



The Leading Global Society for  
Healthcare Technology Professionals

# Boston Area Chapter Newsletter

September 2001

Volume XI, Number 3

## President's Message

**T**he fall schedule will appear unusual since there is just one educational program being held before January 2002 which is October 17 at the Radisson. This is due to the national Fall Conference which was held in Boston, September 10-13 (an unusual circumstance) as well as to the Product Show being held November 15 (the usual schedule starting now). In addition, we have our Christmas party at the brewery scheduled for December 6.

Over the past year, we have offered an excellent slate of educational programs including relevant topics and speakers, variety, three plant tours, and eye-catching titles (another new tradition). The social programs have been expanded with the addition of a March ski trip to the new, but already seemingly established annual Christmas party. The Student Chapter at Northeastern University has solidified over the past year with regular programs and a student poster contest.

I've enjoyed very much my all-too-brief time as President of your chapter. The key component of my ISPE experience in general has been the exceptional people I've gotten to know through our organization. This includes the members of the Boston Area Chapter Board, the Chapter as a whole, those in national leadership positions (officers and committee members), and officers from other chapters. I will enjoy continuing to relate to you albeit in a different capacity.

Among the outstanding Boston Area Chapter Board members I've known was Joel Goldenberg who is missed by those of us who served with him. As many of you know, we have established an academic fund in Joel's name around which we will build our student fundraising efforts.

Please welcome our capable new President, Andre Walker, and the other new Officers, Joe Musiak, James Blackwell, and Larry Weiner. And thank the outgoing Board members for their service, including Jack Campion who served for eight years including four years as treasurer.

Be sure to check our Boston Area Chapter Web site through [www.ispe.org](http://www.ispe.org) for information on both the Boston Area Chapter and the national organization. See you on October 17!

Daniel Lavin 

## Boston Area Chapter 10th Annual Product Show November 15th, 2001 CALL FOR EXHIBITORS!

**S**o, you thought you missed the show this year! Actually, we pulled a fast one and changed the show to a fall format to boost attendance. Register now to be an exhibitor at the upcoming Product Show, being held at the Newton Marriott on November 15, 2001. If you haven't received a registration packet by mail or e-mail and would like to exhibit, please contact us by e-mail at the address below.

### Call for Seminar Presenters

As a registered exhibitor, you are eligible to present a short seminar (30-40 minutes or so) on basic or advanced topics that would be of interest to product show attendees. Topics and presentations must be generic in nature to be accepted. If you are interested, submit an abstract of your presentation along with your registration.

The Boston Area Chapter and the Product Show Committee will make final decisions on presenters and topics covered.

### First Come, First Served

Once you register as an exhibitor, you will be able to select the best location for your booth from available locations. Requests will be handled on a first come, first served basis, so register early for first dibs.

### Want More Information?

For additional information or to receive a registration package, contact us by e-mail at [ISPE@fluid-solutions.com](mailto:ISPE@fluid-solutions.com) or fax 978/453-1223. 

## 2001-2002 Programs... Save These Dates!

October 17, 2001	We're All On the Same Team... Right? <i>See information on page 7.</i>
November 15, 2001	Boston Area Chapter Annual Product Show <i>Register on page 9.</i>
December 6, 2001	Boston Area Chapter Social Party
January 15, 2002	Program
February 28, 2002	Program
April 2, 2002	Program
May 2, 2002	Program



# Process Validation of Existing Processes and Systems Using Statistically Significant Retrospective Analysis

Third of three parts

Andrew W. Jones, Technical Manager, KMI/PAREXEL LLC

**D**etermine the Confidence Interval as compared to +/- 3 S.D. With the +/- 3 S.D. ranges determined, it can be considered important to evaluate what confidence there is that the next data point will fall within this range. The rationale for determining this level is to justify that the +/- 3 S.D. range provides a confidence that 99% of the data is within that range. Similar to the +/- 3 S.D. range, the confidence interval is a range between which the next measurement would fall. This level is typically 99% or greater. Thus a 99% confidence interval means, "there is 99% insurance that the next value would be in the range." To calculate a 99% Confidence Interval, one needs to consider the area under the standard normal curve, the mean, the standard deviation, and the population size. Determining this level can be done using the formula in Figure 7. The confidence interval can be added to our previous example and is displayed in Figure 8.

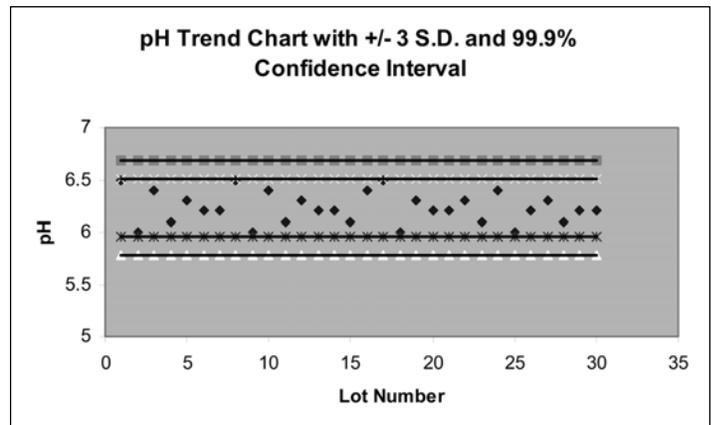


Figure 8: Trend Chart with +/- 3 S.D. and Confidence Interval.

$$\text{Confidence Interval} = \mu \pm \text{area under standard normal curve } (\sigma/(n)^{1/2})$$

Figure 7: Definition of Confidence Interval Formulas.

Following our example:

$$\text{Confidence Interval (99.9\%)} = 6.23 \pm \text{snc} (0.151202/(30)^{1/2})$$

$$\text{Confidence Interval (99.9\%)} = 6.95 \text{ to } 6.02$$

The confidence interval at 99.9% is slightly more narrow than the +/- 3 S.D. range which follows the trend if the +/- 3 S.D. range provides that 99% of the data will be within the range if the data is normally distributed.

As can be seen in the trend charts, the data fits well within the +/- 3 S.D. range, and therefore the confidence level is very high that the next data point that is collected will be within this range. Therefore this range may be appropriate to use as acceptance criteria based on the statistics. If the confidence level was wider than the +/- 3 S.D., then the data would have to be analyzed such to investigate if there were errors in calculating the degree of normality, the +/- 3 S.D., the confidence level, the outliers, or errors in the sampling technique to show that it was not computational error.

## Process Capability Factors

Another method to setting ranges to be used as acceptance criteria are the Process Capability Indices defined by:

$$CP_u = (USL - \mu) / \sigma \text{ (or in our example 3 S.D.)}$$

$$CP_l = (\mu - LSL) / \sigma \text{ (or in our example 3 S.D.)}$$

Where:

U<sub>SL</sub> = Upper Specification Limit

L<sub>SL</sub> = Lower Specification Limit

An industry accepted standard CP would be 1.33.<sup>1</sup> This would mean that only 0.003% of the testing results would be out of the specification or 99.997% would be within the specification. This is a similar concept to confidence level.

## Recording the Maximum and Minimum

Recording the maximum and minimum values in the data is important because it is a quick way to see if the data is all within the +/- 3 S.D. range. Additionally, if the maximum and minimum are within the +/- 3 S.D. range, then there is an additional level of confidence since all of the data would be within the range. Lastly, the data may be determined to be non-normally distributed and in such case, confidence may predict to high a possibility for failure at the +/- 3 S.D. range so in the interim, the maximum, and minimum values can be selected to be the range until further data can be collected to define the range (this refers back to increasing the sample size in order to approach a more normal distribution).

## Assign Acceptance Criteria Range and justify

Using all of the above analysis techniques, knowledge of the process and agreement on by a cross-discipline committee, acceptance criteria ranges can be assigned for the critical parameters and attributes. A general course of action would be to start by recording all the data at a given point in a spreadsheet, calculating the mean, S.D., population size, +/- 3 S.D., 95% and 99% confidence intervals, plotting the trend charts with appropriate ranges, and then deciding on which range makes the best sense. When selecting the acceptance criteria, a cross-functional committee should be utilized with backgrounds of QA, Manufacturing, Validation, R&D, and Engineering present. The

Continued on page 5.

<sup>1</sup> Robert Kieffer and Lynn Torbeck, *Pharmaceutical Technology*, p.66, June 1998.



# Process Validation

Continued from page 3.

ranges should be selected and justified by scientifically sound data and conclusions. The ranges should be within the PAR for the product, which means that if  $\pm 3$  S.D. is selected, the range should be checked at the upper and lower limits to verify that acceptable product is prepared. This should be done prior to a final agreement on the range and incorporation into the validation protocol. A report should be written to document the ranges with the rationale for selecting them and the justification for determining the limits as well as any determination that the ranges are within the PAR. Additionally, those ranges which are not to be included should be discussed within the report to justify why they are not to be recorded. A process validation protocol should be prepared with these ranges for acceptance criteria and the process should be run at a target within the acceptance criteria ranges at least three consecutive times using identical procedures to verify that the process is valid.

## Summary

Since the ideal case of validating a process during its implementation does not always exist in the pharmaceutical, biopharmaceutical, biotechnology or medical device industries, it may be important to determine a way to validate these processes using historical data. The historical data can be found in a variety of places as long as it is approved (e.g. approved and completed BPRs or quality control release documents, etc). A cross-functional team should perform a risk assessment on the parameters and attributes to determine which ones would be included in the process validation. A range establishing study for the attributes and parameters should be performed to evaluate historical data and analyze the data set for the concepts of normality, variation (standard deviation), and confidence. With a high degree of confidence, acceptance criteria ranges should be set for each parameter and attribute and a process validation protocol should be written with the appropriate ranges. This protocol should be approved and executed at target settings within the acceptance criteria ranges, from the start of the manufacturing process to the finish using qualified equipment, approved SOPs, and trained operators. In a final report for the process validation, the degree to which the process is valid would be determined by the satisfaction of the approved acceptance criteria.

## References

1. Box, G.E.P., and Cox, D.R. (1964), "An Analysis of Transformations," J. Roy. Stat. Soc., Ser. B., 26, 211.
2. Kieffer, Robert and Torbeck, Lynn, (1998), Pharmaceutical Technology, (June), 66.
3. Lane, David M., Rice Virtual Lab in Statistics (1993-2000), HyperStat Online, Houston TX, WEB: <http://www.ruf.rice.edu/~lane/rvls.html>.
4. National Center for Drugs and Biologics and National Center for Devices and Radiological Health,(1987) "Guidelines on

General Principles of Process Validation," Rockville MD. 15 MAY.

5. Ontario Ministry of Agriculture, Food and Rural Affairs (2000), Queen's Printer for Ontario, Last Updated March 22, 2000; Web: <http://www.gov.on.ca/omafra/english/research/risk/assum1b.html>.
6. StatSoft, Inc. (1999). Electronic Statistics Textbook. Tulsa, OK: StatSoft. WEB: <http://www.statsoft.com/textbook/stathome.html>.
7. U.S. Department of Health and Human Service, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Veterinary Medicine, "Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients," Rockville MD. March 1998, 36. 

---

**If you are interested in submitting an article for the ISPE Boston Area Chapter newsletter, please contact Amy Norris at 781/449-1925.**

# **NYPRO Facility Tour and Medical Device Program - A Great Success!**

**T**he Boston Area Chapter concluded its 2001 Spring Program Schedule in May with a tour of the Nypro Medical Device Manufacturing Facility in Clinton, Massachusetts. The Nypro facility tour was followed by two presentations regarding the Massachusetts Medical Device Industry. The program's intent was to bring together members of the pharmaceutical, biotech and medical device communities, and to provide an educational forum for understanding the common regulatory quality assurance and financial aspects of these related industries in Massachusetts. Evaluation results indicate that the program was well received.

Attendees were treated to guided tours of Nypro's unique manufacturing facility. The award winning 800,000 sq.ft. facility was constructed within a historic textile mill complex that has been beautifully renovated and modernized. The Nypro staff provided a comprehensive tour noting

in detail methods of material handling, quality assurance and control, and impressive manufacturing and packaging systems.

Following the tours the group returned to the Sterling Country Club for the program presentations and dinner. Dr. Allen Clayton Mathews, Asst. Professor and Director of Quantitative Methods in the Public Policy Program at UMASS, Boston presented information regarding the significant financial contribution to the Massachusetts economy that the Medical Device Industry currently provides. Alan J. Descoteaux, Director of Quality Assurance, Nypro Clinton, gave a talk on the quality assurance programs he and his staff have developed at Nypro and provided insightful comparisons to the pharmaceutical and biotech industries. A fine dinner provided by the Sterling Country Club, concluded the program.

The Boston Area Chapter would like to thank the Nypro staff, our presenters, and

the Sterling Country Club for their efforts in hosting our May 2001 Medical Device Program and making it a great success. 

**JUST  
RELEASED!**

**21 CFR Part 11**

*"A document produced  
jointly by ISPE and PDA"*

Contact ISPE at  
1-813/960-2105  
for an order form.

Don't Miss the Boston Area Chapter's First Fall Program!

## We're All On the Same Team... Right?

**Project Delivery: Integration of Commissioning, Validation, Construction, and Project Management on New Facilities**

**Date:** Wednesday, October 17, 2001  
**Location:** Radisson Hotel, Cambridge, MA  
**Schedule:** Registration: 3:15 pm - 4:00 pm  
Presentations: 4:00 pm - 6:00 pm  
Networking/Cocktails: 6:00 pm - 7:00 pm

### General

The program is intended to provide discussion regarding the real life issues that occur as projects are designed, constructed, commissioned, and validated, and will address value added approaches to minimize duplication of efforts, excessive documentation, excessive qualification, and cost and schedule impacts.

### Speakers

**Tod Troutman, Kvaerner Process**, was a contributing committee member for the publication of the ISPE Baseline® Pharmaceutical Engineering Guide, Volume 5: Commissioning and Qualification, published in March 2001. Troutman will discuss the new Baseline® Guide, and use it as a basis of discussion for the interrelation of design, construction, and commissioning/validation activities on the successful delivery of projects.

**Don Hall, President, Engineered Technologies Corporation**, has more than 30 years of experience in delivering projects to the pharmaceutical and fine chemical Industries. The majority of Hall's experience has been spent developing strategies that incorporate commissioning and start-up activities as a primary consideration in design, engineering, construction, and project management. Hall will discuss the importance of developing a commissioning strategy during the earliest stages of a project and incorporating it into each subsequent stage as a primary consideration.

Additional speakers will address the owner/operator aspects of project delivery, how commission and validation may be incorporated into receiving a turnover package, and internal project delivery issues as commissioning and validation activities are executed.

**Meeting Managers:** Douglas Castle, Engineered Technologies  
George Enos, Hart Engineering

A networking reception, cocktails / hors d'oeuvres will follow the presentation. 

Boston Area Chapter Fall Program

## We're All On the Same Team... Right?

Wednesday, October 17, 2001

	by Oct 9	after Oct 9
<input type="checkbox"/> ISPE Member	\$40	\$50
<input type="checkbox"/> Non-Member	\$60	\$70
<input type="checkbox"/> Student	\$20	\$25

**New Member Special** - \$30 meeting fee when you sign up for ISPE Membership (\$170) for a total of \$200. Please call 781/449-1925 for additional details on the New Member Special.

- Check Enclosed  
 Pay by Credit Card - circle type: VISA MC

CARD NUMBER \_\_\_\_\_

EXPIRATION DATE \_\_\_\_\_

NAME OF CARDHOLDER (AS IT APPEARS ON CARD) \_\_\_\_\_

CARDHOLDER SIGNATURE \_\_\_\_\_

**NOTE: Cancellations received after Friday, October 12, 2001 are subject to billing.**

Member #: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please fill out the registration form and send with payment to:**

ISPE Boston Area Chapter, c/o CAMI  
200 Reservoir St., Suite 309A  
Needham, MA 02194

Tel: 781/449-1925 • Fax: 781/444-6111

E-mail: ISPE@camihq.com

Web site: www.ISPE.org/boston

## 2001 ISPE ANNUAL MEETING: Winning Strategies for the Future

The ISPE Annual Meeting will take place from October 28 through November 1 at the MGM Grand Hotel/Casino in Las Vegas, Nevada. The Annual Meeting is a great place to learn about the industry, network, and see the latest industry products and innovations. The theme for this year's meeting is appropriately called "Winning Strategies for the Future." This year, all the educational programs offered at the Annual Meeting are directed toward

ISPE's four professional areas of interest:

- Development and Manufacturing Technology
- Regulatory and Compliance
- Facilities and Engineering
- Business Operations

Presentations on the Baseline® Guides and the Clinical Materials Educational Forum also will be offered. Table top exhibits also will be open during the conference. Shared Interest Groups (SIGs), ISPE

Career Center, and student poster session are also part of this comprehensive event.

There will be plenty of planned activities in Las Vegas, including the annual ISPE golf tournament, spouse program, receptions, and other networking activities. We hope you will join us in Las Vegas and see how this dynamic event can bring you up-to-date with the issues facing healthcare technology professionals today.

For additional information, please visit our Web site at [www.ispe.org](http://www.ispe.org). 



# 10th Annual ISPE Boston Area Product Show and Seminars

The Boston Area Chapter proudly announces our 10th Annual Product Show, being held this year on November 15, 2001 at the Newton Marriott. We've built on last year's successes to bring you an event really worth attending!! Last year's show featured free food and non-alcoholic beverages, 15 of the best seminar presentations you could find under one roof, free parking, and a mid afternoon start so you won't have to justify missing a full day of work to attend. The show will be sold out this year and packed with new products for you to see. Come join us at the biggest one day gathering of biotechnology and pharmaceutical professionals in the Boston area; it's a decision you won't regret!!!

**When:** Thursday, November 15, 2001  
**Show Hours:** 3:00 pm to 8:00 pm  
**Seminar Hours:** 3:00 pm to 8:00 pm  
**Where:** Boston Marriott Newton  
2345 Commonwealth Ave (Route 30)  
Newton, MA 02466  
(Intersection of 128/Mass Pike & Route 30)  
Tel: 617/630-3505

---

## 10th Annual ISPE Boston Area Product Show and Seminars - - Thursday, November 15, 2001

- ISPE Member - FREE before October 15th or \$10 fee at the door  
 Non-Member - \$10

Member #: \_\_\_\_\_

Name: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail (*important!!*): \_\_\_\_\_

*Please fill out the registration form and mail or fax it to:*

ISPE Boston Area Chapter, c/o CAMI  
200 Reservoir St., Suite 309A  
Needham, MA 02194  
Tel: 781/449-1925  
Fax: 781/444-6111  
E-mail: ISPE@camihq.com  
Web site: www.ISPE.org/boston

# New Members

The ISPE Boston Area Chapter extends a warm welcome to the following new members

Sam K. Aghdam, DuPont Pharmaceuticals  
Sushil C. Amin, Acambis Inc  
Richard Anderson, M+W Zander US  
Operations  
Victor Antoniak, Genzyme Corp  
Russell T. Bailey, SMRT Inc  
Eva M. Banaszek, Geltex Pharmaceuticals Inc  
Peter Biskaduros, Genzyme Corp  
Jack Bradley, Eisai Research Institute  
David J. Brown, Alkermes Inc  
Richard J., Brown, Jr., Air Power of New  
England  
Prosper Calixte, Genzyme Corp  
Todd M. Carpenter, Bayer Diagnostics Corp  
Joel A. Carrigan, Genzyme Corp  
Patrick A. Chambers, Acambis Inc  
Shannon L. Chesterfield, Integrated Validation  
Services Inc  
Sylvia L. Corr, Vanderweil Engineers  
Linda M. Daly Graf, Phoenix Imperative Inc  
Lisa R. de Mars, Genzyme Corp  
Kevin Debasitis, Fluor Daniel  
Roger Deschenes, AstraZeneca  
John J. Desmond, Wyeth-Ayerst  
Amy B. Doughty, The Chisholm Corp  
Linda Dunnells, Genzyme Corp  
Antonio Esteves, Beacon Skanska Construction

Dino J. Farina, Image Therm Engineering  
Raymond Fecteau, Genzyme Corp  
Robert J. Flaherty, Shooshanian Process  
Engineering & Const  
Justin D. Foox, Watson Marlow Bredel  
John L. Freitas, Genzyme Corp  
John J. Froozandeh, PE, DuPont  
Pharmaceuticals  
Brian M. Gallagher, Dacon Corp  
Paul C. Galzerano, Organogenesis Inc  
Christopher J. Gilman, TranXenoGen  
James H. Hayes, Bovis Lend Lease  
Pharmaceutical  
John A. Hurst, Bovis Lend Lease  
Pharmaceutical  
David W. Johnson, Jacobs Facilities Inc  
Aaron H. Jordan, Massachusetts Biologic Lab  
Timothy M. Kachel, Genzyme Corp  
Chester C. Larner, Jr.  
Susan J. Looney, Genzyme Corp  
Anne Love, Genzyme Corp  
Robert D. Macdonald, Avecia Biotechnology  
Arun K. Malhotra, Camp Dresser & McKee Inc  
Robert E. Malsberger, Massachusetts Biologic  
Labs  
Sean McCullough, Genzyme Corp

Craig E. Meadows, Johnson Controls Inc  
David R. Mello, Linbeck/Kennedy & Rossi Inc  
Aline Nadeau, Genzyme Corp  
Scott E. Nadolski, Genetics Institute Inc  
Renato K. Nazareno, Teva Pharmaceuticals USA  
Aparajit Panda, The Gillette Co  
David K. Perry, TEVA Pharmaceuticals USA  
Beverly C. Potter, Wyeth-Genetics Institute  
Jeffrey C. Previte, EBI Consultants  
Kerry Roche-Lentine, Millipore Corp  
Laura R. Rubio, Genetics Institute Inc  
Richard A. Rys, R2 Controls  
Norman L. Schultz, US Filter Corp  
Kathy Schwartz, Genzyme Corp  
Cynthia M. Segnatelli, Camp Dresser &  
McKee  
Todd Shearstone, Bayer Diagnostics Corp  
David M. Simon, Process Facilities Inc  
Kevin Spurr, Genzyme Corp  
Karen Sum, Biogen Inc  
Ziran Sun, Abbott Bioresearch Center Inc  
Michael A. Trasatti, Millipore  
Nels Tyring, TVC Systems  
Yiping Wang, Aspen Technology Inc  
Mark A. Wilkinson, Infimed Therapeutics  
Glen Zeboski, Genzyme Corp 

## ISPE Boston Area Chapter Newsletter 2001 Advertising Rates

Thank you for your interest in advertising in the ISPE Boston Area Chapter newsletter. The following rates are currently in effect:

### Corporate Advertising and Career Opportunities

Type of Ad	Single Issue	4 Issues	Size
Business Card	\$75	\$225	3 x 2.5
Quarter Page	\$300	\$900	3 x 5
Half Page	\$400	\$1200	7 x 5 Horizontal
Half Page	\$400	\$1200	3 x 10 Vertical
Full Page	\$600	\$1800	7 x 10

*The cost for four issues includes a 25% discount!*

**Career Opportunity** announcements may be submitted by prospective employers at the above rates.

### Career Search

These will consist of up to six full-page lines for \$25 for one issue of the ISPE Boston Area Chapter newsletter. *No refunds will be made if the ad is withdrawn prior to publication.* ISPE Boston Area Chapter members will receive this benefit at no charge.

### Additional Articles

The ISPE Boston Area Chapter newsletter staff welcomes and will publish industry pertinent articles, space permitting. All articles are reviewed and subjected to editing by the ISPE Boston Area Chapter Staff. A review of edited articles may be requested if articles are submitted eight weeks prior to the next meeting. We would like articles that spotlight people and subjects relating to both the biopharmaceutical and pharmaceutical industry. If you are interested in submitting an article, please contact Amy Norris at 781/449-1925.

### Terms

Checks or money orders should be made out to the ISPE Boston Area Chapter and mailed to address listed below. Payment also may be made by Visa or MasterCard. **Note:** All ads must be "Camera Ready" as you would like them to appear. (Negatives also accepted.) Ads should be mailed prior to the next deadline. ISPE staff reserves the right to approve, edit, or decline any submission. Mail Newsletter Ads to:

ISPE Boston Area Chapter Advertising  
200 Reservoir Street, Suite 309A • Needham, MA 02494.  
Tel: 781/449-1925 • Fax: 781/444-6111

### 2000-2001 ISPE Boston Area Chapter Officers

**Daniel Lavin, President**  
Acusphere, Inc., 617/577-8800, ext. 219  
lavin@acusphere.com

**Andre Walker, Vice President**  
Bayer Diagnostics, 508/660-4511  
andre.walker.b@bayer.com

**Hank Moes, Treasurer**  
Arion Water, 508/778-6975, ext. 17  
Hank@arionwater.com

**Brian Hagopian, Secretary**  
Fluid Solutions, Inc., 978/453-9600  
brianh@fluid-solutions.com

### 2000-2001 Board of Directors

**Patricia Charek, Past President**  
Linbeck/Kennedy & Rossi  
781/674-3050, ext. 118  
pcharek@linbeck.com

**Janice Abel**  
Invensys, 508/549-6373  
Janice.Abel@ibusiness.invensys.com

**Carolyn Ball**  
Process Facilities, Inc., 617/946-9400, ext. 205  
Cball@processfacilities.com

**James Blackwell**  
Genzyme Corporation, 617/562-4796  
james.blackwell@genzyme.com

**Jack Campion**  
Massachusetts Biologics Laboratories  
617/983-6527, jack.campion@state.ma.us

**Denis Drapeau**  
Genetics Institute, 978/247-2031  
ddrapeau@genetics.com

**Jim Grunwald**  
SPEC Engineering, 781/438-3337  
jgrunwald@spec-eng.com

**Ed Heinle**  
ewheinle@aol.com

**Niall Johnson**  
TKT, 617/613-4459  
njohnson@tktx.com

**Joe Musiak**  
Biogen, 617/679-3345  
Joseph\_Musiak@Biogen.com

**Jon Voss**  
CGMP Systems, Inc., 781/665-7435  
jvoss@cgmpsystems.com



**International Society for  
Pharmaceutical Engineering**  
3816 W Linebaugh Ave  
Suite 412  
Tampa, FL 33624

PRESORTED  
FIRST-CLASS MAIL  
U.S. POSTAGE PAID  
TAMPA, FL  
PERMIT NO. 2661