



President's Message



LeAnna Pearson

Welcome to a new year for the ISPE CaSA Chapter! Your Board of Directors has been working hard throughout the summer to develop plans for the upcoming year and we have many exciting education and networking events in the works! August will kick off our new year with our Annual Planning Session, and this year to shake things up a bit we will have a Key Note from Lou Kennedy,

President, CEO and Owner of Nephron Pharmaceuticals Corporation. So, mark your calendars for August 27th and check the website and our weekly eblast for a link to register. September will have our first YP event with a Networking & Professionalism Symposium followed by a WIP networking reception. October will host multiple events including our 2nd year hosting a golf tournament in Atlanta, an educational event & back by popular demand- Oktoberfest. Be sure to check our website for upcoming events and subscribe to our weekly eblast. This will get you access to upcoming events, news and registration links.

I would like to thank Mike Putnam for his leadership and guidance throughout my tenure on the Executive Board. It is an honor to follow in your footsteps. We have several other board members rolling off this year who are very deserving of a much-needed break! Kevin Debbs, Beth Smullen, Cat Meier, Jason Kelly, David Davis, David Smith, and Mark Yates have supported the CaSA Chapter in more ways than we'll ever know. I am thankful for your friendship and for the opportunity to serve on the board with each of you! It has been said "alone we can do so little, together we can do so much." This is so very true, and this year we have decided to combine several of our committee to allow us to combine efforts and talent. The Newsletter committee will now fall under the IT/Media Committee under the leadership of Dan Santarsiero, and the Student Affairs Committee will now fall under the Young Professional Committee led by Mariessa Perez-Gibbins. I would also like to introduce our new Board

of Directors for 2019-2020. (Please see Board Member List (page 2) and Committee Lists (page 3)).



(continued next page)

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Thank you to all of our advertisers. This newsletter would not be possible without your support!



President's Message (continued from page 1)

We held our board orientation at the end of July at the beautiful Durham Hotel and shared our ideas for the upcoming year. 2019 - 2020 is going to be a year of inspired events, networking and educational opportunities. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please let me or any other board member know how well we are doing or what we can do to improve.

I cannot end without again thanking our 2019-2020 Board of Directors and Volunteers. Whether you drove a gator at the golf tournament delivering lunches, directed members at the Technology Show, reviewed an article for our newsletter,

provided input to our executive leadership, or manned a membership table, our success was not possible without you. Thank you. And now a To Do List: • Let us know if you are interested in a volunteering with a committee or in active leadership of ISPE CaSA. • Send in ideas for 2019-2020 educational programs and networking events. • Stay cool, enjoy, and relax the last few weeks of summer

Sincerely,
LeAnna Pearson
President, ISPE CaSA Chapter

Board of Directors 2019 - 2020

Executive Board

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Vice President

Rich Stanfield
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Chris Small
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Dan Williams
Geoffrey Ramsey
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Chapter Events

Networking Committee

By Chris Smith, Chair


Greater Atlanta Golf Tournament - October 14, 2019

It may be hot in the CaSA right now, but cooler times are coming. Plan ahead, be prepared, and register today for the second annual ISPE-CaSA Atlanta Golf Tournament! Last year's inaugural tournament was a great success and we plan to grow this year's contest even more.

The tournament, scheduled for Monday October 14, 2019, will again be held at Chateau Elan Golf Club in Braselton, Georgia. We received glowing reviews last year about the course's greens, fairways, and clubhouse. It will be an all-day

golf event with sponsors, peers, vendors, colleagues and friends. Breakfast, lunch, drinks, and range balls will be provided. A 50/50 raffle will be held at the end of the day to support the Jane Brown Scholarship.

Start pulling your team together for a great day on the course. Registration is now open.

Sponsorships are available. See the [ISPE-CaSA registration page](#) if interested. 



Join ISPE-CaSA and your colleagues for the

Greater Atlanta Golf Tournament

Enjoy a great round of golf and networking opportunities. Come join us for our 2nd annual golf outing. Help us make this tournament a success!

To register, please visit:

<https://www.eiseverywhere.com/2019-ispe-casa-chateau-elan>



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Chapter Events

Education Committee

By Andy Ferrell, Chair

Emerging Technologies and Data Integrity: Considerations, Challenges, and Compliance

On July 18th, ISPE-CaSA partnered with PRA Sciences to host a half day conference at Raleigh's Marriott Crabtree. This event was attended by more than 90 industry professionals and was highlighted by Eric Staib's opening presentation on GAMP guidelines. The event was headed up by the CaSA Education Committee's own Stephanie Hockeborn.

This event featured speakers from 6 states on Robotic



PRAHEALTHSCIENCES

Process Automation/ BOTS, Artificial Intelligence & Machine Learning, Data Integrity, and Case Studies on Technology Compliance Challenges. All presentations can be found on the ISPE-CaSA website on the [Presentations/ Technical Articles](#) webpage.

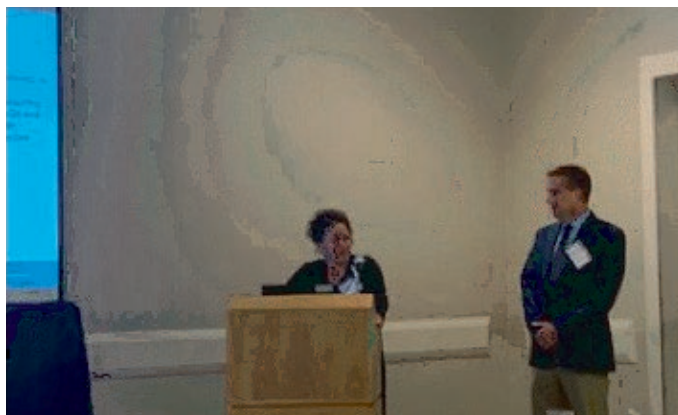
The Young Professionals (YP) breakout session included presentations from Jason Kelly (Laboratory DI) and Dan Montgomery & Eric Staib (Computer Validation Basics). The session was attended by 20 YPs. Following the talks, attendees networked over hors d'oeuvres and cocktails courtesy of the CaSA Education Committee. 🏠



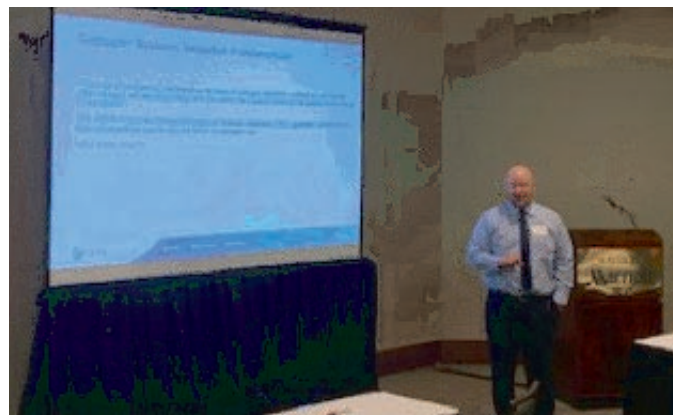
Stephanie Hockeborn welcomes attendees.



Eric Staib presents GAMP guidelines.



Brandi Stockton and Jesse Jones co-present on on Tech Compliance Challenges.



Dan Montgomery presents Computer Validation to Young Professionals.



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Technology Conference

Technology Conference Committee

By Alma Montemayor, Chair

2020 Technology Conference

The Tech Conference Committee is off to a great start! Over the summer we've come together and finalized a few things. As we mentioned earlier this year, we are moving to the Durham Convention Center. This change of scenery will be refreshing, and we're excited for you all to experience the "City of Medicine" and the educational programs that will be located next door at the historic Carolina Theater. Also, the theme next year is "Vision 2020" – a celebration of what's to come as we launch into the next decade of new discoveries, therapies, products,

and processes that will change the industry. We look forward to seeing you all at the Tech Conference on March 10, 2020!

Advance deposits for booth space are due by August 15. If you would like a booth or table at the 27th Annual ISPE-CaSA Life Sciences Technology Conference, an early deposit of \$250 will save you 10% on the fee and offer you an opportunity for early table selection. You can make your deposit in your choice of two ways: By accessing our online payment portal [here](#) or by downloading a [form](#) and submitting it with payment directly to ISPE-CaSA.

The deadline for making your deposit is August 15, 2019. ➡

CaSA COMMITTEES 2019 - 2020

Education

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Monday, October 14, 2019
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Join ISPE-CaSA and your colleagues for the

Greater Atlanta Golf Tournament

Enjoy a great round of golf and networking opportunities. Come join us for our 2nd annual golf outing. Help us make this tournament a success!

To register, please visit:
<https://www.eiseverywhere.com/2019-ispe-casa-chateau-elan>

ISPE | Carolina-South Atlantic Chapter

Technical Corner

By:

Justin Blackwelder (PCI)

Rick Mineo (Kneat)

Lou Killian (Kneat)

Case Study: Productivity and Compliance Improvements through Digitalization of Temperature Profiling

Executive Summary:

Temperature profiling is a standard Validation requirement for GMP chambers used to ensure a temperature-controlled environment for in-process materials, equipment, raw materials, and samples within life sciences. Even though the temperature profiling work process is well established, the documentation activities are inefficient and mostly a paper-based manual effort. This case study describes an innovative validation process that PCI has established for many of their clients. This process leverages the Kneat validation software system to deliver a lean end-to-end digital and compliant work process.

Prior to implementing this new digitized work process, PCI created and tested the concept for one of their customers to provide evidence of cost and labor savings. The proof of concept showed an average savings of 15 labor hours per chamber. PCI was averaging 26 labor hours per chamber and now is averaging 9 labor hours per chamber, which is a productivity gain of over 100%.

Background:

Life science Industry regulations require Commissioning, Qualification, and Validation (CQV) of equipment and facilities. The equipment category includes chambers such as sterilizers, ovens, incubators, freezers, controlled temperature storage rooms, etc. One of the CQV requirements associated with this category of equipment is Temperature Profiling of the chamber to assure that a controlled environment is maintained to support the manufacturing process.

Technology solutions for collecting temperature data such as Kaye and Ellab data loggers are available for monitoring

and recording temperature data at strategic locations within the chambers. However, the associated validation work process activities for conducting and documenting activities such as protocol/test process steps, capturing results, pre- and post-review/approval and final summary report generation are not efficient and continue to be a traditional paper-based and manual efforts process. In addition, key data needs such as validation status, test results, record storage, and retrieval are also an inefficient manual paper-based effort.

This paper describes the benefits and cost savings of an end-to-end digitized CQV validation work process for environmental chamber temperature profiling developed by PCI.

References:

- ISPE Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring
- US Pharmacopeia Temperature Profiling Guide
- Health Canada Guidelines for Temperature Control during storage and distribution
- MHRA Guidelines
- EU Annex 15
- CFR 21 211.142

Business Goal:

PCI's goal was to reduce the labor and cycle times associated with temperature profiling validation for their customers. The objective was to create a best practice lean work process and then to embed that lean process into a software system that would standardize the work process for many of their customers.

Technical Corner

Solution:

After standardizing the work process and understanding their detailed requirements for a software solution, the PCI team evaluated several commercially available systems. They selected the Kneat e-System as it provided the best fit, ease of use, and flexibility. Following the standard business work process developed for temperature profile mapping, PCI was able to create standard approved

document templates in the e-System that are populated from system metadata and shared document data. This meant that documents can be created quickly with a high degree of accuracy, which resulted in reduced review and approval and rework efforts. The table below outlines the standard work process used by PCI and the differences between the paper-based and the digitized work process.

Paper-Based Versus Digitized Temperature Profile Work Process:

Business Process Steps	Deliverables	Paper-Based Process	Digitized Process
Temperature Profiling Plan for Chamber	Validation Master Plan	Create word documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or wet signature.	Select data centric impact assessment checklist (for classification of validation category and metadata)
Create, review, approve design documents	Engineering Specifications Documents	Create word documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or wet signature.	Central review process with document repository for leveraging common specs/ data and templates. Auto-generate "pack of documents" with "changes impact assessment." e-System supports efficient review, comment, approval process.
Create review, pre-approve test protocols	Pre-approved test protocols	Create documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or via wet signature	e-System supports efficient central creation, review, and approval process. Data sharing across documents reduces effort and errors.
Execute validation testing	Completed Validation records	Manual paper-based process: data handwritten into test protocol (data integrity, efficiency, and compliance concerns)	Enter required information directly into smart e-documents in GDP compliant process. Attach temp profile data from data loggers.

Technology Corner

Business Process Steps	Deliverables	Paper-Based Process	Digitized Process
Deviation processing	Deviation forms post-approved and closed	Manual paper-based process: effort required to hand carry documents for wet signature or deviation tracking system	Auto initiate deviation within system at point of observation and link to test step if required. Detail corrective process and route for pre-approval. Complete corrective action, attach evidence, route for post-approval, and close out.
Post review and approval	Post-approved validation records	Manual circulation for post review and approval. Approval using wet signature. Cumbersome and normal for many errors to be found during reviews, requiring back and forth corrections, etc.	Post execution instantly circulate the executed protocol complete with all supporting evidence for review. Use the review by exception aid to speed up the review. All review is completed online with instant access to all supporting information – attached evidence, deviations, validation summary report, etc.
Create validation summary report and approve	Approved final validation summary report.	Manual effort required to type test summaries, deviation summaries, etc into the document. Then circulate it for review and approve manually or in DMS	Auto generates validation summary report eliminating manual effort and GDP errors
Validation records storage	Controlled storage and retrievable validation records	Manual effort required to scan, package, store, and maintain records. Storage offsite in the future. Records sometimes damaged or misplaced.	All records are created, modified, executed, reviewed, and approved centrally in the system. They are never checked out and remain centrally managed for their full lifecycle. Records are always quickly accessed in the system anytime in the future. Record handling and storage is eliminated.
System validation status/metrics.	Validation project status and quality metrics.	Manual spreadsheet efforts. Errors and delays in finding the true validation status of a system.	Any system validation status or project is instantly available and is based on actual work completed

Technology Corner

Key Benefits:

New Temperature Profiling Validation Process Benefits
Simplify protocol generation
Faster protocol review and pre-approval
Leverage existing validation documentation
Faster and compliant test execution
Faster executed protocol review and post-approval
Reduced overall validation cycle time
No document manual handling
Reduced errors - efficient & compliant deviations management
Improved on-line status reporting and real time data/metrics access
Improved audit preparedness
Improved records storage management (no scanning/no PDF storage)
Greater team collaboration and visibility

Customer Success Example:

Application: Client adding 50 new chambers

The customer is very satisfied with the new process that gives them instant real time data access and is delivering both cost and cycle time

reductions. Refer to productivity improvements in the table below.

Labor Savings After Implementing a Digitized Work Process:

Old Process	1 person performing 6 chambers per month equating to approximately 26 labor hours per chamber
New e-Process	1.5 persons performing 26 chamber validations per month equating to 9 labor hours per chamber
Productivity Improvement	<ul style="list-style-type: none"> Productivity improvements greater than 100% 26 labor hours per chamber reduced to 9 hours per chamber Faster Validation Cycle Times – Now performing 26 chamber validations per month with 1.5 full time resources versus 6 chambers with 1 full time resource before.

Next Steps:

PCI is now applying the new e-system process for temperature profiling for all its clients.

Technology Corner

About the Authors:

Justin Blackwelder:

Justin is the Project Services Manager at PCI. He has an extensive background in equipment qualification, including temperature profiling studies. He and his team offer Commissioning, Qualification, Validation, and Consulting services to clients in the Life Sciences industry. He can be contacted at jblackwelder@pci-llc.com

Rick Mineo:

Rick is the Operations Director at Kneat. Prior to joining Kneat he was the founder and President of Encova Consulting, a Division of PCI. He provides extensive technical engineering and validation consulting support to his customers. He can be contacted at rick.mineo@kneat.com

Lou Killian:

Lou is a Customer Success Director at Kneat. He has over 35 years of Life Sciences experience at Abbott, Genentech, and BioMarin. He can be contacted at lou.killian@kneat.com



Advertising Update



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Newsletter Committee Advertising Update

By Jason Kelly (Past-Chair)

You're Reading One of the Final 3 CaSA Newsletters – EVER!

Our chapter has published a newsletter every 2 months for the past 26 years. Over that time, the newsletter has been an excellent tool. It has helped connect our members with each other at CaSA events and with our corporate partners. Over time, the Newsletter has evolved. Originally, it was a print publication that arrived in a physical mailbox. For a number of years now, it has been distributed as a PDF containing links to additional content and advertisers' websites. New communication tools are being introduced at an astounding rate, and our world's preferred methods of communication continue to evolve. We now believe we can communicate more effectively with our membership by social media than with this periodic publication.

The Newsletter and Social Media Committees were combined this month. The very last ISPE-CaSA newsletter will be published in December 2019. Beginning in January 2020 chapter messaging will occur via our website, email, and various social media platforms.

As a result, advertising opportunities with CaSA are changing in a big way. We've made some preliminary decisions, and we need your input to finalize the program!

In broad terms, here is our thinking so far:

- Corporate partners submit articles that CaSA publishes directly on our website and LinkedIn
- Online publicity pairs with real life partnership. Companies that sponsor chapter events will be able to publish event summaries.
- Corporate submissions are expected to contain their own corporate logos and links.
- Articles will conform to a handful of pre-approved formats to ensure consistency of appearance and messaging.
- CaSA will promote all articles to our followers on LinkedIn, Facebook, Twitter, and any other social media platform that gains prominence in the future. Companies are welcome to link back to their own articles on the CaSA website during advertising campaigns.

How can you help?

- If you're an advertiser, share your ideas with us. Let us know we can best serve you!
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- If you're a CaSA member, volunteer for the IT/ Media Committee!
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Advertisers:

We will run your articles online at a greatly reduced rate through the end of 2019. Contact us for details!

We members of the Newsletter Committee have treasured the opportunity to serve the chapter over the years. We look forward to continuing that service as part of the IT/ Media Committee.

Thank you for reading!
-CaSA News

ISPE CaSA 2019 Annual Sponsorship Program



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Major Education Events - 10 Attendees
Tech Conference - Career Fair Table, 25 Attendees, 2 Leaders in IAC Lunch Meeting
Golf Tournament - foursome in one golf tournament
Newsletter - Business Card Ad in 2019 newsletters
Membership - One (1) Annual ISPE Membership for Site Lead

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Annual Sponsorship: \$1,750
(37% Discount)

Includes:

Major Education Events - 10 Attendees
Tech Conference - Premium Table, 10 Attendees
Golf Tournament - foursome in one golf tournament
Newsletter - Business Card Ad in 2019 newsletters
Membership - Five (5) Annual ISPE Memberships

Total Retail Value: \$5,895

Annual Sponsorship: \$5,000
(15% Discount)

Includes:

Major Education Events - 10 Attendees
Tech Conference - University Table, 15 Attendees
Golf Tournament - twosome in one golf tournament
Newsletter - Business Card Ad in 2019 newsletters
Membership - One (1) Academic and fifteen (15) Annual ISPE Student Memberships

Total Retail Value: \$2,729

Annual Sponsorship: \$750
(72% Discount)

* Manufacturer - business entity with primary concentration on drug or medical device manufacturing. Not intended for equipment manufacturers supporting drug or medical device manufacturing industry

** Education event attendance may exclude plant tours due to capacity limitations

*** 2019 Sponsorships (e.g. Gala attendance, Tech Conference sponsor, etc.) purchased prior to joining Annual Sponsorship Program will be credited toward program cost at the time of joining

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