



President's Message



Mike Putnam

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 Education Event on

Emerging Technologies and Data Integrity 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

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Connecting a World of Pharmaceutical Knowledge

Chapter Events

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

Chapter Events


Education Committee

By Andy Ferrell, Chair

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.



PRAHEALTHSCIENCES

See below for program topics. For more information, [visit the Continuing Education section on ISPE-CaSA's website.](#) 

[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



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Technology Conference

2020 Technology Conference

ISPE-CaSA Technology Life Sciences Conference Will Move to Durham in 2020

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. 🏠



CaSA COMMITTEES 2018 - 2019

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Technology Conference

Chris Small, PE
techconference@ispecasa.org



Membership Corner

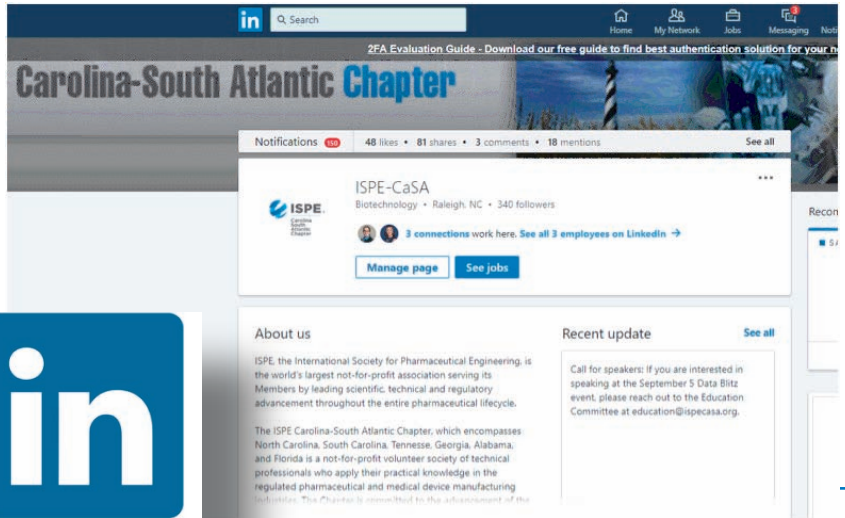
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By Daniel Santarsiero, Chair

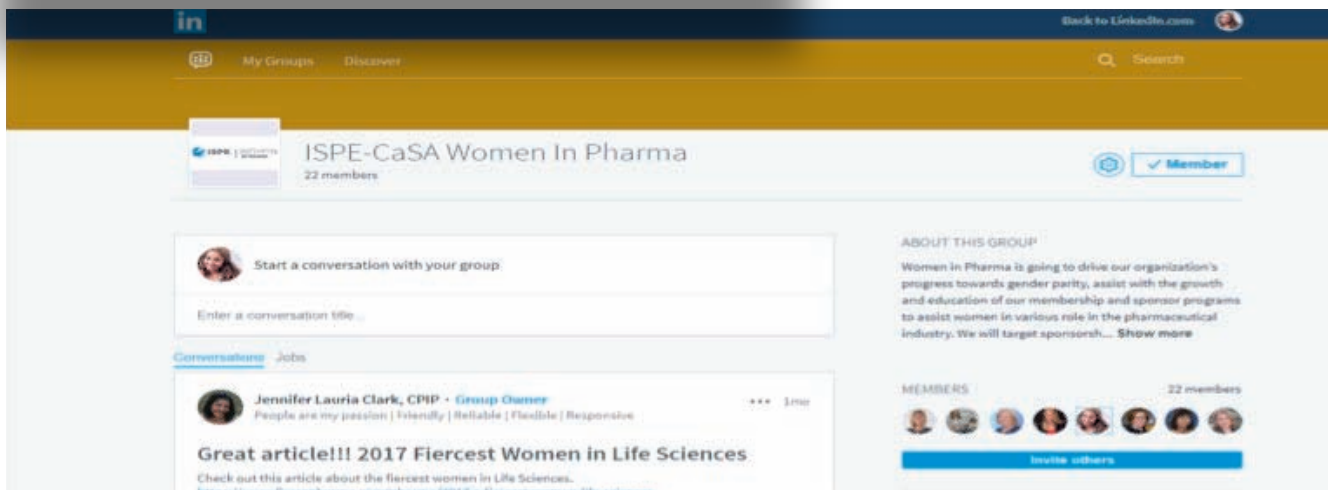
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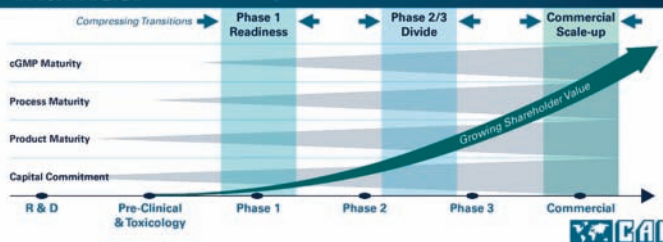


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Technical Corner

CSV Strategy: Automation

By: Chris Darwin,
Consultant &
Project Manager

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 I

Automation Element	SFAT	SAT	Software IQ	Software OQ	Equipment IQ	Equipment OQ
System Infrastructure (Application Software, Network)	X	X	X	X		
Control Module Class	X	X	X	X		
Control Module Instance		X			X	X
Equipment Module Class	X	X	X	X		
Equipment Module Instance		X			X	X
Unit Class	X					
Unit Instance		X			X	X
Phase Class	X					
Phase Instance		X			X	X
Operation	X	X			X	X
Unit Procedure / Procedure	X	X			X	X

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.

Technology Corner

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.

Table II

Example Phases	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
Water Transfer	X				
Raw Material Addition		X			
Manual Addition			X		
Wait				X	
Agitate					X
Prompt	X				
Transfer Out		X			
Complete			X		
Integrated Sequence Test	X	X	X	X	X

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"!



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.

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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.

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Tech Conference - Premium Table, 10 Attendees

Golf Tournament - foursome in one golf tournament

Newsletter - Business Card Ad in 2019 newsletters

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