evolution tend to regard something people do very well, such as language, Dr. Tyler Lorig, PhD at Washington & Lee University studies one of the least understood senses, and something people tend to do poorly: smell. He studies the olfactory (a.k.a. sense of smell) system in his lab, specifically how the brain responds to an odor. His work led him to develop his own olfactometer, an instrument used to deliver and help measure odors. He built it out of mostly off-the-shelf chromatography parts that required little modification. All parts of the olfactometer that could contaminate smells are high purity, and hence minimize residual odors that could affect the experiment results. Overall, the instrument needed essentially seven features: (1) computer control; (2) effective delivery of a variety of odors, in series or randomly; (3) production of an odor stimulus of selectable and reliable duration in a constant airstream, without any additional type of ancillary stimulation (e.g., tactile,

line is stopped during odor stimulation making the net change in air zero. Because the switching in the valves lead to very brief airflow changes (around 20 milliseconds) the constant flow line acts as a buffer for the airflow change, thereby reducing any extraneous sensory stimulation to the test subject.

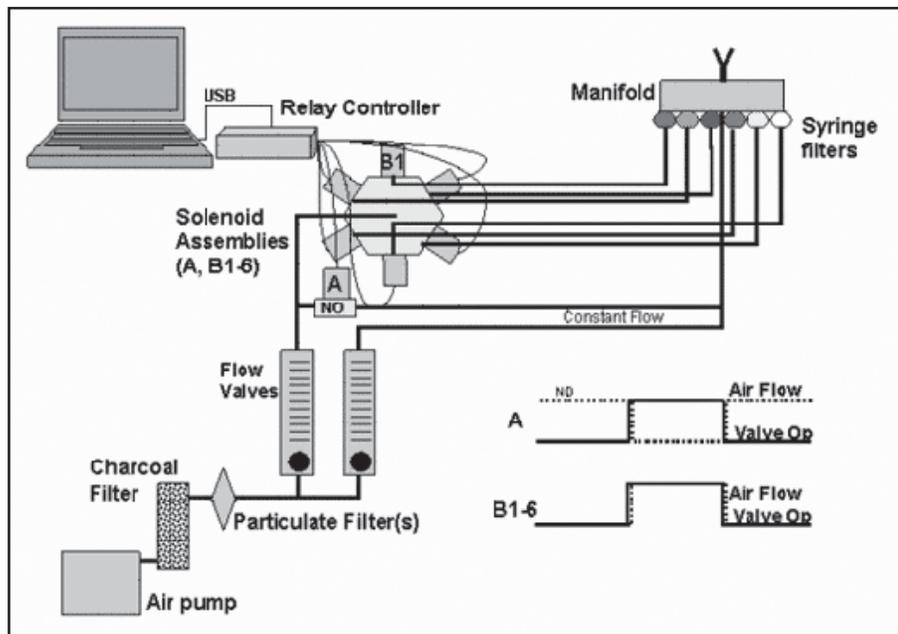
In relatively normal test subjects, Lorig finds people have measurable brain activity induced by odors, even when the test subject reports not smelling anything!

“Some of the research done shows we are exquisitely sensitive to smells, contrary to our expectation.” states Lorig. Furthermore, when an odorous chemical is blindly switched from one to another—neither reported as smelled—the brain responds differently. There’s now understanding of the connection between olfaction and certain health problems, and Lorig states he would like to see olfaction analysis become simplified and used more in clinical applications. Current research

examines the relationship between olfaction and maladies such as Parkinson’s Disease, Huntington’s Disease, Korsakoff’s Syndrome, Schizophrenia, Depression, and Alzheimer’s Disease (AD). Recent evidence suggests that areas in the central nervous system processing olfactory information are affected at the early stages of AD, even before the onset of cognitive decline, and that olfactory dysfunction might be an early indicator of AD (Murphy, 1999). Aside from aiding pathological diagnosis, Lorig’s current and future toils include research on how the brain is organized, pathways the brain uses to process odors, and the many relationships between smelling and the other senses.

References

1. Lorig TS, Elmes DG, Zald DH, Pardo JV (1999), A computer-controlled olfactometer for fMRI and electrophysiological studies of olfaction. *Behav Res Methods Instrum Comput* 31: 370-375.
2. Murphy, C., 1999. Loss of olfactory function in dementing disease. *Physiol. Behav.* 66 (2), 177-182.



auditory); (4) resistance to contamination; (5) durability; (6) ease of operation, refilling, and cleaning; and (7) low cost (Lorig et al. 1999). And since he uses the olfactometer near an fMRI (functional magnetic resonance imaging), to measure brain activity, it obviously has to be free of ferrous metals, which will wreak havoc near the magnet.

Following the drawing above, air from a compressor is passed through a charcoal filter to remove odors and then through particulate filters to prevent charcoal dust from being administered to the test subject. After passing through the particulate filters the flow is divided and metered through variable-area flowmeters. One of the lines is always open and provides a constant low-volume air stream. The other flowmeter provides the air that will be passed over the odors. This stream is also divided and passed to two solenoid valves. Valve A is a single valve that is normally open. The other valve is a multi-port valve that can have from 1 to 6 individual normally closed solenoid valves (B1-6). To send an odor to a subject, the computer turns on valve A (stopping airflow in that line) and turns on valve Bn commencing airflow in that line. The syringe filter connected to line Bn contains odor, and the air now passes over the filter and through the manifold to the subject. Turning the valve off stops airflow over the filter paper and stops the blockage cause by actuating valve A. To avoid any increases in airflow, one non-odorized

Ben Wilbert is a Product Manager of life-science-related products with Cole-Parmer Instrument Company.

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Share your Technical Knowledge with ISPE Members

The ISPE Boston Area Chapter newsletter offers a perfect opportunity for you to share your technical expertise with fellow members. The survey conducted last June provided excellent feedback regarding topics of interest to our members. Beginning with the area of greatest interest, these topics include:

1. CIP
2. Clean room technology
3. Chemical sanitization/steaming
4. Process filtration
5. Water quality/water purification technology
6. Vessel design
7. Sterile connections
8. Mixing

9. Disposable technology

10. Basic microbiology

11. ASME or PED

It is our goal to present technical articles on these topics over the upcoming months but to do this we need your help! Whether you are directly involved in research, pilot production or scale-up, or provide products or services to the industry, our members are eager to learn from your experience.

The requirements are simple. Your article must be 750 words or less (500 words or less with 2 charts, graphs or photos) and technical, not promotional, in nature. The ISPE Boston Area Chapter will provide light editing to correct any spelling and/or grammatical errors and reserves the right to accept or reject articles based on technical merit. Please be sure to review your employer's policy concerning publication before submitting your article.

To submit your article, email it to ispe@camihq.com with the subject header: **ISPE Boston Area Chapter Communications Committee - Tech Article**. The article should be in text format with any graphs, charts or photos as attachments. 

Janet Tice

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Member Spotlight - Monique Sprueill

How long have you been a member of ISPE?

I joined ISPE in 2002 while working at GlaxoSmithKline in Clifton, NJ. I was relocated to the Boston area by Wyeth BioPharma later that year and became active in the ISPE Boston Area Chapter in the fall of 2002.

When did you start your professional career?

I started my professional career in 2001.

What does your work involve and how is it connected with ISPE?

I began my career as a process engineer, then began working in validation. I qualify manufacturing process equipment used in the pharmaceutical industry. All the companies that I have worked for are involved with ISPE.

How will your membership in ISPE help you professionally?

My membership will help me professionally by allowing me to have access to current standards, journals, and other professionals. This access helps me perform my job more efficiently by equipping me with the knowledge and other resources necessary to ensure that I am meeting the compliance standards and business goals. The documentation that I have received and the people I have networked with have helped me learn more about validation principles, compliance standards, continuous improvement process methods, and industry trends.

What is your most memorable event or activity of ISPE membership?

I enjoyed last year's volunteer dinner. It provided an opportunity for me to meet and network with local professionals and share ideas. It was also a great experience to be acknowledged by the Chapter for participating on the ISPE Boston Area Chapter Programs and Communications Committees.

What do you see for our industry in the next five years?

In the next five years, I think the Biotechnology industry is going to grow significantly. I believe that interest in studying and working in the field will continue to rise. Engineering programs will offer more courses to students that will prepare them for careers in biotechnology. Enrollment and participation in Biotech Certificate programs will also increase in the Boston area.

On a more personal note, where are you from, where do you live, and what do you and your family like to do outside of work/ISPE?

I am from New Jersey. I currently live in Tewksbury, MA. I like to volunteer at the food pantry at my church. I enjoy helping people and this offers the opportunity to do so on a weekly basis. I also like to read, shop, and spend time with my family and friends.

Do you have any advice for new members?

My advice is to participate in the various committees. It is a great opportunity to interact with other professionals and make new friends. 🌐

Christine Lindberg

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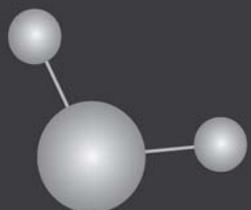
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ISPE Boston Area Chapter 13th Annual Product Show Photos

Photography: Meghan Moore.



Tom Finneran Keynote Speaker, Dave Novak, and Scott Sarazen Keynote Speaker.



Show Floor



Andre Walker and Dick Priester.



Dave Novak introducing Keynote Speakers.

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pull Jun 04 pg 5

Regulatory Highlights

FDA Completes Review of Reprocessed Single Use Devices

The Medical Device User Fee and Modernization Act of 2002 required the submittal of validation data by organizations that reprocess medical devices that were originally constructed for single use. The FDA has completed its review of that data and determined that some can no longer be distributed.

(Source: www.fda.gov 2 November 2004)

FDA Announces Major Initiatives for Dietary Supplements

Regulatory strategy, open public meetings, and draft guidance documents are being issued to further implement the Dietary Supplement Health and Education Act of 1994. These measures will help the agency ensure that safety, product quality, and raw material monitoring are conducted in the dietary industry.

(Source: www.fda.gov 4 November 2004)

FDA Strengthens the Safety Program for Marketed Drugs

The FDA has developed a program that assesses adverse effects associated with the use of approved drugs. Clinical reviewers and epidemiologists work together to evaluate and respond to recognized concerns. The FDA is committed to identifying and examining the risks of using approved drugs. The agency is also taking steps to ensure that the benefits of using prescription and over-the-counter drugs are communicated to the public.

(Source: www.fda.gov 5 November 2004) 

Monique Spruill

NEWSBRIEFS

Tackling Anemia in Diabetics

Amgen Inc. is conducting a clinical trial to evaluate the impact of treating anemia on cardiovascular risks in people with type 2 diabetes and chronic kidney disease. The trial will examine whether treating anemia with the drug Aransep lowers the risk of death and non-fatal cardiovascular events in people with chronic kidney disease (CKD) and type 2 diabetes. The international, multi-center study will include 4,000 patients.

(Source: *Health Day News*, 11 November 2004)

Ariad Pharma President Sekhri Resigns

Ariad Pharmaceuticals Inc. announced Friday 12 November 2004 that Paul Sekhri, president and chief business officer, will leave Ariad in mid-December to become CEO of a start-up pharmaceutical company centered on lifestyle therapies.

(Source: *Associated Press*, 12 November 2004)

Amgen Announces the Formation of Amgen Ventures

Amgen announced the formation of Amgen Ventures, a corporate venture capital fund designed to provide emerging biotechnology companies with resources to develop pioneering discoveries focused on human therapeutics. Amgen Ventures can offer early stage companies access to Amgen's capabilities while providing Amgen with insight into research innovations from external entities that may lead to future collaborations.

(Source: *Business Wire*, 11 November 2004) 

Vincent Nee

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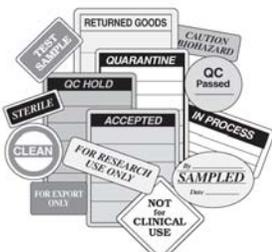
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1/8 page

p/u Jul 04 pg. 5

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Peter Arneson, Sr. Project Manager, Process Construction Management

Abbe E. Bjorklund, Associate, Sebasta Blonberg & Assoc. Inc.

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Lewis H. Brown, Director, Sales & Marketing, Fluid Imaging Technologies

Chris Buder, Project/Validation Engineer, V. I. Technologies, Inc.

Timothy J. Bugbee, Project Engineer, Wyeth BioPharma

William Carney, Marketing Dev., Stratus Technologies

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Timothy A. Elliott, Arden Eng Const. LLC

David W. Foggo, Critical Utilities Eng., Wyeth BioPharma

Scott L. Fossier, QA Validation Manager, Lonza Biologics Inc.

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Paul Grden, Process/Chemical Eng., Wyeth Biopharma

Evan B. Grunbaum, Quality Assurance Specialist, Phase Forward

William Held, Project Executive, Bovis Lend Lease

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Kristin Page, Analyst, University of Massachusetts

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William Piombino, Facilities Manager, Lonza Biologics

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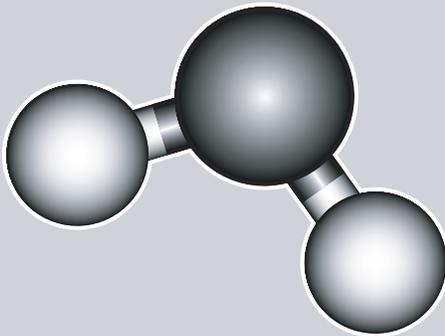
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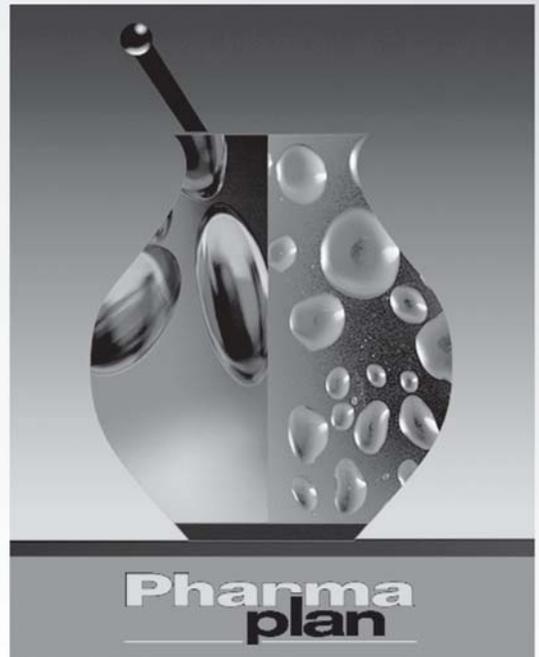
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