



Connecting a World of
Pharmaceutical Knowledge

Carolina-South Atlantic Chapter



Volume 19 • Number 3

JUNE 2012

INSIDE THIS ISSUE



Overview of the 19th Annual ISPE-CaSA Technology Show	2
Board List	2
Spotlight on the 2012 Technology Show Venue	5
Spotlight on Marketing the 2012 Technology Show	7
Spotlight on the 2012 Technology Show Educational Programs.....	9
Winning Student Abstracts from the Technology Show Poster Competition	10
Event Calendar.....	13

Special TECH SHOW REVIEW ISSUE

The 19th Annual ISPE-CaSA Technology Show



ELEMENT

Intelligent valves,
sensors and
controllers

www.burkert-usa.com

O'NEAL *Delivers*

THE BUSINESS OF PROJECT DELIVERY



Our full range of planning, engineering, and construction solutions
consistently deliver satisfaction in the pharmaceutical industry.

Contact Us • www.onealinc.com • (919) 840-9500

A UNIQUE APPROACH ▼ PROVEN EXPERIENCE ▼ CLIENT SATISFACTION

Featured Sponsors

DEDICATED TO PROJECT SUCCESS

VALIDATION
COMMISSIONING
QUALITY & COMPLIANCE
PROCESS IMPROVEMENT
IT SERVICES & PRODUCTS

Local Contact:

John Hannon 336.558.6025 John.Hannon@CAgents.com
David Yaffe 919.696.3721 David.Yaffe@CAgents.com
Jennifer Lauria Clark 919.696.2335 Jennifer.Clark@CAgents.com



WWW.COMMISSIONINGAGENTS.COM

DCC
DUNBAR
CONSTRUCTION
CONSULTANTS

Daniel B. Dunbar, P.E.
dan@dunbarcc.com

Over 25 years of successful local Bio-Pharm
experience. Put us to work for YOU.

www.dunbarcc.com 919.412.1054

2012 Tech Show Highlights

Overview of the 19th Annual ISPE-CaSA Technology Show

By Bruce Craven, Technology Show Committee Chair

Wow! Spring has come and gone and now summer is here at last. Where did the time go? It seems just yesterday, I was writing a reminder about our Technology Show and anxiously anticipating the 10th of April. Well, the day did come and for those few hours I was fortunate to witness teamwork, camaraderie, networking and personal reconnections at their best. So, before I go any further, please allow me to say thank you to this year's committee members for tirelessly helping create one of the best shows our Chapter has had to date. Without them, April 10th would not have happened.

As a thank you to all of our members, this edition of the newsletter is dedicated to this year's Technology Show. Within its pages, you will find several articles written by various leaders within our committee, explaining and highlighting some of the activities and functions within the Technology Show—Marketing, Facilities and Programs. This information will give you an idea of the inner workings within our group and what it takes to put on a show of this magnitude.

As the Committee Chair, one of my jobs is to analyze and review the overall success of the show and use this evaluation to improve next year's event. To do this, I need feedback and data; and since this year's show was filled with many individual successes, the act of "data gathering" has not been difficult. Let me give you an overview of some of these "successes."

- We had a record sellout of exhibitor tables (181). Thank you to all our exhibitors and sponsors. You are the ones who make our event possible!
- Our Programs Committee provided attendees with 20 different and diversified education sessions divided into 4 tracks.

- The "New Member Breakfast" was heavily attended and generated many in-depth conversations for all—new and seasoned members alike.
- Our new registration process was voted the best ever by both exhibitors and attendees. The online and "day of show" registration was flawless.
- The poster competitions were exciting and engaging. There were two winners named during the show:
 - *Undergraduate Winner:* Ryan Boehm, University of North Carolina
 - *Graduate Winner:* Brandon Berry, North Carolina State University
- This year we were able to grant donations to two different charities:
 - Duke Hospice: On behalf of one of our Chapter members who recently lost a loved one prior to the show

(continued next page)



RGD
Project Management, Inc.

**Specializing in Construction
Management of Pharmaceutical &
High Tech Facilities**

Uncompromising Values...
www.rgdinc.com



**Carolina-South
Atlantic Chapter**

Officers

- David Brande, President
- Jennifer Lauria Clark, CPIP, Vice President
- Matt Gilson, Treasurer
- Heather Denny, Secretary

2011-2012 Board of Directors

Directors

- Eric Mayer
- David Smith
- Patrick Buckner
- David Knorr
- Lisa Kerner
- Andy Ferrell

Committee Chairs

- Wendy Haines, Communications
- Nancy Padgett, Membership
- Amy Lineberry, CPIP, Programs
- LeAnna Pearson, Students
- Bruce Craven, Technology Show
- Blake Derrick, Young Professionals

2012 Tech Show Highlights

(continued from previous page)

- Kids 'N Community: A charity that is "The Heart of the Carolina Hurricanes".
- (We made the donation on behalf of the PNC Arena Event Staff)
- Finally and one of the most important for next year's success, we had record participation from exhibitors and attendees in our end-of-event survey.

So more about the surveys... and a couple of "hot topic" questions. As with any survey, the general idea is to determine the pulse and perception of several key points and from the responses, determine an overall success ratio and a development plan for improvement. I must say, our Chapter members are full of great ideas and are not shy about providing positive and useful feedback. Out of the questions provided to both exhibitors and attendees, the ones related to our venue location and time for next year generated the most in-depth responses. What I thought highly interesting was how equally divided the responses were in regards to keeping the show at the PNC Arena or moving it to the new Raleigh Convention Center as well as moving the start time to later in the day and/or shortening the event duration. In addition to our survey, I tried to do some personal polling during our event with various people I would meet, and even that "unofficial" poll was equally divided — however, I did

come away with the overall sense that everyone I spoke to would like the Technology Committee to at least investigate the potential of evaluating a new venue. So as a promise to all of our sponsors, exhibitors and attendees, we will be investigating different venue opportunities and utilizing the wealth of feedback and suggestions provided through our survey so that we can make our "20th Annual ISPE-CaSA Technology Show" an even greater success in 2013.

In closing, please allow me the opportunity to say "thank you" to the following:

- Corporate Sponsors: STI, Burkett, CRB, PCI, Fluor, Hipp Engineering, Mangan Biopharm, and Pharma-Sys
- All of our exhibitors and general sponsors
- All of our attendees
- ISPE International (for their support and involvement)
- ISPE-CaSA Board of Directors (for their guidance and continued support)
- First Point Resources and their supporting staff
- 2012 ISPE-CaSA Technology Show Committee members (for their tireless support and continued dedication the success of this event)

Please look for updates on our progress for next year's show in future editions of the newsletter.



Front Row: Bruce Craven, Amanda Wujcik, Doug Warf; Second Row: Mike Putnam, Eric Mayer, Peter Kralka, Katrina Ryan, Kristina Boyce; Back Row: Rob Douglas, Paul Chapman

2012 Tech Show Highlights



**MEASURE, MONITOR AND VALIDATE
IN LIFE SCIENCE ENVIRONMENTS**

phone +1 800 683 8374
sales@vaisala.com

VAISALA

www.vaisala.com/lifescience

COMPLIANCE SERVICES VALIDATION

PROPHARMA GROUP

AUTOMATION PROGRAM/PROJECT MANAGEMENT

4819 Emperor Boulevard, Suite 400 • Durham, NC 27703
Toll-Free (888) 242-0559 • Office (919) 321-0369

www.propharmagroup.com

SEQUENCE
Validation Consulting Services

Validation Consulting | Project Leadership
Assessment and Remediation | Regulatory Compliance
21 CFR Part 11 Compliance | Training

P 919.855.9955 F 253.736.8446
6817 Falls of Neuse Road, Suite 102
Raleigh, North Carolina 27615
www.sequencevalidation.com

2012 Tech Show Highlights

Spotlight on the 2012 Technology Show Venue

By Eric Mayer, Co-Chair of Venue Committee

ISPE-CaSA led the way in 2012 with The 19th Annual Technology Show at the PNC Arena in Raleigh on April 10, 2012. The show is the Chapter's largest and most popular event. Once again, this year's show was very well received by the community with well over 800 attendees.

The event featured 20 different technical education sessions on compelling topics ranging from validation, quality by design, risk-based validation, water and steam Baseline® Guide, calibration, sterile fill isolators, PAT, an HR Panel, and many others

Once again the vendor community strongly supported the event selling a record 181 tables this year. We truly appreciate the enthusiastic turn out from all the companies that support the show year in and year out.

Also, as always, the PNC Arena event staff did an absolutely outstanding job with show set up and food services. They always make ISPE-CaSA feel very welcome at their arena and see to every detail. As a result of the show's success, the ISPE-CaSA Chapter was able to pro-

vide the Carolina Hurricanes Foundation a nice donation to support their Kids 'N Community charity. The Chapter awarded the donation on behalf of the PNC Event staff for a job well done.

ISPE-CaSA recognizes and thanks the Show's Corporate Sponsors for all their support. They were STI, Burkett, CRB, PCI, Fluor, Hipp Engineering, Mangan Biopharm, and PharmaSys.

After a long day of classes and learning, the event concluded with a wonderful networking reception at the Arena Club on the second level overlooking the ice. The reception was extremely well attended, and a good time was had by all as they enjoyed delicious food and libations!

The Technology Show Committee of ISPE-CaSA thanks our great community for making the show possible and looks forward to gathering again at the 20th annual show in the spring of 2013.

(photos continued next page)





Your challenges **today**
are not what they were **yesterday**
and will not be the same **tomorrow**.

We Listen. We Deliver... **more flexibility.**

If you're ready to be heard, CRB is ready to listen.

John Marr
919.334.7048
www.crbusa.com

CONSULTING
DESIGN
CONSTRUCTION
COMMISSIONING
QUALIFICATION





HIPP ENGINEERING
& CONSULTING, INC.

**PHARMACEUTICAL/
BIOTECHNOLOGY PROJECT
SPECIALISTS**

- Project Planning/Design
- Process Design
- Scheduling/Cost Estimating
- Construction Support
- On-Site Resources

BUDD HIPP
919.755.1033
www.hipp-usa.com

2012 Tech Show Highlights



Hyde
Engineering + Consulting

Robin Elleston
Regional Manager
Southeast Operations

919-819-7793 cell
robin.elleston@hyde-ec.com
www.hyde-ec.com


astropak.com





The Premier Passivation Provider in the South East

Astro Pak Helps You:

- ✓ DeRouge and Reduce Contamination
- ✓ Regulatory Compliance
- ✓ Increase Resistance to Corrosion
- ✓ Extend Equipment Life

[Contact Us Today!](#) 919.659.1917

2012 Tech Show Highlights

Spotlight on Marketing the 2012 Technology Show

By Wes Robbins, Marketing Co-Chair

Ever have those special days when the expectations and excitement leading up to them is so great and then the day comes and goes and you wonder what happened? That's a pretty fair assessment for members of the Tech Show Committee. We spend an entire year planning this event to have it unfold and evaporate in approximately ten powerful hours. This year was no different and although the show day may pass quickly, the deep breath and sigh at the end is always taken as a reflection on the day's success rather than in relief that it's over.

Many of us have had the honor and pleasure of serving on this committee for several years. We have seen the show grow from 60 or 70 exhibitors and 200 attendees to what it is today. Proof of that growth came four years ago when we outgrew the area's largest hotel conference center and we moved to the RBC Center (now PNC Arena). Marketing the show has changed as well. Part of the committee's current discussions center around whether or not we have outgrown our own ability to handle an aggressive marketing campaign as volunteers. The 2013 show committee will look into additional options for marketing next year's event to be even better at promoting the show.

In planning the show, many factors have to be considered. We must first pick a date and to do that, we have to consider holidays, school breaks, other industry shows and events such as INTERPHEX. When holding the event at a facility such as the PNC, we have to look at their events like basketball, hockey, concerts, etc. We even work around the ACC and NCAA's basketball tournaments. No matter the venue, their schedule comes into play as well. The show has even grown to a point where we have people from all across the country and Canada exhibiting and attending, so we pass on Mondays and Fridays to accommodate travel for those individuals. For years, the committee tried to create a new theme for that year's show. This proved to be a formidable task utilizing valuable

energy so we branded the event four years ago with the graphics that you see in our e-blast and printed material in an attempt to create that recognizable eye catching identifier for the show. This allowed the committee to focus on new challenges such as the show's growth and implementing new things, such as the career development fair.

(continued next page)





CLARK • NEXSEN

Architecture & Engineering

Jim McGlade, AIA, LEED AP
jmcglade@clarknexsen.com

4000 Westchase Boulevard, Suite 280
Raleigh, North Carolina 27607
919.828.1876 Office
919.828.1877 Fax

www.clarknexsen.com



Specialists in
Ultrapure Water
since 1967

Serving Pharmaceutical, Biotech, Research, Academic, Microelectronics,
Medical/Clinical, Food/Beverage, and Industrial Applications

Charles Lane
System Specialist

513 United Drive
Durham, NC 27713
919-452-6107
clane@hydroservice.com



2012 Tech Show Highlights

(continued from previous page)

The first step in marketing happens after the date is confirmed with "Save the Date" e-mails/e-blast and mailers. Next, we construct a show schedule and this is when we can begin to market the things happening during the actual show day. As speakers are confirmed or other events of the day are put into place, we continue to expand our marketing to exhibitors and attendees all the way to the show day. We market to other organizations, such as PDA. The final component is the program, which has taken on a whole new look. We even worked with a PR firm this year but we think we can do better with that in the future.

Planning and marketing the show go hand in hand and part of the committee's new challenges for the future will be the best avenues for advertising and getting the word out. Today's work climate surfaced this year, meaning that most organizations are requiring more from fewer so freeing up time to attend must be considered. Do we change the time of the show and make it a late afternoon and evening event? Are we reaching every individual that would benefit from attending? Are we providing educational sessions that reach across all workplace disciplines within the industry and are we marketing correctly to all of those individuals? One thing is for sure: the support from our exhibitors is phenomenal and between them all, there should be something of interest for just about everyone or any discipline within our industry.

Going forward, there will be much discussion about marketing the show for 2013. The marketing budget will be reviewed and many other options are already being researched in an effort to enhance and improve an already great event. As always, we would like to thank our exhibitors. Without them, there is no show. This event is for the attendees and our true measure of success is in the attendee turnout and what they gain from the experience. Even though the attendance is great, we think it can be better and that's the focus of our future marketing. Some of you may have participated in the post-show survey and we appreciate those responses. We

encourage everyone to pass along any comments to help us better serve you with a new and improved Technology Show so if you have an idea, please send it to us. We look forward to seeing you at next year's show.



IPS North Carolina
2803 Slater Road, Suite 130
Morrisville, NC 27560
T: 919.460.6636

www.ipsdb.com

Engineering | Construction | Commissioning & Qualification

Knowledge, Skill, and Passion

2012 Tech Show Highlights

Spotlight on Technology Show Educational Programs

By Clay Schaeffer, Programs Co-Chair

The 2012 Tech Show education program was a resounding success, offering eighteen industry-focused seminars to well over 100 attendees. Topics covered design, quality, maintenance, regulatory, and operations. New this year to the CaSA show was a dedicated track for ISPE Communities of Practice groups. Seminar presenters included a wide mix of representatives from owner organizations, consultants and vendors.

The maintenance and calibration seminar track, sponsored by PCI, covered topics on in-line instrumentation, aligning calibration and maintenance systems with ASTM E2500, and paperless maintenance and calibration systems. Also included in this track was a discussion on projected manufacturing and packaging issues related to clinical trials.

The facilities track presented a variety of subjects from modular facility design, to sterile fill isolators, to tech transfer. Two of the presentations were focused on Grifols and their current operation.

The quality track showcased presentations on quality by design (QbD), and methods for cleaning verification. Also covered in this track was a discussion on the impact of governmental policy uncertainty to the life sciences industry.

The ISPE Community of Practice track presented topics on the current USP Water Guidelines, GAMP, and issues related to procurement in the pharmaceutical industry. Be sure to look for more ISPE Community of Practice participation in future shows.

Thanks to all of the dedicated presenters who made this year's education program a great experience for all those who attended.



We put **MYWay**® to work for our Life Sciences clients.



Learn more at www.mcdonaldyork.com

Contact: Mike Kriston, LEED®AP
McDonald York Building Company
801 Oberlin Road, Suite 235
Raleigh, NC 27605
(919) 832-3770

Follow us:



2012 Tech Show Highlights

Winning Student Abstracts from the Technology Show Poster Competition

GRADUATE WINNER

Cross-Scale Predictive Modeling of CHO Cell Culture Growth and Metabolites Using Raman Spectroscopy and Multivariate Analysis

Brandon Berry

Raman Spectroscopy presents a very attractive option for bioreactor monitoring and control. Raman technology, a form of vibrational spectroscopy, was investigated for its potential to provide live monitoring of bioreactor metabolites and growth data without the use of offline analyzers. Chemometric models were created from reference Raman spectra collected from a Kaiser Optical, Inc. Raman RXN2 in-situ probe with iCRaman software and the resulting spectra were correlated with offline metabolite and cell growth data from multiple CHO cell based process runs at the 5L, 200L, and 2000L scale utilizing SIMCA-P+ software and multivariate analysis techniques. The resulting models were used to make real-time, live predictions of a 2000L scale batch. Models were also retro-actively applied to various scales to test predictive model robustness across scale. Bioreactor constituents modeled are: viable cell density (VCD), total cell density (TCD), glucose, lactate, glutamate, ammonium, and osmolality. Although not evaluated in this study, feedback control for optimized continuous feeding based on live measurements (rather than a typical daily bolus feeding schedule) would be the next step in implementation in a production environment.

UNDERGRADUATE WINNER

The Antibacterial Properties of Acid Anhydride Copolymer Microneedles

Ryan Boehm

Department of Biomedical Engineering at the University of North Carolina and North Carolina State University

Microneedles are microscale needle-like devices which can be utilized for the transdermal delivery of pharmacologic agents. In this work, microneedle arrays of biodegradable acid anhydride copolymer were prepared using a combination of visible light dynamic mask micro-stereolithography and micromolding. Gantrez® AN 169 BF was used as the biodegradable material for the microneedles. Nanoindentation, fourier transform infrared analysis, and energy dispersive x-ray spectrometry were performed on this material to examine the mechanical and chemical properties. Gantrez® AN 169 BF microneedles were tested for in vitro antimicrobial activity against *Bacillus subtilis*, *Candida albicans*, *Enterococcus faecalis*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Zones of growth inhibition were observed for *E. coli*, *S. aureus*, *E. faecalis* and *B. subtilis* following application of the Gantrez® AN 169 BF microneedles in agar plating studies. Our results suggest that solid microneedle arrays prepared of these acid anhydride copolymers by indirect rapid prototyping techniques may serve as a delivery mechanism for pharmacologic agents and may be useful in treating a variety of skin infections.



2012 Tech Show Highlights



2012 Tech Show Highlights



CTGsouth

COMPLIANCE TECHNOLOGY GROUP, SOUTH

Commissioning & Validation, Steam Quality Testing, HEPA Filter Certification

Suites 407 & 408, 16 West Martin Street, Raleigh, NC 27601
office: 919.926.8CTG



2012 Tech Show Highlights

Technical Tip from IPS

When considering the use of alcohol based solutions (e.g., buffers for chromatography media, solvents for dissolution, special cleaning practices) keep in mind the potential impact on the electrical classification of the preparation and processing areas. Not only can fixed equipment be impacted but portable devices like barcode scanners and two-way radios would need to be evaluated.

*Erich Bozenhardt, P.E.
BioProcess Engineer
Integrated Project Services - IPS*



STI Components, Inc.

**Premier Supplier of
Ultra Pure Fluid
Handling Components**

**Please visit us at
WWW.STIFLOW.COM**

Biotech, Pharmaceutical, Food & Beverage and Cosmetic processing companies choose STI for products such as:

Hoses, Tubing, Aseptic Sampling, Disposable Tubing Sets, Stainless Steel Componentry, Peristaltic Pumps and much much more...

Got News or Story Suggestions for Upcoming Newsletters?

Send it to:

omni_tox@yahoo.com

Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for your Business!

Our Chapter produces six e-newsletters per year, and we depend on the support of our advertisers. We send out the newsletters via e-mail and via web link to all of our Chapter Members throughout the Southeastern U.S.

That means you get targeted access to top-notch pharma, biotech, and bio-science professionals and managers. These newsletters are also posted on our [website](#) so your ad can be accessed by interested visitors to our site.

Best of all, the cost is only \$650 for your full color, business-card-sized ad for six insertions. That's only \$650 for targeted advertising in full color for an entire year!



Ask About HOT LINKS!!

Would you like to have targeted customers simply click on your ad and get right to your website?

A hot-link can be added to your ad, connecting readers directly to your company website for an additional \$500.00 for a whole year.

If you are interested in advertising with the ISPE CaSA e-newsletter, please contact our Chapter headquarters at:

ISPE-CaSA
1500 Sunday Drive
Suite 102
Raleigh, NC 27607
919-573-5442
info@ispecasa.org

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE CaSA Communications Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5" x 2") may contain your logo or other artwork. Artwork should be sent directly to pkralka@FirstPointResources.com.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG or TIF formats are easiest for us to work with. Space is limited, sign up today!

ISPE Carolina-South Atlantic Chapter Newsletter

1500 Sunday Drive, Suite 102

Raleigh, NC 27607

Tel: 1-919/861-4531 • Fax: 1-919/787-4916

omni_tox@yahoo.com

EDITORIAL POLICY

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Manuscripts should be forwarded to a Member of the Communications Committee at omni_tox@yahoo.com for review 30 days prior to publication. A brief three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment must accompany the article.

Got News?

Send it to:

omni_tox@yahoo.com

Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

A word to the ISPE CaSA Newsletter advertisers: Thank you all for your continued support. Without it we could not have the wonderful support staff to get our ISPE CaSA Members the news in such a timely and professional fashion. If you have updates to your advertisements or find any other error, please contact us so that we can serve you better.