Hello ISPE CaSA Members! What an awesome time to be part of the Life Sciences industry. With many new facilities, plant expansions, and product transfers in our area, CaSA members and guests came in droves May 22 for a beautiful day on the course at Prestonwood Country Club. The 25th Annual CaSA RTP Golf Tournament brought in 264 players (66 teams), representing the largest attendance in our 25-year history! Following the tournament, CaSA Women in Pharma hosted an educational wine tasting where more than 90 attendees sampled wines from across the globe. More than $7,700 was raised throughout the day to benefit the CaSA Jane Brown Scholarship.

As we approach the end of our board term in July, I would like to thank the amazing team of board members and volunteers that make CaSA such a special organization. Over the past year, you collaboratively led CaSA to a higher standard of success. Some of the many accomplishments include:

- Higher quality educational and networking events held at manufacturing sites
- Increased manufacturer engagement including 27% of Tech Conference attendees
- Improved university involvement including 2 new student chapters at USC and Georgia Tech
- Local community impact including $17K towards Tea Chris Combs/Project ALS and $18K towards the CaSA Jane Brown Scholarship

Looking forward, plan to join us at the Summer Event on Thursday, July 18, 2019 at Marriott Crabtree in Raleigh, NC. Register here today!

Thank you to all Members, Board of Directors, Sponsors, Volunteers and Students that so generously support ISPE CaSA. I have enjoyed serving as your President and look forward to many great things to come!

President, ISPE CaSA Chapter
Did You Know Some Of Our Advertisers Use Hyperlinks?

The following advertisers are using our hyperlink feature in their ads, Gemu Valves, Burkert, AdvantaPure, Sequence and CRB. You can "click" anywhere in their ad and you will be directed to their link. You can find them more easily by looking for the ads that are outlined in GOLD.

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

INSIDE THIS ISSUE

President’s Message................................................................. 1
Board of Directors 2018 - 2019 .................................................. 2
25th Annual RTP Golf Tournament & 1st Annual WiP Wine Tasting................................................................. 3
Education Committee Event.................................................... 4
CaSA Committees 2018 - 2019................................................. 5
2020 Technology Conference................................................... 5
Social Media Committee.......................................................... 6
Technical Article: CSV Strategy - Automation.......................... 7
2019 Newsletter Advertising and Sponsorship Opportunities... 9
2019 CaSA Annual Sponsorship Packages.............................. 12

CASE STUDIES on
• Filling assemblies
• Tubing
• Container closures
• Pass through systems
AdvantaPure®
www.advantapure.com

Board of Directors 2018 - 2019

Executive Board
President
Mike Putnam
president@ispecasa.org

Vice President
LeAnna Pearson Marcum
vicepresident@ispecasa.org

Treasurer
Rich Stanfield
treasurer@ispecasa.org

Secretary
Kevin Debbs, CPIP
secretary@ispecasa.org

Past President
Wendy Haines, PhD ASQ CQA
nominations@ispecasa.org

Manufacturing Engagement Advocate
Beth Smullen

Directors
Director at Large
David A. Davis

Director at Large
Mark Yates, PhD

Director at Large
David G. Smith

Connecting a World of Pharmaceutical Knowledge
Networking Committee
By Chris Smith, Chair

The 25th Annual RTP Golf Tournament and First Annual Women in Pharma Wine Tasting

The 25th annual ISPE-CaSA Golf Tournament was held on Monday, May 20th to a sold-out field of 264 players. The group required all three courses of the Prestonwood Country Club in Cary, NC. Morning clouds burned off to a warm 89 degree, sunny afternoon. Hole sponsor organizations on the courses supported players with giveaways, food, and beverages.

After returning from their games, players congregated in the Ballroom of the country club for a classic golf tournament lunch and the annual raffle supporting the Jane Brown Scholarship. Approximately 30 items were raffled off to winners from all over the ISPE-CaSA region, and Jane Brown herself served as the ‘Guest of Honor’ to pull the winning raffle tickets. Approximately $7,700 was raised for the scholarship.

Following the completion of the golfing event, approximately 75 people attended the first annual Women in Pharma (WiP) wine tasting event. The wine tasting was also in the Prestonwood Ballroom and was led by a sommelier. The group learned about the origins and production of a Cava, a Prosecco, and a Sauvignon Blanc before an open networking evening with Aperol Spritz and Mimosa stations. The Networking committee looks forward to further growing this great event next year.

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

July 18, 2019
Marriott at Crabtree
Raleigh, NC
An exciting line-up of speakers and session topics are featured at ISPE-CaSA’s latest education event July 18 in Raleigh. Set at the beautiful, newly renovated Marriott at Crabtree, the event features leading experts in the exciting field of Data Integrity. Special thanks go out to our event networking sponsor: PRA Health Sciences.

Register Here

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

Date: 18 July 2019
Location: Marriott Crabtree, Raleigh, NC

Schedule of Events:

12:30 - Registration Opens
1:00 - 1:15 (COA): Opening Remarks/Speaker Introductions: Education Committee and Eric Staib
1:15 - 1:45 (COA): Block Chain presented by Jamey Canterbury
1:45 - 2:15 (COA): Robotic Process Automation (RPA) / BOTS presented by Denzil Burriss with PRA's Innovative Intelligence Group (IIG)
2:15 - 2:45 (COA): Artificial Intelligence and Machine Learning (AI/ML) presented by Eric Staib
2:45 - Break
3:00 - 3:45 (COA): Data Integrity (DI) presented by Lorrie Schuessler
3:00 - 3:45 (CRE): YP Session: GAMP & Computer Validation Basics presented by Eric Staib and Dan Montgomery
3:45 - 4:45 (COA): Technology Compliance Challenges CASE STUDY presented by Jesse Jones and Brandi Stockton
3:45 - 4:45 (CRE): YP Session: Laboratory Data Integrity (DI) CASE STUDIES presented by Yael Snyder.
4:45 - 5:15 (COA): Q&A by Eric Staib / Closing Remarks: Education Committee
5:15 - Break
5:30 - 7:30 (COA): Networking & Refreshments (Cash Bar)

(COA) = City of Oaks Room  (CRE) = Creedmoor Room
It’s time for a change!

Next year, ISPE-CaSA is expanding the reach of its Life Sciences Technology Conference across the Research Triangle to Durham. The 27th Annual Tech Conference will take place in the Durham Convention Center complex in the heart of downtown on March 10, 2020.

The Convention Center (photo at top) blends modern amenities with beautiful, historic buildings, like the Carolina Theatre (photo at bottom) which are sure to delight and inspire.

Durham, known as the “City of Medicine,” is home to many of the more than 6,000 biotechnology corporations in our state, making the city a hub of innovation. Durham is also a dynamic place to live, work and play. There’s no shortage of art galleries, entertainment, sports, gathering places, and meeting space, all within easy walking distance.

Watch for more information as the 2020 Tech Conference unfolds and mark your calendar for March 10, 2020 in Durham.

Advance Deposits for Booth Space Due by August 15

If you would like to have 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.
Stay in immediate communication with your favorite professional organization by connecting with us on our ISPE-CaSA Company page. Stay in touch with all exciting upcoming events, industry news, and other relevant information related to the Chapter and National Organization. Follow this link to join the ISPE-CaSA page for updates! And follow our Women in Pharma Group! www.linkedin.com/company/ispe-casa/

Join the movement and be part of the first 1000! Join us now! Don’t delay!
A common question that is asked at the beginning of any project with an automation component is, “What is the best, most efficient way to qualify the software?”

There are a few techniques that can efficiently qualify the automation without non-value added steps. These techniques involve leveraged testing and using a “family” approach – the classic “Risk-Based” approach allowing the project team to focus on what’s important and to not waste time on simply “checking a box”.

With any large project, there are two testing paths: Hardware and Software. These paths converge onsite for integrated testing where a sequence is developed to ensure each progressive element is tested at the appropriate time. The control module classes are typically the first items to be tested. This sequence then transitions into more specific module testing. Each section of code will progress through the same sequence: Software Factory Acceptance Test (SFAT), Site Acceptance Test (SAT), and Qualification. Depending on what exactly is being tested, the automation may be integrated with the equipment qualification. Table I outlines a sample test matrix to demonstrate this concept:

<table>
<thead>
<tr>
<th>Automation Element</th>
<th>SFAT</th>
<th>SAT</th>
<th>Software IQ</th>
<th>Software OQ</th>
<th>Equipment IQ</th>
<th>Equipment OQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Infrastructure (Application Software, Network)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Module Class</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Module Instance</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Equipment Module Class</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment Module Instance</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Unit Class</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit Instance</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Phase Class</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase Instance</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Operation</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Unit Procedure / Procedure</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

In the above matrix, class functionality is tested only once. Individual instance (or configuration verification), is tested early in the process. The subsequent equipment testing ties the functionality of the class and the configuration of each instance together. The philosophy is, if the equipment performs as designed, then the function and configuration of the individual classes are correct. This is a primary tenant of a “Risk-Based” approach.
There are two additional testing concepts that are determined during the requirements phase. The first concept is one of leveraging and testing functionality only once. If alarms are tested in the FAT, there may not be a need to retest during subsequent protocols. The benefit of this approach is that the project team is not expending resources to re-test something that theoretically doesn’t change; however, the downside to this approach is that the rigor of validation testing is implemented at an earlier stage and the engineering team may not have the opportunity to “shake down” the system. The cost of each discrepancy is higher during leveraged testing and happens at a time when most changes occur.

The second concept is called the “family” approach to validation. This approach is applied when there are multiple units that are essentially the same. Formulation vessels, bioreactors, and CIP skids are examples of a family of units. The phase testing is spread out across the units in such a way that no one unit qualifies the entire sequence, and each phase and unit is tested through the execution plan (see Table II). A final Integrated Sequence Test is executed once each S88 element (module class, phase, operation, etc.) has been completed to verify that the entire sequence will run from start to finish without operator intervention.

Finally, the documentation approach must support the testing approach. Organizing the life-cycle documents into individual unit documents allows for a waterfall approach to document approval. Testing is written against approved documents and combining too many elements in one approved document will delay the implementation. If an entire purification suite is captured in one document, testing cannot begin until each unit has been designed and implemented. Moreover, the testing duration will be extended until the entire purification train is tested. This will delay deviation resolution, approval, and subsequent closure of the document.

**Bottom line:** The documentation approach must be flexible enough to release elements for testing; therefore, the testing approach drives the documentation approach.

Planning for these strategies in the initial Validation Master Plan will save time and reduce the overall risk to the project. It takes planning and a willingness to identify the risks and quality critical components upfront. It may seem that this planning delays the project, but in the end, the time and cost savings greatly outweigh the costs of planning. Plan your work, work your plan. And remember, “Risk-Based” does not mean “Zero Risk”!

---

**Table II**

<table>
<thead>
<tr>
<th>Example Phases</th>
<th>Unit 1</th>
<th>Unit 2</th>
<th>Unit 3</th>
<th>Unit 4</th>
<th>Unit 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Transfer</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw Material Addition</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual Addition</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wait</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Agitate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Prompt</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer Out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Complete</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Integrated Sequence Test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

---

Chris Darwin has been a Project Manager with Avid Solutions since 2014. Since his first Pharmaceutical project in 2005, he has served in a variety of roles including Project Engineer (Avid Solutions), Fill Finish Automation Lead (Novartis), and Senior Global Project Manager (Novartis). He currently is engaged in several projects ranging from legacy system replacements to new Greenfield installations. He can be contacted at (919) 410-9634 for additional information.
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 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

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 submitted with a brief, three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, job affiliation, job responsibilities and major areas of accomplishment.

Would you like to see your name in the newsletter? Contribute content! We’re looking for the following:

Reviews of ISPE-CaSA Events
Did you meet someone inspiring, find a job, or just have a great time at one of our events? Let us know!

Lessons Learned
Have you learned an interesting lesson at work recently? Write it up and share it! Our members are always interested in improving their skills.

Pharmaceutical Funnies / Biotech Bloopers
Did something entertaining happen at work? Tell us about it! If we laugh, we’ll publish it and give you the credit.

Your contributions help us keep the newsletter fresh. You’ll get full credit, and bragging rights, when we publish them. We love to hear from you, and our members do, too!

Please send your submissions to newsletter@ispecasa.org or directly to our Newsletter Chair, Jason Kelly at jason.kelly@cagents.com.

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.
Advertising Opportunities in ISPE CaSA 2019 Electronic Newsletter

The ISPE CaSA Chapter produces six e-newsletters per year. ISPE CaSA sends out the newsletters via e-mail and via Web link to all of our Chapter Members throughout the Southeastern U.S., which reach top-notch pharmaceutical, biotechnology, and bio-science professionals and managers. These newsletters are also posted on our Web site so your ad can be accessed by interested visitors to our site.

The cost for a full color business-card-sized ad is $1000 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional $1000 per year for six issues. Space limits the number of front page to only four, and is offered to the first four paid advertisers on a first-come, first-served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad, a hot-link can be added to your submitted ad file for an additional $500 for the entire year.

You may choose one of the special offers below (pro-rated for partial-year advertising):

☐ $2,000 Full-color ad for six issues on the front page of each newsletter ($333/issue)
☐ $2,000 Full-color double-sized ad for six issues ($333/issue)
☐ $1,000 Full-color ad for six issues ($167/issue)
☐ $500 Adding a hot link for directing customers to your website by a simple click

We hope you will take advantage of these opportunities and advertise in the 2019 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2019 please complete the form and send via e-mail to info@ispecasa.org. Deadline for 2019 advertisements, to start in the February 2019 issue is January 25, 2019.

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE-CASA Newsletter Committee and asked to submit your advertisement digitally. Full-color business card-sized ads (3.5” x 2”) or double-sized ads (3.5” x 4”) may contain your logo or other artwork. Artwork should be sent directly to newsletter@ispecasa.org.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!
# 2019 Newsletter Advertisement Order Form

<table>
<thead>
<tr>
<th>Company Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name:</td>
<td></td>
</tr>
<tr>
<td>Billing Address:</td>
<td></td>
</tr>
<tr>
<td>Contact Email:</td>
<td></td>
</tr>
<tr>
<td>Contact Phone:</td>
<td></td>
</tr>
</tbody>
</table>

Check all that apply:

- $2,000 Full-color ad for six issues on the front page of each newsletter ($333/issue)
- $2,000 Full-color double-sized ad for six issues ($333/issue)
- $1,000 Full-color ad for six issues ($167/issue)
- $500 Adding a hot link for directing customers to your website by a simple click

**Payment:**

Make checks payable to: ISPE-CASA
Mail to: ISPE-CASA / Newsletter, 1500 Sunday Drive, Suite 102, Raleigh, NC 27607-5151

Or pay by Credit Card: ___VISA ___ MasterCard ___ AMEX

CC#: ___________________________ Exp Date ___________

Signature: ___________________________ Date: ___________

- info@ispecasa.org • Ph: (919) 573-5442 • Fax: (919) 787-4916

For office use only: GL000-2240/100-3300 Pd by Ck #__________ CC processed: Date:______ Initials
# ISPE CaSA 2019 Annual Sponsorship Program

## Manufacturer

**Includes:**
- 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

Total Retail Value: $2,769  
Annual Sponsorship: $1,750  
(37% Discount)

## Vendor

**Includes:**
- Major Education Events - 10 Attendees
- Tech Conference - Premium Table, 10 Attendees
- Golf Tournament - twosome 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)

## University

**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

### Organization Type:
- [ ] Manufacturer  
- [ ] Vendor  
- [ ] University

### Organization Name: __________________________  
Contact Person: __________________________

### Phone: __________________________  
Email: __________________________

### Payment:
Checks: make payable to ISPE-CASA  
Mail to: ISPE-CASA 1500 Sunday Drive, Suite 102, Raleigh, NC 27607
Credit Card: [ ] VISA  [ ] MasterCard  [ ] AMEX  
Email info@ispecasa.org  |  Ph: (919) 573-5442  |  Fax: (919) 787-4916

CC#: __________________________  
Exp Date: __________  
Signature: __________________________  
Date: __________

---

To join Annual Sponsorship Program, complete above section and email form to info@ispecasa.org

Office use only: GL100-______ Pd by Ck # __________ CC processed: [ ] Date: __________ Initials: __________