ISPE® | Carolina-South Atlantic Chapter
Connecting a World of Pharmaceutical Knowledge

CaSA News

Volume 26 • Number 1 February 2019

President's Message

Mike Putnam

Brrrrr ISPE CaSA Members! Although I'm not a fan of cold February mornings in NC, I am thankful not to be a member of ISPE Great Lakes chapter where Chicagoans recently experienced temps of -23! Only two months into 2019, CaSA has already held two smoking hot events including the Automation Forum in conjunction with International Society of Automation and the Winter Gala casino night at Umstead Hotel and Spa. On March 12, 2019, CaSA will host our 26th Annual Life Sciences Technology Conference at the Raleigh Convention Center. This is our Chapter's premier event and is one you will not want to miss! With expected attendance of more than 1,200 and over 200 manufacturing and vendor exhibits, the conference will feature educational seminars throughout the day and a keynote address by Andy Stober, SVP and CTO of AveXis. The event will be followed by an exciting networking reception at the Stockroom banquet hall where we will rock out to 80s classics from Steel-water Band and raise support for Team Chris Combs and Project ALS. Register now and I hope to see you there!

To facilitate increased industry engagement in 2019, CaSA is offering discounted annual partnership packages to manufacturers, vendors, and universities. These packages not only score marketing visibility for your organization, but also include admission to most CaSA events as well as annual ISPE memberships. Please encourage your organization to take advantage of this offering and sign up today to maximize your value.

Thank you to all Members, Board of Directors, Sponsors, Volunteers, and Students who so generously support ISPE CaSA. I look forward to serving with you in 2019 to accomplish great things!

Mike Putnam

President, ISPE CaSA Chapter

Featured Sponsors

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Connecting a World of Pharmaceutical Knowledge

Chapter Events

Networking Committee

By Chris Smith, Chair

ISPE-CaSA Winter Gala 2019

The 2019 ISPE-CaSA Winter Gala turned out to be a night to remember and a HUGE success. Over 175 individuals packed the casino tables and dance floor at the Umstead Hotel in Cary, NC on the evening of Saturday, February 2, 2019. Food from around the world, desserts, and an open bar led to fantastic networking opportunities and fun for all.

Over $1,700 was raised for the Jane Brown Scholarship via company sponsorship, a 50/50 raffle, and a 32-bottle wine-pull. The winner of the 50/50 raffle, Kyle Davidson of Evans General Contractors, opted to give his share of the raffle winnings back to the scholarship.

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ISPE Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

Chapter Events

25th Annual ISPE-CaSA Golf Tournament

The 25th Annual ISPE-CaSA Golf Tournament is scheduled for Prestonwood Country Club in Cary, NC for Monday, May 20, 2019. It will be a full day event that includes breakfast, drinks, lunch, prizes, give-aways, and lots of laughs. Registration is now open. Gather your team and get registered! Last year's event sold out.

25th ANNIVERSARY 1994 – 2019

Join ISPE-CaSA and your colleagues for the

25th Annual Golf Tournament

Help us make our 25th anniversary the best ISPE-CaSA Golf Tournament ever!

To register, please visit:
www.etouches.com/2019-ispecasa-golf

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Chapter Events

Therapeutic Thursdays
February 28

Two Therapeutic Thursdays will be offered in February. The networking event in Greenville, NC will be at Winslow's Tavern at the usual time of 5:30-7:30pm, and the event in Athens, GA will be at the Southern Brewing Company from 5:00 to 7:00pm.

Greenville, NC

Winslow's Tavern
120 W. 5th Street, Greenville, NC

Athens, GA

Southern Brewing Company
231 Collins Industrial Dr, Athens, GA

March 28

One Therapeutic Thursday will be offered in March. It will be held from 5:30-7:30pm at the World of Beer – Tioga in Gainesville, FL.

There's no need to register for any of these events. Please come out for a great opportunity to connect with colleagues

Our generous sponsors provide appetizers and soft drinks. Cash bar.

Gainesville, FL

World of Beer – Tioga
140 SW Street, Suite B, Gainesville, FL

Membership Corner

Education Committee

By Andy Ferrell, Chair

BPD Spotlight on Education

Ten area organizations came together at the North Carolina Biotechnology Center on Thursday, January 17th to showcase local educational opportunities in biopharmaceutical manufacturing. The afternoon event was organized by the Biomanufacturing and Process Development (BPD) exchange group, which is supported by the North Carolina Biotechnology Center in the Research Triangle Park, NC.

The goal of the event was to highlight biomanufacturing educational programs in and around the Triangle, including programs offering associate degrees, certificates, 4-year degrees, graduate degrees, and professional development opportunities. The 90 attendees included current students, industry professionals looking to further their education, and others interested in joining the biomanufacturing workforce.

In addition to informational booths, there were two panel discussions that were the highlight of the afternoon. The first panel featured past students who shared how their experience in a local educational program has led to success on the job, while the other featured company executives touting the benefits of and demand for a well-trained and educated workforce. In addition to emphasizing the advantages that a good education and training program offer, both of the panel discussions stressed the importance of networking, and the student panel specifically cited their ISPE student chapters as a part of their success in finding a position coming out of school.

In addition to ISPE-CaSA, there were booths by Durham Tech, Wake Tech, Vance-Granville Community College, Campbell University, East Carolina, NC Central BRITE, NC State BTEC, The BioNetwork Capstone Center, and Kymanox

C3DG: Calibration, Commissioning and Consulting Discussion Group

By Kakki Collins, PCI

On February 6, 2019, the annual C3DG (Calibration, Commissioning and Consulting Discussion Group) was held at the RTP Foundation on Davis Drive. This one-day educational event brought together fifty biopharmaceutical professionals from twenty-five companies to share common approaches, issues, and solutions. Industry associates from over twenty operating companies attended this year's event.

The keynote speaker, Darren Dasburg, discussed market technology trends in his presentation on *"Emerging Product Modalities."* Dasburg discussed the future of cell and gene therapy in the pharmaceutical industry. From smaller footprints to one batch per patient, Dasburg enlightened the group with his insights on the shift from treating patients to curing patients.

The theme of this year's event was Emerging Platforms, Technologies and Approaches for Electronic Life Cycle Management. Industry subject matter experts led discussion topics which included:

- *Scientific Equipment Life Cycle Asset Management*
- *Innovative Trends – Future of Gene Therapy*
- *Engineering Data Strategies with Capital Project Best Practices – Asset Induction, Calibration, Start Up, and Operation Readiness*
- *Predictive Maintenance Technologies*
- *Digital Transformation of Validation Life Cycle Management for CQV*

The open forum, networking, and presentations resulted in a better understanding of industry trends and common program approaches.

The C3DG (Calibration, Commissioning, and Consulting Discussion Group) was established in the early 1990s in response to the lack of training courses offered for instrumentation professionals working in the pharmaceutical industry. In 1990, local leaders from companies including Abbott Labs in Rocky Mount, Glaxo in Zebulon, Miles Laboratories in Clayton, and Burroughs Welcome in Greenville collaborated to form a one-day meeting for pharmaceutical instrumentation professionals. The leadership of the C3DG consists of regional biopharmaceutical calibration professionals who are addressing the same issues and asking the same questions as their constituency. As a result, the learning techniques applied at a Calibration Discussion Group allows attendees to return to their company with information and tools that can be directly applied at their facilities. In recent years, the attendees have expanded to include professionals from QA, Maintenance, Engineering, and Manufacturing.

Membership Corner

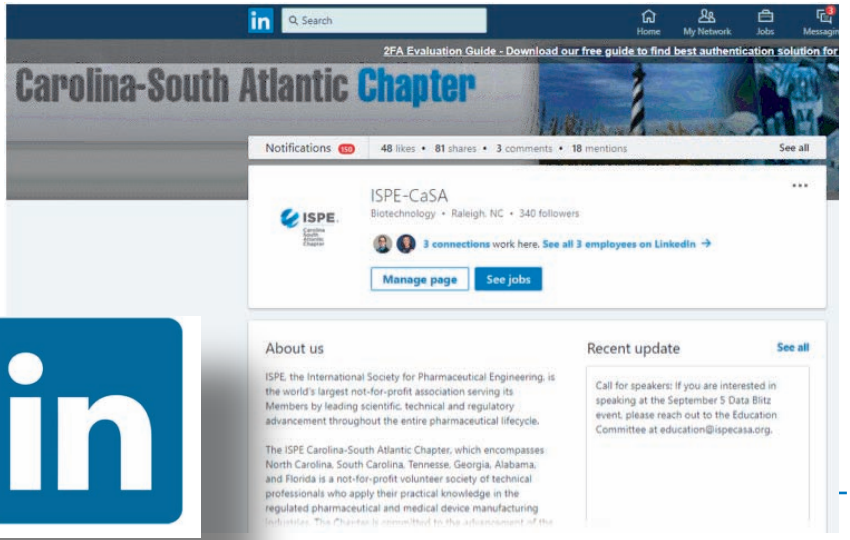
Social Media Committee

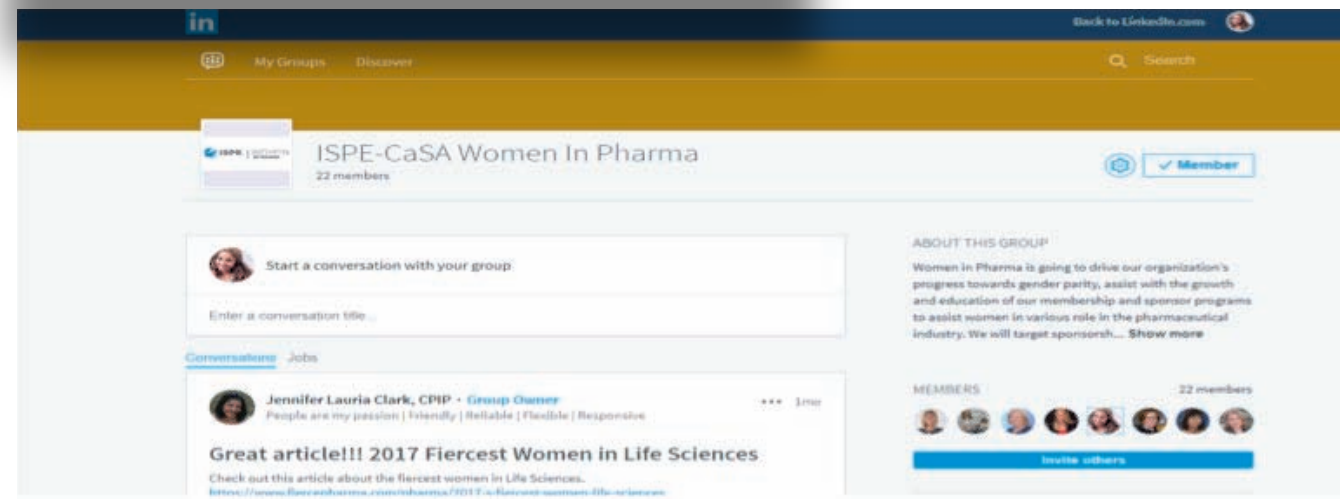
By Daniel Santarsiero, Chair

Attention! LinkedIn Update!Follow Us On LinkedIn

Join the movement and be part of the first 1000! Join us now! Don't delay!

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/





Membership Corner

Education Committee

By Andy Ferrell, Chair

Automation Forum

ISPE CaSA brought back the Automation Forum on January 24th. This half-day event was held at the ISA Headquarters in RTP, NC. Over 65 life science professionals were in attendance.

The speakers and topics were spectacular. **Brendan Bradley** of Vanrx Pharmasystems shared lessons from customer case studies in *Aseptic Filling Workcells – Gloveless Robotic I solators for Aseptic Filling*. **Thai Le**, Work Package Owner responsible for implementing the MES system and interfaces at the Novo Nordisk DAPI-US project, presented *Balance Automation Standardization and Flexibility in an Agile Organization*. He described MES optimization techniques used at the diabetes API production facility in Clayton, NC. **Pete Durand** gave an overview of current trends in automation entitled *Enterprise Control, Industry 4.0 and IoT, what does it all really mean?* **Thomas Jacobsen** of NNE focused on the future in *The Future State of Pharma 4.0 within Automation*.

A special thanks to MaChelle Beason of ISA for allowing us the use of ISA's facility and CASA's Education Committee's Jamie Godbout for coordinating the event and introducing the speakers. Also, thanks to NNE for their generous event sponsorship.

Technical Corner

A Different Approach to Automation Requirement Specifications

By: Jamie Godbout, President, CEO, Godbout PCS

It is not about level of detail

When starting a new automation project, one of the first challenges the automation team has to overcome is drafting requirement specifications. The most common requirement specifications are the user requirement specification (URS), functional requirement specification (FRS), and hardware/software requirement specification (HRS & SRS).

Each document should be drafted with the appropriate audience and purpose in mind. Many of my previous clients determined the content of each document by level of detail. I often hear the URS should be a high-level document describing "what" is needed, while the FRS document should contain more detail as to "how" a function works. I don't necessarily disagree that the document will result with the URS describing the high level "what" and the FRS describing the more detailed "how", however, this should not be the author's goal. The author should draft the specification so that it can effectively accomplish its purpose and be understood by the intended audience. This poses the question, what is the purpose of each document, and who is the intended audience?

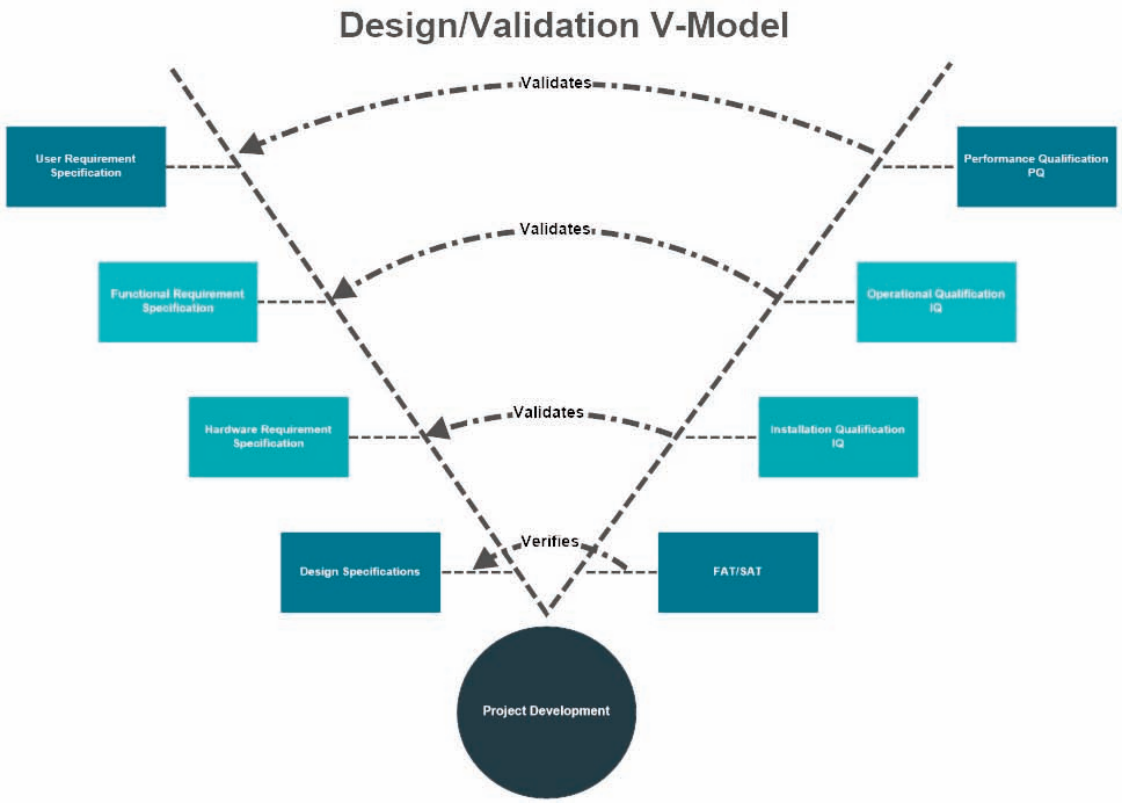
Introducing the Software V-Model

In software development there exists the V-Model, which describes a common methodology to design, develop, and test software. In a perfect world, the process would start on the left with the URS, then move on to the FRS, HRS & SRS, the design documents before starting project development. After the project has been completed, an acceptance test would be done, then the qualification protocols executed. However, in the real world, if the team follows this process, they quickly find themselves going back to previous steps for re-work. The fact is, it is rarely possible to know ahead of time exactly what the complete system will look like.

Instead, use the V-model as a guide to determine the purpose of each document and its intended audience. For example, the URS document will be verified by the performance qualification (PQ). The FRS document will be verified by the operational qualification (OQ), and the HRS & SRS will be verified by the installation qualification (IQ). The audience for each of these documents will be validation and quality. Keep the level of technical detail and jargon appropriate so that it can be easily understood by these departments.

Write the URS to Facilitate the Performance Qualification Protocol

The PQ protocol will test the limits of the control system, so it is reasonable that the URS should be written to specify those limits. Go through the IO list and call out limits of each process variable. Each process variable should have a maximum limit and a minimum limit; however, the limits should be reasonable for the process. If you happen to have a sensor that has a lower limit of -40˚F and an upper limit of 300˚F but the process limits are 50˚F to 90˚F, it is not necessary to specify beyond the process limits. Testing to the limits of the sensors may not be feasible. Think about how the PQ will be written and draft the URS to suit the PQ.



Technical Corner

The User Requirement Specification

Prior to writing an automation URS, the process usually has been pretty well defined. Often there is already a set of P&IDs, even an I/O list. The temptation is to combine the URS and FRS into one document that includes too much detail about how the program is to be structured, details regarding control loops, PID controls, and all the programming that happens under the hood. It is best to resist this temptation, draft separate URS & FRS documents, and keep those requirements limited to what can be tested in a thorough PQ protocol.

For example, imagine the system will utilize a mixing tank. It will require sensors to monitor level, temperature, pressure, and weight. The URS would include the following specifications:

- Mixing tank V-5000 shall monitor level from 0-100%
- Mixing tank V-5000 shall monitor weight from 0-5000 KG
- Mixing tank V-5000 shall monitor temperature from 50-120°F
- Mixing tank V-5000 shall monitor pressure from 0-30 PSIG

Each requirement is specific to a particular piece of equipment and provides process variable limits. The PQ test would ensure that the control system can in fact monitor each process variable to the extents of the specified range.

Control requirements should be created to convey results of a process or control. For example:

- The automation system shall include controls to mix the contents of mixing vessel V-5000 from 0-1000 RPM
- The automation system shall include controls to transfer contents from mixing tank V-5000 to reactor R-1200
- The automation system shall include controls to add water for injection (WFI) into mixing tank V-5000 at variable rates between 0-300 GPM
- The automation system shall include controls to control product temperature to a configurable setpoint

The idea for the URS document is to establish "what" the system will do and include performance criteria. The document will result in a high-level specification that describes the "what" but will also include performance boundaries that can be verified by the performance qualification. Any specification that does not reference some sort of performance criteria should be addressed in the FRS document and will be verified by the OQ protocol.

Write the FRS to Facilitate the Operational Qualification Protocol

Previous clients created OQ protocols using the "do this" and "expect that" approach, then signed off indicating that the control system performed as expected. For example, you might see a test script that says "Click the power button on screen xyz", then in the expected results column "System power indicator turns green", initial and date. Drafting the OQ protocol is much more straightforward when the specification document was structured in a "do this" then "expect that" format as well.

The Functional Requirement Specification

The FRS document will be verified by the OQ protocol, so it should be written from an operational point of view. It should not contain specifications pertaining to code, programming methodologies, lookup tables, or functions not exposed to the operator. Some of the best FRS documents I have seen were mostly screen shots of the HMI, with a legend describing the various sections of a display, icon, or faceplate. This is wonderful way to draw up an FRS section for user displays. If a picture is worth a thousand words, a picture with a legend is priceless.

Use tables to display data requirements such as tag names, description, labels, engineering units, scaling parameters, etc. If a piece of data is visible on the operator interface it should be included.

Alarms, alarm messages, limits, and automated actions should also be included in the FRS alarms table. Use screen shots to show what the operator should expect when an alarm is triggered or if there is some sort of automation procedure that will occur when an alarm is activated.

The FRS should also include any and all sequences or procedures. Again, screen shots are great in showing the reader what to expect when a sequence is started. This information can also be moved into an SOP for the control system. Use the graphic to instruct the operator to click a button, then show additional graphics of what happens next.

This approach will make drafting the OQ protocol a breeze and will make sense to anybody who happens to audit the control system. The OQ protocol will contain a series of checklists to make sure items exist and then a sequence of steps with expected results to ensure the system functions as intended.

This approach will require concurrent development of the control system in order to take the screen shots. However, it also provides the opportunity to get feedback from project stakeholders as to how operators will interact with the control system in real time.

The New Mindset

Writing user and functional specifications with as much information as possible while using level of detail to determine the language used in each document leads to unnecessary challenges. The documents are not very functional and long-term maintenance becomes difficult. Writing the specification document to facilitate the drafting and execution of the corresponding validation protocols clarifies much of the confusion regarding these documents and will eliminate the information noise often contained within each specification.

In the long run, it makes life simpler and saves the company money. It makes the specification documents functional beyond checking the box indicating that they simply exist for the sake of GMP.

Jamie Godbout is the founder and owner of Godbout PCS and has over twelve years of experience with process control systems. Jamie's career has focused on plant-wide process control systems working with the Rockwell and Inductive Automation platforms.

He is a subject matter expert with industrial networks, virtual environments, PLC & HMI/ SCADA programming, and batch process control systems. He has managed, developed, and deployed batch process control systems along the eastern seaboard, and excels in system architectures.

Jamie holds a bachelor's degree in electrical engineering from the University of New Hampshire with a special focus in control systems.

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Would you, or someone you know, like to publish your technical content in these pages?

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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, title and job affiliation, job responsibilities and major areas of accomplishment.

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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

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

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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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ISPE | Carolina-South Atlantic Chapter

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