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

CaSA News

Volume 21 • Number 4
August 2014

Featured Sponsors

President's Message

Heather Denny

Whew! Things are heating up for the 2014-2015 ISPE CaSA calendar. After our board retreat last week, plans are coming together for education and networking events that you will not want to miss. A big thank you to Ken Ewan, director at large, for leading a strategic session that we believe will not only guide us in the current year but also as we look at putting together a three and five year plan.

(continued next page)

INSIDE THIS ISSUE

MARK YOUR CALENDARS!

YP Educational Event - September 30, 2014 at Biogen Idec
Annual ISPE Meeting - October 12-15, 2014 at Caesar's Palace, Las Vegas
Big Event – Oktoberfest/Gala/Planning - October 30, 2014
ISPE Classroom Training - November 17-20, 2014, Hilton North Raleigh/Midtown, Raleigh, NC.
Automation Forum - December 11, 2014
Technology Conference - March 10, 2015 at Raleigh Convention Center
Tri-Sci Expo - April 11, 2015 at NC Museum of Life Sciences, Raleigh, NC
Golf Event - May 18, 2015 at Prestonwood Cary, NC

President's Message

(continued from previous page)

After our Therapeutic Thursday events in August and September, we will kick off on Tuesday, September 30th with a Monoclonal Antibody Symposium planned by the Young Professionals Committee. With Jamie Sigmon at the helm, this committee is full of energy and buzz. Don't procrastinate on this one as there is a cap on the number of attendees and you will regret missing it!

To spice things up, we are combining our committee recruitment session with the fall networking event and here it is – Oktoberfest! Come connect with old and new friends on Thursday, October 30 from 5:30pm – 8pm. Under the stars and cover of the deck at Koka Booth Amphitheater, we will enjoy live music from Old Habits, food and local beverages all while getting to know what the committees have been brewing and how you can get engaged. John Marr, chair of the Networking Committee, and Chip Chappell, director at large, are teaming to lead this effort.

In early December we will convene at the NC Biotech Center for the Automation Forum. With all brand-new Members, Jim Hubbard has the Education Committee humming along. Prior to the session, we will enjoy networking while bringing toys for our annual Toys for Tots drive.

Mike Putnam and the Technology Conference Committee start ramping up mid-August for the 2015 Conference on March 10.

This year I have challenged all committee chairs to work collaboratively as we work to provide you, our customer, with experiences and knowledge that will fulfill your needs. Terence Morrison, Membership Chair, is your voice and to make sure we are hearing you, he is planning several road shows. If your facility would like a visit, please let Terence know; if there is a specific education topic you would like, we can do a combined event.

Our college students are about to start classes and LeAnna Pearson is working to make sure each of our seven, active, Student Chapters at NC State, Campbell University, UNC, NC Central, ECU, Virginia Tech and East Tennessee State have the resources they need. If you have an alumni connection or desire to get involved, let LeAnna know – she is always looking for Industry Advisors and speakers.

Rich Stanfield, editor of the newsletter and committee chair is currently wishing I would finish so the committee can get this out on time! I promise Rich, I will not always be late.

Let me not forget David Smith, Ben Hund, Lisa Kerner, Bruce Craven, Wendy Haines, Matt Gilson and our staff, who are also working on your behalf.

This is going to be a great year! If you have any ideas, please let us know. It is my hope that for those of you that have been involved - continue, if you have not been involved - come join us, if it has been a while - please come back, we miss you!

We would not be at this great place without those that have come before. Thank you to Matt Gilson, Jennifer Lauria Clark, David Brande and many others that created the foundation from which we now build.

Hope to see you soon!

Heather Denny
President, ISPE CaSA Chapter

Past President's Message

Matt Gilson

It's hard to believe the ISPE CaSA fiscal year is up! It's been my pleasure to serve as the Chapter's President for the past year. I've been blessed with a great Board of Directors and support and encouragement from many past BOD Members throughout the year and I'm grateful for that – thank you! Your BOD and staff have worked tirelessly this year to provide events and programs that allow Members and prospective members a chance to learn and network with other industry professionals. I hope you've taken advantage of those. We're already planning another great year for you!

I'd like to thank the Executive Board, all the Committee Chairs, the Directors at Large, and the ISPE CaSA Staff for all you've given to the Chapter over the year. We would not have been successful without all of your hard work and dedication. Thank you to you, the Members, for supporting our committees and events this year! A BIG thank you to our sponsors – we can't do this without your support!! I hope you've enjoyed the year as much as I have and I look forward to continuing to support the chapter as Past President. The chapter is in great hands with Heather Denny as your next President!

Some Of The Highlights From The 2013-2014 Year

- Added 300+ Members
- TriSci Expo with the Museum of Natural Sciences was another great community event
- FDA Video-conference event with the Delaware Valley Chapter
- Social media engagement on Twitter and LinkedIn
- Lots of great Therapeutic Thursday events (including in Tampa and Atlanta locations)
- Very nice Gala featuring local FOYA winners at The Umstead Hotel
- Toys for Tots at Novartis
- A golf tournament at Prestonwood Country Club that was well-supported
- Six excellent newsletters
- Scholarship program kick-off
- New Student Chapter at Virginia Tech
- A Leadership Symposium at NC State that was well-attended
- Sent 13 Students to the ISPE Annual Meeting in DC
- One of the best Technology Conferences the Chapter has produced
- CEO night and Bowling Networking event with the YP Group
- Awesome sponsor support throughout the year and over all facets of the Chapter – thank you!
- Successfully managed the CaSA budget and exceeded financial goals

2014-2015 Board of Directors

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

Officers
Heather Denny, President
Lisa Kerner, Vice President
Bruce Craven, Treasurer
Wendy Haines, Secretary
Matt Gilson, CPIP, Past President

Directors
Ben Hund
Chip Chappell
Ken Ewan

Committee Chairs
Rich Stanfield, Newsletter
Jim Hubbard, Education
LeAnna Pearson, Student Affairs
John Marr, Networking
Terrence Morrison, Membership Development
Jamie Sigmon, Young Professionals
David Smith, BioFest Committee
Mike Putnam, Technology Conference

Young Professionals Corner

Wine Tasting at Adams Vineyard

By Jon Doyle

On Wednesday July 16, the ISPE CaSA Young Professionals Committee hosted a Wine Tasting at Adams Vineyard in Willow Spring, NC. The night was full of networking, wine, cheese, and chocolate tasting! Attendees even learned about the history of the Adams Family Farm which currently resides on part of the original 'Land Grant' from the King of England to the first American Settlers.

The family farm consists of over 100 acres, with at least 12 acres dedicated to grapes and other fruits used to produce their wines. Many of the Adams Family Wines have won numerous awards throughout the region including a Double Gold Medal at the NC State Fair in Raleigh and a Best in Show at the Mid-Atlantic Wine Competition in Winston-Salem. We are definitely able to vouch for those awards as everyone thoroughly enjoyed their wine – a few even purchased bottles of their own to bring home! Thank you to everyone who joined us!

Membership Corner

20th Annual ISPE CaSA Golf Tournament

By Heather Denny, ISPE CaSA Chapter President

Finally we hit the mark and sold out two courses! There was record attendance as golfers played both the Fairways and Highlands courses at Prestonwood Country Club. (Trivia: do you know what year we started playing two courses? Answer: It was the 17th annual tournament and we barely had enough participation to start a 2nd course.) Fortunately, the weather was much improved for our 20th Annual ISPE CaSA Golf Tournament.

Co-sponsored by Biogen Idec, this year's tournament raised awareness, support, and money for Hemophilia NC. In addition to a check presented by Biogen Idec, the Membership raised over $2,500 for the organization.

This year's participants found opportunities to win a Harley Davidson motorcycle and an Apple package on three Par three holes in one thanks to Hipp Engineering and Consulting, ICQ Consultants, and Integrated Project services. Unfortunately, no one found that magic hole in one.

Did you try your skills in the putting contest sponsored by Hydro Service and Supplies? I do not believe anyone took home the $10,000 prize - so maybe start practicing for next year.

A BIG thank you goes out to Mangan Biopharm and Pharma Matrix who were so gracious to sponsor our awards dinner and breakfast, respectively.

And on such a lovely day we all needed to stay hydrated. Thanks to RGD Project Management and CRB who made this possible.

Thanks to all of our hole sponsors including Burket, Clean Seal Doors, Sequence, RoviSys, M.G. Newell, Clark Nexsen, Riverside Resources, Bahnson Environmental Specialties, Avid Solutions, Festo, and EHS Solutions.

To all of our sponsors - it is your continued support that enables the chapter to continue to bring you these great events. For all of you that work with these companies, please take a moment and thank them for their support.

One last sponsor of the scoreboard and range we want to recognize is Advent Biotech. Our winning team for the day was Jeff Brownell, Chris McDonald, Dan Rouse, and Bruce Buckoski.

If you were not able to make it out this year, next year's event is planned for May 18, 2015. You don't want to miss this.

Thank you to John Marr, Wes Robbins, Jim McGlade, and team for a great event.

More Shots from our 20th Annual ISPE CaSA Golf Tournament

Membership Corner

CaSA Member Spotlight: Matthew Gilson

By ISPE CaSA Newsletter Committee


Matthew Gilson

Q: What is your full name?
A: Matthew Gilson

Q: Birth Place?
A: Alabama

Q: College?
A: North Carolina State University

Q: Tell me a little about your personal life.
A: I have been married to Jennifer, a UNC graduate (pray for me) and Cary native, since 1996. We have a daughter, Taylor, and a dog named Daisy (I wanted a Great Dane – Daisy is an 8 lb. Maltese Shi Tzu mix). We have lived in Apex since 1998 and love it! We are active members of Hope Community Church in Raleigh where I volunteer as an usher. As a family, we enjoy Disney (making the trip about every 2 years), the Chicago Cubs, and have recently tried to pick up tennis. Taylor and I have enjoyed doing the Y Princesses program the last three years, go to breakfast together every Saturday (La Farm and Dunkin Donuts are favorite spots), and take an annual Daddy/Daughter trip.

Q: What is your present position? What do you do at your job?
A: I am currently Director, Computer Systems QA at GSK. Our group is responsible for ensuring that R&D's GxP regulated computer systems are compliant with GSK policies and regulatory expectations and are inspection ready. This involves internal and external auditing of systems and suppliers, working with project teams upgrading or implementing systems, and helping to host regulatory inspections when they occur on-site at RTP.

Q: How long have you been with your current employer?
A: 19 years.

Q: Tell me about your career path, and how you ended up where you are today.
A: I started as a co-op student (while at NC State) with Burroughs Wellcome in the analytical chemistry labs. Thinking I wanted to pursue an advanced degree in Chemistry upon graduation, I began a graduate program at Duke. After a year, I decided that wasn't what I wanted and returned to Glaxo Wellcome where I took a position as a contractor in the inhaled products department. After a short stint in QA, I moved into the clinical supply organization that managed the supply of clinical products for clinical trials. At some point in the clinical supply group, I got involved with validating the computer systems used by the department. That led me to my current area of computer systems QA. I also spent about five years conducting GMP audits of clinical supply manufacturing facilities, labs, and suppliers all over the world. That role took me to more than 25+ countries.

Q: What is your favorite part of your job?
A: Working with our group to solve challenging issues that are presented to us each day. Advances in technology are rapid and continuous, creating new concerns that require us to stay on top of regulatory changes to ensure GSK remains compliant. We've had very little personnel turnover in our department too, so I've had the benefit of getting to know my colleagues well. We work hard but also have fun.

Q: How long have you been a member of ISPE/when did you first join ISPE?
A: I've been an ISPE Member since 2000. I joined because my director in the clinical supply group, Lou Capalbo, was a big proponent of ISPE and encouraged our team to become involved. I attended the 2000 Annual Meeting in San Diego and have been an active member since. I became more involved with the CaSA chapter when my friend and former GSK colleague Jane Brown asked me to consider applying for the CaSA Board of Directors.

Q: What benefits have you realized from being a member of ISPE?
A: Working at a large company like GSK in the position I'm in, it's easy to become very insular and not work with others outside the company. ISPE has allowed me to grow my professional network, affording numerous opportunities to meet people in different areas across the pharmaceutical industry – both locally and beyond. I've made many friends through ISPE. I'm also involved with the Investigational Products COP which allows me to collaborate with like-minded professionals who can be a resource for answers or a sounding board.

Q: Why are you still involved with ISPE?
A: I remain involved for many of the benefits listed previously. I still enjoy networking with, learning from, and spending time with other ISPE Members. It's been rewarding serving on the CaSA Board and working to keep the Chapter operating at the same high level it has for many years. We've got a great team of individuals, committees, and staff who give tremendous personal time and energy to keep our chapter thriving.

Q: Any Mentors/Role Models that have helped to shape your life?
A: Paul Newby, NC Supreme Court Justice, led a Bible study and mentored me and few friends in my younger years. I still go back to things I learned during that time of my life. I've also had several great managers throughout my career at GSK who have encouraged and challenged me.

Q: If you weren't involved in pharma/biotech, what business do you think you'd be in?
A: I enjoy woodworking and building/fixing things - cabinetry, decks etc.

Q: What is one skill you wish you had that you don't?
A: Patience – I'm constantly aware of my lack of!

(continued on page 11)

Q: Any hobbies? What are they?
A: I'm trying to get back into playing tennis. I used to play when I was younger and am working with my daughter to teach her to play.

Q: Do you collect anything?
A: I have a license plate collection from my grandfather and I've added to that. It goes back to 1912.

Q: Finish this sentence – "I need more…."
A: Selflessness

Q: Favorite Food?
A: Rey's filet mignon

Q: What is something that people would be surprised to learn about you?
A: I worked at Disney World's Magic Kingdom one summer on the Davey Crocket Explorer Canoes. I got to wear a coon-skin hat in 100 degree weather while paddling and telling guests corny jokes. They closed the canoes a few years ago but you can still ride them at Disneyland in California.

Q: Last movie you saw?
A: Dawn of the Planet of the Apes

Q: For those in the early stage of their careers, what advice would you give them?
A: Get a mentor. Network and talk to lots of people about what they do. Don't be afraid to work in areas outside your degree. Give back.

CaSA COMMITTEES

Newsletter Committee
Rich Stanfield
rich.stanfield@cagents.com

Education
Jim Hubbard
jhubbard@amts.com

Student Affairs
LeAnna Pearson
Leannapearson@gmail.com

Networking
John Marr
John.marr@crbusa.com

Membership Development
Terrence Morrison
terrence.morrison@crbusa.com

Young Professionals
Jamie Sigmon
jamiesigmon@gmail.com

BioFest
David Smith
David.smith@ustechsolutions.com

Technology Conference
Mike Putnam
mike_putnam@sequencevalidation.com

Membership Development Corner

Grow ISPE • Grow Your Affiliate or Chapter • WIN PRIZES!

By Terence Morrison, P.E., LEED AP BD+C, ISA 84 SFS

From June 1, 2014 until September 30, 2014, the challenge is on to recruit and retain the most Members, the most new Young Professionals, and the most Annual Meeting attendees. Help ISPE reach its overall membership growth goal for 2014!

$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Applications can be found online at www.ispe.org/join. Click Join Now under Industry Membership, and enter CASA2014 in the promotion code box. Please remember ISPE's Refer-A-Friend Program! Earn one free month of membership for every friend you refer. All the details are available at the following link: http://www.ispe.org/membership-referral-program

This discount is not applicable to Students, Young Professionals, Academics, and Regulatory Authority / Government as these all hold discounted memberships already.

If you have any question about ISPE or the CaSA Chapter, please contact me at membership@ispecasa.org.

Welcome New Members

New Members who joined March 15, 2014 through July 27, 2014

Dr. Steven R. Poehlein, Ph.D.
Ms. Melissa Seymour
Ray M. Frey
Ms. Arpitha Rao Teegala
Mr. Robert M. Orazi
Edward Willigan
Dr. Dustin M. Lockney
Dr. Michael D. Bair, PhD
Mark A. Whitlock
Ms. Rona Painter
Alaa Rashid
Ms. Meghan Snare
Mr. David J. Craft
Ms. Laura J. Lorenzo
Charles Kristian Johnson
Mr. Robert Wesley
Mr. Leonard Novelli
Mr. Virgil B. Mason
Mr. Michael DeCollibus
Thurai Singam Ponnudurai
Sandra M. Williams
Ms. Emily B. Ostrander
Mr. Mac Beaty
Victoria Li
Mr. Drew C. McManus
Robin L. Smith
Dr. Grady T. Fortune, Jr.
Mr. Ronald L. Keith
Bruce Buchholz
Mr. Vincent J. Narbut

The Manual Sampling Document Team has identified the Commissioning and Qualification, Critical Utilities, Engineering Standards Benchmarking, GAMP, Operations Management, Process Analytical Technology, Process/Product Development, and Sustainable Facilities Communities of Practice (COPs) as Subject Matter Expert groups for reviewing the draft ISPE Good Practice Guide: Manual Sampling.

If you might wish to be considered to review the technical content of the draft Guide, we would appreciate it. Please indicate your experience in the topic and forward your contact details, including email, to: Feedback@ISPE.org.

Optimizing Defect Elimination Program Results

By Reid Jenner, Vice President, Canadian Operations, Commissioning Agents, Inc.

Reid is a senior leadership consultant with broad experience managing strategic accounts and designing and implementing performance improvement solutions across the enterprise. He specializes in critical thinking and project management processes, such as developing systems, procedures, and skills to maximize productivity and quality while minimizing risk. Reid has extensive experience with designing and managing large-scale, multi-year asset management consulting projects, facilitating the selection, commissioning, operational planning, risk management, and decommissioning of physical plant assets, designing and implementing enterprise project portfolio management systems and procedures, and facilitating root cause analysis on complex equipment problems.

Nowadays, it is fashionable to talk about and focus organizational reliability efforts on preventive and predictive maintenance programs designed to prevent equipment failures. Most of these programs deploy rigorous analytic tools such as FMEA, RCM, and PMO to identify and address the causes of failure in such a way as to minimize the impact on production, safety, and the environment. Rightly so, since numerous studies have demonstrated that preventive and proactive maintenance is four to eight times more cost-effective than reactive maintenance. As the old saying goes, an ounce of prevention is worth a pound of cure.

But no preventive maintenance program, no matter how carefully planned and constructed, can eliminate all critical equipment failures. There are always acts of God, acts of careless humans and unforeseen failure modes that create unanticipated failures. A fully optimized reliability program requires an equally robust approach to identifying and eliminating the inevitable and often very costly unplanned failures requiring corrective action.

Webster's dictionary defines the word Defect as 'a physical problem that causes something to be less valuable, effective, or healthy.' When we talk of defects in the context of asset reliability, we generally mean an asset impairment that has been discovered, as opposed to a functional failure that we had previously anticipated and taken action to prevent. Even though equipment defects and their associated corrective maintenance is an after-the-fact condition and action, I am continually surprised by the 'reactive' manner in which most organizations tackle such equipment failures.

These are the common and repetitive themes I've seen that result in unnecessary loss when it comes to corrective maintenance:

- delayed identification of equipment failures impacting production
- rush to judgement as to the cause of failure and the decision as to appropriate corrective action
- failure to properly diagnose the root cause(s) of failure before implementing the fix
- lack of rigor and appropriate staff involvement in the investigation of equipment failure causes
- lack of accurate, specific, and complete equipment history
- lack of specific problem specification in the initial work request and equipment notification
- lack of proper updating to preventive maintenance protocols for newly found failure modes

Corrective maintenance—and defect elimination in the broader sense of minimizing loss from found failures—can and should be more 'proactive', starting with some simple and clear defect elimination business process design and implementation.

The illustration on the next page depicts the steps in an optimized defect elimination process, together with the information inputs and outputs and associated EAM system linkages, to ensure timely and optimized corrective action of any equipment defect. For the system to work optimally, all steps must be carefully defined, linked, and installed with uniform and consistent application by all of the organization's reliability stakeholders—from operators, to maintenance technicians, to reliability engineers, to supply chain professionals, to top management. Just as Total Quality Management (TQM) and Total Productive Maintenance (TPM) can't be optimized without the fully integrated involvement of all the organization's functional stakeholders, so is the case with the asset defect elimination process (which could be argued is really just a subset of one or both of the others).

Step 1 in optimizing your defect elimination process is identifying and installing clear and effective feeds for recognizing equipment defects requiring corrective action. These signals can come from multiple sources: from boots-on-the-ground operators who recognize unusual deviations in the operating condition of installed assets, to maintenance technicians performing scheduled maintenance and inspections on equipment, to reliability engineers performing reliability analytics, to real-time electronic condition monitoring equipment, to product quality discrepancies identified by the organization's quality control department, to internal incident investigations, and external regulatory inspections. For the defect elimination program to be fully optimized, each of these sources and signals should be configured via the organization's integrated enterprise asset/resource management system (EAM/ERP) to provide immediate, clear, and direct notification that initiates appropriate and timely corrective action.

Once equipment defects or deviations are recognized and input into the relevant systems, the next step is to ask if root cause analysis needs to be performed before moving to corrective action. This is a critical and often overlooked consideration in the process flow of defect elimination. How many times have you seen your maintenance (or operations or engineering) department take action to 'correct' a found defect—presuming a familiar cause—only to subsequently find the applied fix doesn't correct the problem because it didn't address the underlying cause? How much time and money, not to mention production, is lost when the corrective action has to be redone or retried until the correct fix is applied?

These losses can be minimized by having a gatekeeper (or cross-functional team of relevant operations, maintenance, and engineering staff) review every new notification before moving it forward to work order planning and scheduling. This does not need to be a long or difficult process; it simply requires that these three questions be asked and clearly answered:

1. Is this equipment deviation an out-of-tolerance condition? If Yes, move to the next question; if No, continue the standard PM and PdM activities and reject the notification.

2. Is the cause of this condition unknown? If Yes, move to the next question; if No, choose and apply the appropriate known corrective action for this condition.

3. Do we need to know the cause of this problem in order to return the asset to its desired performance level? If Yes, move to the next step in the Defect Elimination process; if No, apply the standard or recommended asset restoration or replacement action to restore the asset's performance.

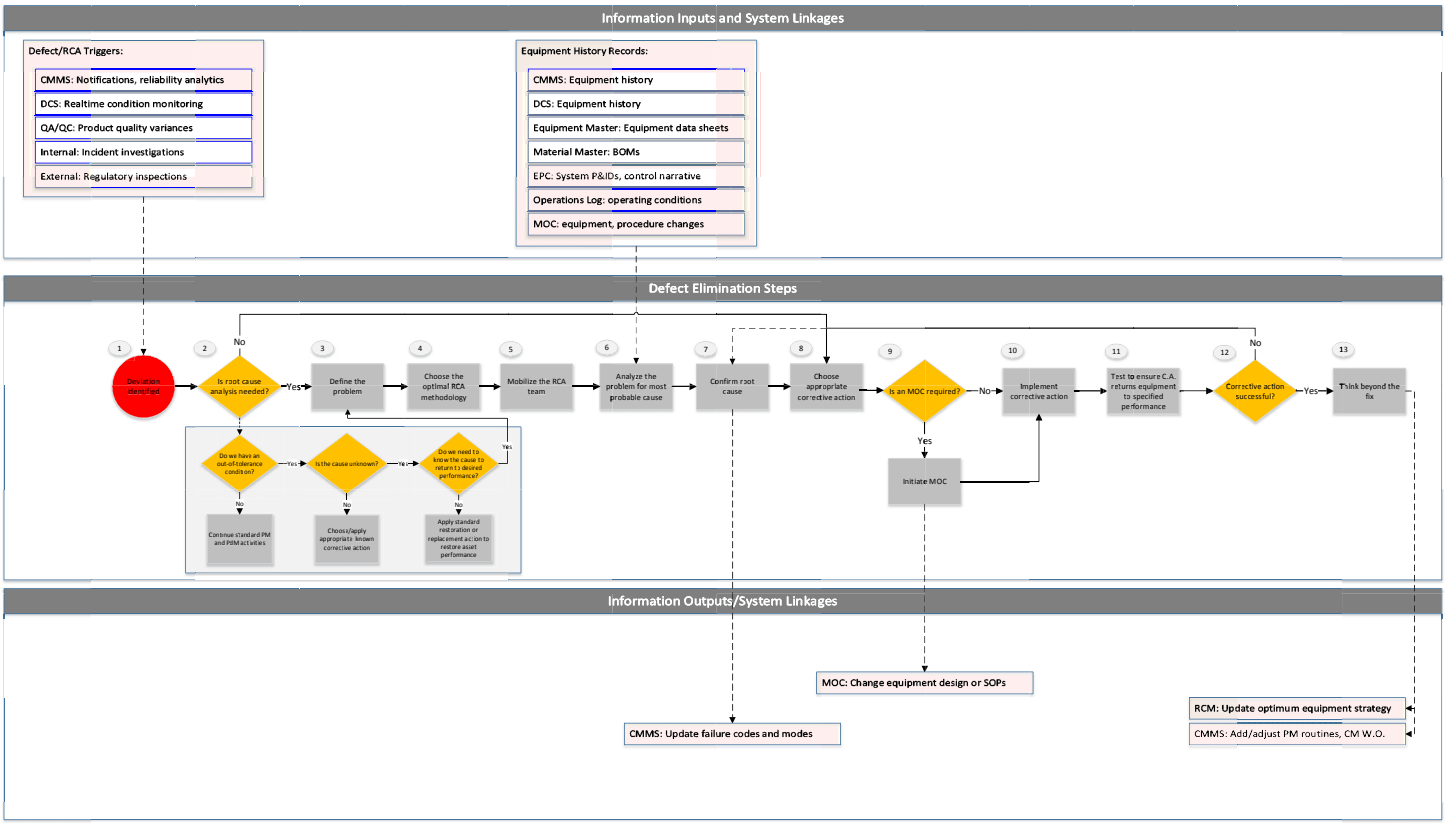
These three simple questions can and should be asked for all newly found equipment deviations and notifications in order to choose and dispatch the optimal and least costly corrective action. Sometimes the perceived 'defect' is not really a defect at all, but simply a piece of equipment operating within its normal and acceptable defined operating parameters. The most effective and least costly action is to reject any further corrective action and continue with the current preventive maintenance program to maintain its current condition. Other times, the defect may be deemed truly unacceptable (a measured out-of-tolerance condition), but cause is known (though this should ideally be confirmed before taking the next stipulated step), and thus the appropriate corrective action can be ascertained and/or applied without unnecessary time spent performing root cause analysis. Other times, the cause is unknown, but action to treat the symptom/effects is more appropriate and cost-effective than action to determine and treat the cause (as in the case of a flat tire on a maintenance vehicle, where the normal appropriate action is simply to replace the tire with a full-size spare). Only when the answer to all three question is "Yes" is it appropriate to move forward to a full root cause analysis in the defect elimination process flow.

The next step is to define the problem clearly. A clear and concise statement of the problem can focus and save tremendous time in the analysis of the problem's cause. I once facilitated a root cause analysis at a paper mill where the problem was initially presented as "Beater pit overflowing". When I tested the problem statement by asking the foregoing problem definition questions, this was the dialogue and subsequent disposition:

Question: Is this an out-of-tolerance condition?
Answer: No, this is normal during periods of peak production
Question: Then what is the out-of-tolerance condition?
Answer: The pump well is overflowing
Question: Is this an out-of-tolerance condition?
Answer: Yes
Question: Is the cause known for this condition?
Answer: Yes—pump #1 is unable to remove the flow of pulp from the pump well
Question: Is the cause known for this problem?
Answer: No
Question: Do we need to know the cause of this problem to return the asset to its desired condition?
Answer: Yes

At this point, one of the operations managers asked for a brief recess of the analysis so he could quickly check on a probable cause. When he returned fifteen minutes later he disclosed that the cause had been confirmed to be a new operator who had failed to follow standard operating conditions and close the by-pass valve on pump #2, which was allowing recirculation of the pulp flow back into the pump well. A few minutes of careful problem definition saved many hours of scheduled root cause analysis effort.

Once the problem is clearly and concisely defined, the next step is choosing the appropriate root cause analysis approach to tackle the problem. At times it seems there are almost as many root cause analysis techniques and methodologies as there are problems to solve. Everyone seems to have his or her own approach or one that he or she has been trained to use. The key is to agree on one process that the team can focus its collective thoughts around and that offers the right level of rigour needed for the problem that has been defined. The selection of the optimal RCA technique for each problem requires more time and space afforded by this article, but



suffice to say that the process selection criteria should be pre-defined, together with a short-list of organizational RCA alternatives to choose from.

The next order of business is to assemble and mobilize a cross-functional team of stakeholders to investigate the root cause of the problem. Too often this is left to the narrow expertise of the reliability engineering group, who often feel only they have the requisite training and intellectual horsepower to tackle these kinds of technical issues. However, the people closest to the problem—the equipment operator(s)—often have the most familiarity with the equipment and with the problem, and can be the best source of information in specifying the equipment history and suggesting cause. Similarly, maintenance technicians have the best knowledge and familiarity with the relevant maintenance history as well as the 'as found' and 'as left' conditions from scheduled maintenance. Engineers have excellent knowledge of process and equipment design conditions, and can often be better utilized as subject matter experts on the other side of the table. If the problem is complex and intransigent enough, it may be better served to utilize a dedicated RCA facilitator who can focus the team's input to follow the defined RCA process more rigorously while enabling the team to concentrate its efforts on supplying the relevant data.

Once the team is mobilized under the direction of a capable facilitator and sufficient time and a quiet workspace is set aside, the tough business of analyzing the problem to find its root cause can begin. The success or failure and the time necessary to discover the probable cause is very much dependent upon the factors already touched upon: the discipline and experience of the facilitator, the subject matter knowledge of the cross-functional investigation team, the analytical technique chosen to tackle the problem, and the availability of relevant data needed to effectively analyze the problem. The more complete, accurate, and specific the equipment records are kept, the quicker and more effective will be the analysis. Systems and records that feed into the analysis include, but are not limited to: CMMS (for equipment history and related analytics), DCS/SCADA (for real-time monitoring of equipment condition and associated alarms), Equipment Master (for nameplate data and detailed data sheets), Material Master (for bills of materials and part modifications), EPC systems (for greenfield information including P&IDs, process control narratives, etc.), Operations Log (for operating conditions and changes), MOCs (for equipment and procedure changes), etc.

The first goal of the analysis team should be to identify and narrow the field of possible causes to a most probable cause that can then be subjected to various tests for cause confirmation. Corrective action should never be taken for a suspected or probable cause—only confirmed causes. There are at least four discrete ways to confirm a probable cause:

a. Perform a Design of Experiments to simulate or reproduce the conditions found suspect (by controlling all other variables other than the suspected dependent variable and observe the effect on the independent variable);

b. Where possible, observe the suspected cause in action (as in the case of the unclosed by-pass valve on pump #2);

c. Confirm the assumptions listed during the analysis to support the most probable cause (all assumptions must be validated to support the cause based on facts);

d. Remove the suspected cause and see if the equipment returns to normal/specified performance levels.

The team should select the cause confirmation method that is most accurate, safe, quick, and cost-effective—this will vary from problem to problem.

Once the cause is confirmed, appropriate corrective action can be investigated and applied. It is also important to remember to review and update the preventive action program for the equipment in question, to avoid or minimize the probability of similar failures in future. If the confirmed cause is one that had not previously been considered or addressed, the CMMS system should be properly updated with the new failure mode(s), along with the optimal preventive maintenance strategy using FMEA or RCM analysis techniques. The appropriate range and scope of corrective actions should be considered and evaluated, focused on preventing or ameliorating the confirmed cause, based on sound business case and NPV analysis considering all organizational risk and return aspects (safety, environment, production, reputation, financial, etc.). If the recommended corrective action requires a management of change (MOC) prior to implementation, this of course should be undertaken where warranted.

The next important step is confirmation that the chosen corrective action worked as specified to return the asset to its required/prior performance. If not, either the cause was not correct, there are additional causal factors at work requiring further investigation, or alternative corrective actions must be considered and tested. The defect elimination process is not complete for a given failure until the asset can be demonstrated to return to sustainable targeted levels of performance.

Lastly, in order to optimize the return on each failure investigation and/or corrective action, the reliability team should ask these questions to investigate where additional benefits can be realized from the learnings and actions taken so far:

1. Is there similar equipment in our installed asset base that could be experiencing, or likely to experience, a similar defect? If so, can/should we look into applying a similar corrective and/or preventive action for this additional equipment?

2. Is there other equipment in our installed asset base that could experience an out-of-tolerance condition from this same found cause? If so, can/should we anticipate and update our preventive maintenance strategies for this equipment?

3. What new and/or other potential problems might this corrective action create? If these potential problems are significant and/or likely, what can we do to mitigate or prevent their occurrence?

4. What is the cause of the cause for this out-of-tolerance condition? Have we identified and addressed the root cause, and do we need to extend the root cause analysis accordingly? What are the human and organizational causes or conditions that permitted and enabled the technical cause to manifest, and what can we do to readjust our procedures and policies to reconfigure these elements to minimize similar future problems?

If these steps and procedures are applied to the organizational defect elimination and corrective action process, significant time and resources can be saved in the identification, analysis, and correction of unplanned equipment failures.

Finally, in order to keep the organizational defect elimination process current and optimized, a periodic review and benchmarking of the underlying business process should be undertaken, with a similarly robust analysis and correction of any gaps and discrepancies applied to the overall process. Best practice organizations always seek to continuously improve their practices and business processes and learn from others.

Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

Advertising Opportunities in ISPE CASA 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 $750 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional $750 per year for six issues. Space limits the number of front page ads to only **four**, and is 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 $500.00 for the entire year.

You may choose one of the special offers below:

- $1,500 Full-color ad for four issues **on the front page of each newsletter** ($250/issue)
- $ 750 Full-color ad for six issues ($125/issue)
- $1,500 Double business card size ad for six issues ($250/issue)
- $200 Full-color ad in 1 newsletter of your choice
- $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 2014 ISPE CASA e-newsletter.

To reserve a placement of your ad for 2014 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at 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 info@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, JPEG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!

Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

Electronic Media ISPE-CaSA.org

Now you can reach www.ispe-casa.org audience by advertising on our website. A limited number of advertising spots are now available so don't delay. Contact the ISPE Carolina-South Atlantic Chapter to reserve your space.
(Please note: ISPE-International-forbids website ads on our chapter's home page, so they are on subsequent web pages.)

To learn more about this opportunity, contact Penney De Pas, Chapter Manager, at 919-573-5442 or pdepas@ispecasa.org. If you are interested in signing up for the program, please complete the form and return to pdepas@ispecasa.org or fax 919-787-4916. Advertisements are sold on a first-come first-served basis.

SPECS OF ADVERTISEMENT:

Top Placement Ad 120 pixels wide by 240 pixels high; File formats accepted: .GIF, .JPG, .SWF
Bottom Placement Ad 240 pixels wide by 400 pixels high; File formats accepted: .GIF, .JPG

	12 months	6 months
240 x 400 Vertical Rectangle	$500	$300
120 x 240 Vertical Banner animated	$400	$250
120 x 240 Vertical Banner - non animated	$300	$200

- ☐ 240 x 400 Vertical Rectangle ad 6 Months, $300
- ☐ 240 x 400 Vertical Rectangle ad 12 Months, $500
- ☐ 120 x 240 Vertical Banner animated ad 6 Months, $250
- ☐ 120 x 240 Vertical Banner animated ad 12 Months, $400
- ☐ 120 x 240 Vertical Banner - non animated 6 Months, $200
- ☐ 120 x 240 Vertical Banner - non animated 12 Months, $300

Name: _____ Member #: _____
Company: _____
Title: _____
Address: _____
City: _____ State: _____ Zip: _____
Tel: _____ Fax: _____
Email: _____
PAYMENT TYPE: ☐☐Visa ☐☐MasterCard ☐☐AMEX
Or ☐☐Check (Payable to: ISPE-CASA)
Card #: _____ Expiration Date: _____
Cardholder Name (as it appears on card): _____
Cardholder Signature: _____

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 info@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, 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
whaines@manganinc.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 whaines@manganinc.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: whaines@manganinc.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.