ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

CaSA News

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Featured Sponsors

President's Message

Jennifer Lauria Clark, CPIP

Happy New Year! Greetings from the Low Country. Since the last newsletter there have been some changes in my life. My husband got a great promotion and we have moved our family right outside Charleston, SC. With that being said, our networking committee has already planned our first Therapeutic Tuesday event in Charleston, SC for February. If you are interested in helping expand our networking and educational opportunities to the southern part of our Chapter, please let me know.

We are out of the gate running this year with several great events already planned. My last message talked about providing outstanding educational events. Tuesday, January 29, we did just that with our *Risk Management* seminar. We offered CEUs, CPIP™ recertification points and had a good turnout as attendees learned about the *Effective Implementation of a Risk Management Program*. If you have a topic you would like to hear about please email us or let someone on the Board know your interests.

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President's Message

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Our Young Professionals hosted a great networking event at Boylan Bridge Brewpub Thursday, January 24. There was a great group of people at the event and they got a tour of their brewery. Our next Therapeutic Thursday will be in Rocky Mount, NC. Look for details to come to your email inbox.

This year we are projecting to hold our most successful Technology Show yet. Bruce Craven, Mike Putnam and the rest of the Tech Show Committee have been working diligently to put on a fantastic show. We have exceptional educational tracks planned as well as reputable Key Note Speakers. There are some exciting new additions to the show this year and we can't wait to see you all on March 26, 2013 at the Raleigh Convention Center.

Our sponsorship program is still available for the 2013 year. If you are interested please check out our website www.ispe-casa.org for more details.

It is important to know how our membership understands what we are doing. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please let me or any other Board Member know how well we are doing or what we can do to improve.

Each newsletter you will see me thanking our volunteer members who spend their time reviewing newsletters, cleaning up after events, or helping with whatever we need done to make the Chapter successful. The entire Board appreciates our good friends for staying involved and welcome fresh ideas and new faces at our committee meetings. And now a To Do List:

- **Get Involved.** Let us know if you are interested in a volunteering with a committee or in active leadership of ISPE CaSA. Specific committees have stated in this newsletter if they are in need of help. Membership and Education are two committees that are in the most need of volunteers. Please contact info@ispe-casa.org or the committee chairs if you are interested in any of the committees. Thank you to our new volunteers that have joined our committees recently.
- **Share your ideas.** Please send in some fresh ideas for 2013 educational programs and networking events. We will have a drawing from everyone who sends in an idea by March 1, 2013. The winner of a gift card will be announced in the next newsletter.
- **Come see us at...**
  —*Charleston Therapeutic Tuesday*, 6:00pm – 8:00pm, California Dreaming, Tuesday, February 12
  —*CaSA Leadership Forum,* McKimmon Center, Friday, February 22
  — *Casino Night*, Capital City Club, Saturday, February 23

As project work increases in our area, we are seeing our membership numbers increase as well. There is no better time to get involved with the CaSA Chapter than now. Together, we are making a difference.

Jennifer Lauria Clark, CPIP
Chapter President

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

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Membership Corner

New Members (and Member Benefits) Abound!

By Jerry "Patch" Paciorek, CPIP, Membership Development Chair

To enjoy some of the benefits of your membership, I hope you're planning to attend one or more of our many upcoming events. I'd enjoy the opportunity to meet you, and our fellow CaSA Members who have volunteered their time and efforts to put these events together would love to see you there as well.

Remember to invite your co-workers to join you at our events, so they too can see what our Chapter is doing. To answer questions about the benefits of ISPE membership, we will have a Membership Development Committee representative at each event. Please contact me if you have any questions about ISPE at paciorek@cagents.com.

I'm excited to report that we've had 30 new CaSA Members join since our last newsletter was published, bringing our total to 139 new CaSA Members since July 1, 2012.

Congratulations to CaSA's First 2013 CPIP!

Jerry "Patch" Paciorek, CPIP

Join the Team ISPE

LEUKEMIA & LYMPHOMA SOCIETY® | TEAM IN TRAINING®

About TEAM ISPE...

Team ISPE is part of an all-new Member experience; our cycling team (now in formation) will be joining **The Leukemia and Lymphoma Society's (LLS) Team in Training Program and "cycling for a cure" during America's Most Beautiful Bike Ride on June 2, 2013 in Lake Tahoe, NV.**

Our team's mission is to build awareness of ISPE's commitment to producing safe medicines while also giving back to our patient customers and to our industry through fundraising that supports critical blood cancer research.

TNT at a Glance

Since its inception in 1988, Team In Training® (TNT) has grown into the world's leading endurance sports charity training program. The program provides hands-on training for beginner to advanced athletes to run or walk a full or half marathon, cycle a 100-mile bike ride, participate in a hike adventure, or complete a triathlon.

- Participants raise funds for The LSL in exchange for training, team support, lodging, and transportation to the event of their choice.
- To date, TNT has trained over 540,000 participants raised over $1.3 billion for cancer research.
- TNT has 61 chapters across the U.S. and Canada

Event Weekend Benefits

- Race entry
- Transportation to & from event
- Weekend hotel accommodations
- Inspiration dinner
- Team meet & greet
- Victory celebration
- Race day jersey
- TNT Staff manage

Details

- Go to www.teamintraining.org and enter your zip code or hit First Time Here to find your local Chapter
- Contact Team ISPE's TNT National Captain: Nancy S. Berg, President & CEO of ISPE, at NBerg@ISPE.org. Website: www.ispe.org
- Register online with code: ISPE13 ($50 registration fee for all national teams)
- Let local TNT staff know to enter your "employer" as ISPE-(Your Company)
- Attend Chapter Kick-Off. Training begins in Jan-Feb.
- Family and friends welcome! Start your own local office team!

TNT Contact:
Jason Rice Jason.Rice@lls.org

Membership Corner

Member Spotlight: Jim McGlade

By Wendy Haines, Newsletter Chair

Jim McGlade

Q: What is your full name?
A: James William McGlade

Q: Birth Place?
A: Omaha, Nebraska

Q: College?
A: Iowa State University for undergraduate studies, Clemson University for graduate studies, including one semester in Genoa, Italy.

Q: Tell me a little about your personal life.
A: I am the youngest of six children and have the scars to prove it. I will have been married to my lovely wife, Abbie, for 13 years by the time this gets published. We have two wonderful children, Kylie (10) and James (7).

Q: What is your present position? What do you do at your job?
A: My position title is Senior Project Manager. Formally, I am responsible for a project's performance with respect to schedule, cost, and quality. Sounds fairly routine, however, each day is filled with a variety of tasks such as leading a design phase coordination meeting, resolving a field construction issue, discussing design options with clients, reviewing project performance projections, etc. I also support business-development activities.

Q: How long have you been with your current company?
A: Just over one year.

Q: Tell me about your career path, and how you ended up where you are today.
A: I knew I wanted to be an architect since I was eight years old. After receiving my undergraduate and master degrees in architecture, I passed the exam and became a licensed architect. From there, my pragmatic side took over as I evolved into project management. Although I do very little "architecture" now, I use the problem solving skills I learned in design classes every day.

Q: What is your favorite part of your job?
A: I get a great deal of satisfaction from overseeing teams who execute their roles in unison and achieve their goals. Of course, this most often results in satisfied clients, which is nice.

Q: How long have you been a Member of ISPE/when did you first join ISPE?
A: I joined ISPE in July of 2000. CaSA has been my only home Chapter.

Q: What benefits have you realized from being a Member of ISPE?
A: This could take a while. ISPE has been instrumental in my career development. It has provided me with educational opportunities to better understand the biopharm industry beyond my brick-and-mortar world. As a Committee Member, executive Board Member, presenter, or co-author of the ISPE Project Management Guide (shameless plug), ISPE has been a safe and supportive environment for my professional growth. ISPE has also been a catalyst for expanding my professional network. I envy the students who join ISPE before their careers have even started and can only imagine how vast their networks will be in 20 years. Finally, the friendships that have evolved from this network have been priceless.

Q: Why are you still involved with ISPE?
A: I believe the real strength of ISPE is in the relationships of its members. These relationships have become vital to my career. Also, I enjoy the challenges that each new role offers.

Q: Any Mentors/Role Models that have helped to shape your life?
A: I've been fortunate to have several mentors/role models throughout my life. My siblings were very beneficial in that they never failed to show me examples of how to get in trouble - I mostly avoided repeating those! Ben Pearce was an Architect, in Charlotte, who showed great patience while guiding me through the first years of my career. Within ISPE, there have been numerous individuals who have influenced me, knowingly and unknowingly. However, beyond a doubt, there are several CaSA past-presidents who were and still are, my go-to gurus for all things ISPE.

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Membership Corner

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Q: If you weren't involved in Pharma, what business do you think you'd be in?
A: I often think I should have pursued being a Golf Course Designer or a hockey player, probably on defense.

Q: What is one skill you wish you had that you don't?
A: The Force! Then I could get everyone to agree with me and I could win Olympic gold in weight-lifting.

Q: Any hobbies? What are they?
A: Travel. Golf. Triathlons-the short version, you won't see me in Kona. Trying to shorten my endless home repair list.

Q: Do you collect anything?
A: Grey hair and any coins older than I am.

Q: Finish this sentence – "I need more…."
A: time to play.

Q: Favorite Food?
A: Pesto Gnocchi

Q: What is something that people would be surprised to learn about you?
A: I was the starting center for my high school football team which won the Nebraska state championship in the largest class, despite weighing only 162 pounds. I also have some scars to prove this, too.

Q: Last movie you saw?
A: Madagascar 3 – Europe's Most Wanted (the McGlade family gives it eight thumbs up)

Q: For those in the early stage of their careers, what advice would you give them?
A: 1) Realize the immeasurable potential of your relationships. Invest time in building your network beyond LinkedIn. Join a committee, volunteer to help a task team, attend educational/networking events – step away from the computer!
2) Embrace the power of communication. Seek out any opportunity to improve your public speaking skills. You don't have to be perfect. 3) Help others without expecting anything in return. What comes around goes around.

Welcome New Members

These new Members joined November 30, 2012 through January 24, 2013

Abhiruchi Agrawal
Edwin Alston
Edgar Arvelo
Swanalika Avula, Jr.
Tony Clements
Douglas Commerce
Michael Dickens
Alicia Eddings
Daniel Egbe
Charles Fletcher
Eric Franson
Swathi Gunuganti
Abel Hastings
Kevin Henning
Stewart Kohnberg
Pratibha Koneru
Brian Larmon
Joe Maniace
Phil McKinney
Paul Piccillo, PE
Thomas Rajala
Rex Roberts
Scott Rohlf, CIH
Lauren Shields
Marc Suter
Monica Tindel
Kevin Ventura
Pravallika Vinnakota
Debra Weigl
Oscar Bernal Zuniga

CaSA COMMITTEES

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IT Committee
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Technology Show Committee
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Membership Development Committee
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Networking Committee
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Newsletter Committee
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Young Professionals Committee
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BEST Fest Committee
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davidglennsmith@gmail.com

Student Affairs Committee
LeAnna Pearson
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Communities of Practice

Spotlight — Investigational Products

By Matt Gilson, Past-Chair of the North American Steering Committee for the IP-COP and current Vice President of ISPE CaSA

The Investigational Products Community of Practice (IP-COP) within ISPE comprises members from around the world working in the clinical trial material arena of the pharmaceutical industry. The scope of the IP-COP is global and broadly covers all aspects of clinical trial materials, in particular, clinical drug product manufacturing, packaging, labeling, warehousing, and global distribution. In addition, the group focuses on current "hot" topics; recent examples include removal of "Use By" dates from IMP labels in Europe, leveling of the GCP/GMP interface, comparator sourcing, and import/export regulations. Our global scope is facilitated through IP-COP Steering Committees in North America, Europe, and Japan. Our membership represents academia, pharmaceutical and biotech companies, contract services providers, and professional consultants.

Drug development is becoming ever more complex: clinical trials are larger, more complex, and are breaking new frontiers in search for patients. The IP-COP supports its members to: better understand the changing landscape, influence regulators worldwide, create forums for new technology, provide educational opportunities for complex to simple clinical supply challenges, and leverage the experiences of each other at conferences, meetings, and online.

IP-COP Objective

Our objective is to equip IP-COP members to meet the changing environment head on. We do this by collaborating with our ISPE Affiliates, Chapters, and COPs as well as other related Investigational Products organizations with a common interest to improve our ability to support global clinical studies.

IP-COP Resources and Education

The IP-COP is actively engaged in writing and publishing guidances, technical documents and knowledge briefs. We also conduct webinars on new and innovative thinking and are engaged in efforts to influence the global IP regulatory environment. The guidance documents can be found on our website at www.ispe.org/ipcop/guidancedocs. The most recently produced guidance documents cover Comparator Management and Interactive Response Technology.

The IP-COP also produces an educational track at the ISPE Annual Meeting every year. Look for information later this year about these topics at the meeting in Washington D.C. in November 2013.

The IP-COP is interested in collaborating and sharing best practices on all issues related to Investigational Products. As a Member of the IP-COP, you can:

- Access our IP-COP website which contains numerous references (http://www.ispe.org/ipcop)
- Participate on committees and task teams that are of interest to you
- Review current industry trends
- Communicate with other subject matter experts and generate solutions to everyday problems 'in real time'
- Contribute to the understanding and interpretations of industry regulations
- Utilize convenient global networking forums that foster professional commitment and industry reputation

Join Us!

The IP-COP is committed to serve you! We need your input, wisdom, and assistance and encourage you to join us on what promises to be an exciting journey for IP COP over the next several years.

Upcoming Event Highlights

Young Professionals Event of the Year: "Take Control of Your Career"

By Blake Derrick, Event Chair

Come join us and...

"Take Control of Your Career!"

2013 CaSA Leadership Symposium
February 22, 2013
NC State McKimmon Center

What is this day all about?

The all-day event will center on career planning and leadership development for students, young professionals, and professionals working in the pharmaceutical manufacturing and services industry. Even if you are a seasoned professional in the industry, you are encouraged to attend as well! The day will include networking opportunities and local industry speakers while offering a great venue to connect and learn about career paths in the pharmaceutical industry via round-table discussions. Job seekers that register for the event will also have an opportunity to submit their resume electronically to be shared with some of the sponsor companies. For industry veterans, this is a great way to network with those early in their career and pass along knowledge and best practices you wish you had known! Light Breakfast and Lunch will be provided, as well as snacks/drinks in the afternoon.

Registration and details can be found at http://2013CLS.eventbrite.com, with registration due by 2/19.

Speaker Highlights Include

- Panel Discussion with Talent Acquisition and Staffing Specialists from Biogen Idec, Novartis, Novo Nordisk, and PCI
- "Avoiding the Career Fiscal Cliff…Take Control!!! " by Neil Jones, VP of Scientific Operations, Kryosphere
- Brian Nunnally, Associate Director of Regulatory Affairs, Biogen Idec
- Panel Discussion on career development in technical areas. Speakers include:
  — Marianne Lorenc, QA Manager, Medicago
  — Mike Newcomb, Engineering Manager, Novozymes
  — Mark Yates, Principal Validation Specialist, Pfizer
  — Joe Cobb, Director, Pharmaceutical Services, Metrics Inc.

Sponsorships are still available for Platinum, Gold, Silver and Bronze levels – please contact Blake Derrick at919-467-1752 or casaleadershipsymposium@gmail.com for more information.

We would also like to give a special thanks to our Gold sponsors!

Novartis Vaccines
Commissioning Agents Inc.
KBI Biopharma
Biogen Idec
Fujifilm Diosynth Biotechnologies

Upcoming Event Highlights

Feelin' Lucky? 5th Annual ISPE CaSA Casino Night — February 23

By Newsletter Committee

Are you feeling lucky? Then press your luck at Roulette, Craps, Triple Shot, Black Jack, or Poker.

Heavy hors d'oeuvres and a cash bar will be provided in addition to prizes awarded to the top three "fake money" winners.

Come out and enjoy a night of gambling, food, and fun at the:

5th Annual CaSA ISPE Casino Night
February 23
Capital City Club, Raleigh, NC

Dress to impress (dressy casual) and blow the competition away with your card prowess and knowing when to bet on red or black.

Visit the CaSA website for registration details and sponsorship opportunities.

Don't Miss Fun & Networking at the Sparian's Bowling Event: March 14th

By YP Committee

The ISPE Young Professionals are hosting an exciting night of networking and bowling March 14th from 6:30 to 8:30 at Sparians in North Hills. The evening will include unlimited bowling, appetizers, and a cash bar. Keep an eye out for the ISPE event email for registration details.

Thanks to our sponsors, CRB, PCI-LLC, and Sequence for making this event possible. Be sure to tell your friends and coworkers to come out for some fun and networking!

One more sponsorship is available.
Call Jon Doyle at: 919-438-5859

YP Bowling Event Sponsors

CRB

PCI

SEQUENCE
Validation Consulting Services

Upcoming Event Highlights

Save the date! BEST Fest at the NC Museum of Natural Sciences — April 6

By David G. Smith, Chair of the BEST Fest Committee

The NC Museum of Natural Sciences is partnering with the NC Science Festival and ISPE to hold the first-ever Triangle BEST Fest! The Triangle BEST Fest (Biotechnology, Engineering, Science and Technology) will expand upon the huge success of last year's Biotechnology Day and seeks to bring scientists, researchers, engineers, students, universities and industry together to showcase, using fun, hands-on and interactive activities, the amazing advances in these areas.

The event also aims to demonstrate how the Triangle of North Carolina is an innovative leader in these areas. Visitors will learn about why these fields are important to their daily lives and will, hopefully, be inspired to pursue education and careers in biotechnology, engineering, science and technology.

There will be exhibits in both buildings and outside the Museum on Bicentennial Mall. In addition to the many interactive exhibits, there will be a series of presentations in the Daily Planet Theater in the Nature Research Center and Windows on the World Theater in the Main Building.

BEST Fest Details

Saturday, April 6, 2013
9am-5pm
NC Museum of Natural Sciences
Downtown Raleigh

20th Annual ISPE CaSA Technology Show

New Venue, New Location, New Everything! Don't Miss It!

By Bruce Craven, Committee Chair

Are you ready? Have you registered? The time is almost here for the 20TH ANNUAL ISPE CaSA TECHNOLOGY SHOW!

This is the show you asked for and we are going to deliver, but it won't be the best show to date without you.

When we announced the plans for the new venue back in September of 2012, the most important reason for the big changes was to make sure that your suggestions for improvement were heard and answered. That is why we are doing the following:

- **Moving to the Raleigh Convention Center** – a better venue that gives better layout and access to the exhibitors and an improved learning environment for the training sessions.
- **Later start time** – to help alleviate some of the potential traffic issues
- **Better food, more food** – food, snacks, drinks provided all day – no one will go away hungry
- **Internet access throughout the event for everyone** – you can stay connected or just check-in with work
- **Easy parking** – we are renting a parking deck for the day. Remember to bring the parking voucher you received during registration – this lets you leave without paying.
- **Keynote Speaker** – this is going to be a great surprise – we have two this year – one during lunch and one before the "networking event" – forthcoming e-blasts will announce the names!
- **Fewer and more defined education tracks** – we'll have relevant and current issues discussed at this year's event. Registration allows you to pick your tracks and help you define your day.
- **Expanded exhibitor spacing** – to include bigger booth setup. We even have product demos scheduled throughout the day.

Raleigh Convention Center

Why are we doing all of this?

The committee's goal for this year was to take what we have learned over the past 5 years and use that knowledge to make an event that gives back 100% to you, the members of our technology community. Everything is changing around us and this event needs to change with us. You asked for an easier way to have attendees get to your booth, we did that. You wanted better food and more of it, you will have that. You asked for internet access, we have that. You wanted something new and different –this is it.

EXHIBITOR AND ATTENDEE REGISTRATION IS NOW OPEN

Your chance to attend the grand event is here. The Tech Show Committee has volunteered many hours to make this gathering the best one in 20 years, but it won't be without your attendance. This event does it all, by bringing the technology and experience of service/equipment providers, life sciences corporations, non-profit organizations, and universities throughout the ISPE CaSA Chapter together for one day of networking and education. There is no other event that does that. We are expecting record attendance of all those groups mentioned above.

Please plan to join us by visiting the exhibitor or attendee registration site today at www.ispe-casa.org/2013.

On behalf of the 2013 Technology Show Committee, we thank you and look forward to seeing you March 26!

Technical Section

Systems and Techniques for the Removal of Volatile Organic Compounds (VOC) in Process Gas Streams

By JT Cochran of CRB Engineers, Inc.

Standards defined by local, state and federal government agencies are continually tightening the requirements for the allowable release of airborne contaminants from industrial processes. This presents a standard that is under constant refinement by these regulatory agencies. The design engineer must be familiar with these regulatory standards and must adhere to them even before the design phase of projects are underway.

As early as possible in the development of the bid on a project it is important to determine if volatile organic compound (VOC) abatement will be required as a part of engineering services. This line item alone can represent a large portion of the engineering fee as well as equipment and installation costs on any given project.

Upon execution of a project, it is imperative that a detailed analysis be performed to define what chemicals are present, if those chemicals may be discharged from the process in vapor (and liquid) form, and if treatment is required. Unless specifically excluded from the scope of work by the client, it is the responsibility of the design engineer to ensure that the most economical and effective abatement technology is applied to meet regulatory demands.

Adequate VOC abatement not only protects the client from possible code violations and hefty fees or lawsuits, but more importantly protects the environments and habitats we live in and the people in our communities.

There are many various techniques for VOC abatement but by far the four most common methods are; carbon adsorption, condensation (often cryogenic), liquid scrubbing, and thermal oxidation.

Carbon Adsorption

Activated carbon is a porous material that removes organic compounds from process gases by a process known as “adsorption.” In adsorption, organic molecules contained in the gas stream are attracted and bound to the surface of the pores of the activated carbon as the gas is passed through it. Eventually the activated carbon will become saturated with the organic molecules and will require replacement or regeneration to remain effective. Regeneration can be accomplished by steam cleaning the carbon bed. Any condensate that is drawn off of the steaming process must be handled and treated as hazardous waste. Replacement of the carbon beds can be accomplished in one of two ways; removal and replacement of the carbon canisters, common in smaller carbon bed systems, or removal and replacement of only the carbon material while the canisters are kept in place. In either method the carbon material also must be considered as a hazardous material and further treatment will be required. Typically the provider of the carbon bed systems will also provide services for regeneration or removal and replacement of the activated carbon.

Condensation

Using a refrigeration process or a cryogenic fluid such as liquid nitrogen, gasses are passed through a heat exchange process where the temperature of the gas is cooled to a very low temperature. By lowering the vapor pressure as a function of vapor/liquid equilibrium the cryogenic process is able to separate out pollutants into liquid form. One of the advantages of this process is that depending on the composition of the effluent gases, vaporized solvents may be reclaimed in pure form, and reused in the process or sold to recoup some of the operating costs.

Liquid Scrubbing

Liquid scrubbing works by contact of the process gas stream with a scrubbing solution. The scrubbing solution may be simply water, for instance if used for removing dust particles, or may be a solution of reagents that specifically target a certain compound in the vapor emission. The efficiency of the removal of pollutants can be improved by increasing the residence time in the scrubber or by increasing the surface area of the scrubber solution by the use of a spray nozzle, packed towers or an aspirator. The target contaminant is then captured in a liquid phase and can be easily collected for disposal.

Thermal Oxidizers

Thermal oxidizers are used for process gases containing small particles of combustible solids or liquids. Exhaust air will be oxidized (burned) as much as possible, so that the exhaust consists of little but non-toxic carbon dioxide or mineral solids (soot). The types of thermal oxidizers can be divided into two categories; non-flame oxidizers, which use slow heating to incinerate pollutants, and direct flame thermal oxidizers, which use plumes of flame. Thermal oxidizers may also use a process called catalytic oxidization. In catalytic oxidization, organic compounds pass over a support material coated with a catalyst that encourages the pollutants in the air to burn. Catalytic oxidizers can break down pollutants at lower temperatures than thermal oxidizers lacking catalytic action.

A number of factors must be evaluated to make the best decision on which abatement technique is suitable for any given process. Some of those factors include:

- Severity of hazard of the target contaminant. This can be determined by consulting the MSDS for the contaminant and local building and fire codes.
- Concentration of all of the components in the vapor

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Technical Section

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stream, typically reported in percent by volume, ppm, or ppb (by mol)
- Vapor pressure of the components (if contemplating cryogenic condensation)
- Amount of water vapor present in the process gas in lbs/hr, ppm, or ppb (by mol)
- Flowrate of the process gas (continuous, batch, instantaneous, maximum, minimum)
- Target removal rate, or end concentration of the contaminant
- Incoming pressure of the process gas. There must be sufficient motive force to overcome the pressure drop across the abatement equipment which could lead to additional design time and equipment costs for booster fans, coolers, and controls.

Also of importance is the amount of discharge of the contaminant to the environment that is allowed by regulation as none of the above abatement technologies are 100% efficient. Typically local and federal regulatory agencies must be consulted to determine this limit. A review of the client's APCD (Air Pollution Control District) permit is one source of this information.

If an APCD permit does not exist it must be applied for as part of the project execution. The APCD should provide the documented and referenced emission standards. The EPA department in the county or state in which the project resides should also be a viable source for emission standards.

In addition to the above considerations for equipment selection, the short and long term economic impact must also be evaluated. Each abatement technology will come with consumables. Carbon adsorption will require change out and/or regeneration of the carbon beds as they become saturated. Condensation will have a steep installation cost compared to carbon adsorption and will consume liquid N2 or a heat transfer media which may require refilling on a regular basis. Liquid scrubbers will need the reagent solution replaced with clean solution, and the thermal oxidizer will use natural gas or will need the catalyst replaced on a regular schedule. Each must be carefully considered since one technology may be attractive from a capital expense perspective, but may be very costly to a company's maintenance and operating budget.

For example, an economic analysis was conducted between carbon adsorption and cryogenic condensation for the removal of a carcinogen from the process vent stream on a project being done for a local San Diego client. After the analysis was completed it was determined that carbon adsorption was the most economically attractive abatement system in terms of both initial installation costs and long term operating costs. During the execution of the project a change in the process was made to implement a 2X increase in the sparge rate which had a proportional affect on the off gassing of the carcinogenic material. The change resulted in a significant upsizing of the carbon beds, and an increase in the frequency of change out of the beds to prevent saturation and breakthrough. The economic analysis was redone and even though the initial installation costs of the carbon beds was still significantly less than using a cryogenic system, long term operating in terms of both labor and consumable costs made the cryogenic system much more advantageous.

The technologies discussed within this brief are not an exhaustive list by far and even within these offerings equipment manufacturers are continually improving their products with sophisticated controls systems, updated materials, and even improved supply chains for supplying consumables. Look towards the vendor as a valuable resource as they know their systems best, and should be able to simulate operations of their equipment given that the process parameters are well defined. However, be sure to adequately scrutinize any sizing calculations performed by the vendor to ensure they are accurate and that the selection made for the project meets the needs of the client as well as the applicable local, state, and federal regulations.

Technical Section

Quality Risk Management (QRM)

By Mike Porter and Steven J. Wisniewski of Commissioning Agents, Inc. (CAI)

Quality Risk Management (QRM) is an expected element of a company's site quality system that is subject to review as a part of a regulatory inspection, and is typically governed by corporate or site policy and procedures. Many times, QRM can be perceived as a documentation exercise where the results get filed in the site document management system, yet have no real impact on driving improvements or reducing the company's overall risk profile. A fully functioning QRM program can lead to shared process understanding between cross-functional team members, identification of critical aspects for processes or equipment that can streamline qualification and validation activities, recognition of critical gaps in process understanding, and a clearly defined and documented risk control strategy.

For the pharmaceutical and biotech industries, ICH Q9, Quality Risk Management, and ISO/IEC Guide 51 define risk as "the combination of the probability of the occurrence of harm and the severity of that harm". While detection is not specifically mentioned in this definition, it may be included as part of the overall definition. As described, the intent of a QRM program is to identify those harms that can impact patient safety or product quality, evaluate the severity of that harm if it does occur, and drive discussions around how these harms can be controlled through design, automation, alarms, or procedure to reduce the overall risk profile.

Risk Management is utilized by a number of diverse industries including aerospace, commercial aviation, petrochemical, rail, nuclear and others. While the specific harms, hazards, causes and risk profiles may vary between industries, the risk assessment process is similar across all these industries in its attempt to answer the following questions:

- What can go wrong?
- How often does it happen?
- How bad are the consequences?
- Is the risk acceptable?

This approach has traditionally been used by the Medical Device industry with a focus on product use, design, and manufacturing, primarily through the implementation of Failure Mode and Effects Analysis (FMEA). However, the utilization of risk approaches is relatively new to the Pharmaceutical and Biotech industries. Driven by a focus on Quality by Design and risk-based decision making, risk is being utilized to drive continuous improvement initiatives, deeper equipment and process understanding, and development of comprehensive control strategies through the utilization of a variety of tools.

ASTM E2500-07 "ASTM Standard for Specification, Design & Verification of Pharmaceutical & Biopharmaceutical Manufacturing Systems & Equipment", is a consensus standard based on sound scientific, engineering and quality principles that applies QRM to the qualification and fitness for use of manufacturing systems by providing a focus on risk to patient safety. Other types of risk such as Financial, Operational or Strategic Risks are not within the scope of this document.

Although qualification and validation have been required since the mid-1970's, the paradigm shift to QRM based approaches began around 2000. Qualification, characterized by Installation Qualification (IQ), Operational Qualification (OQ), and Process Qualification (PQ), followed by Process Validation (PV) had become a broken process where: (1) IQ and OQ had become more intensive than PQ, (2) organizations refusing to leverage commissioning, defined as up-front engineering testing prior to qualification, (3) automated systems and the controlled equipment were qualified separately and inefficiently, and (4) deviations for trivial items diluted the attention of the Quality organization.

This ultimately led to a "change-is-bad" attitude that was primarily driven by the significant cost and time to re-qualify a manufacturing system. ASTM E2500-07 addresses these issues by providing three fundamental principles behind its QRM qualification approach:

- A focus on the identification and testing of risks that impact product quality
- Utilizing risk assessments and design/process knowledge to identify critical elements
- All activities must contribute value

It is important to note that this approach is applicable to all elements of manufacturing systems including facility equipment, process equipment, supporting utilities, and associated process control and automation systems that have the potential to affect product quality and patient safety. This can be applied to both new and existing manufacturing elements/ systems and may be used for the implementation of changes to existing elements/ systems, including their continuous improvement during operation. The process overview for the ASTM risk-based approach is shown in Figure 1 below and highlights the following key elements of the program:

- **Product and process requirements** must be documented and approved at the beginning of the project. This requires investing more time and effort at the initiation of the project but will lead to savings in both project cost and project time.
- **Risk assessments** are conducted early in the project so that design solutions can be developed to mitigate the identified risks by controlling the identified Critical Aspects. The most effective risk reduction is system design, followed by automation/system controls, followed by procedural controls, therefore, early identification of risk allows for the maximum opportunity to influence the system design.
- **Verification testing** is conducted during the project execution lifecycle to test all aspects of the equipment including the critical aspects determined in the risk assess-

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ment to show that the system is operating as designed and is fit for its intended use.

- The system is accepted and released based on the **collection of documents** providing evidence of the system's fitness for use, with emphasis on those documents showing the defined requirements have been met and the critical aspects of the risk assessments are in control.

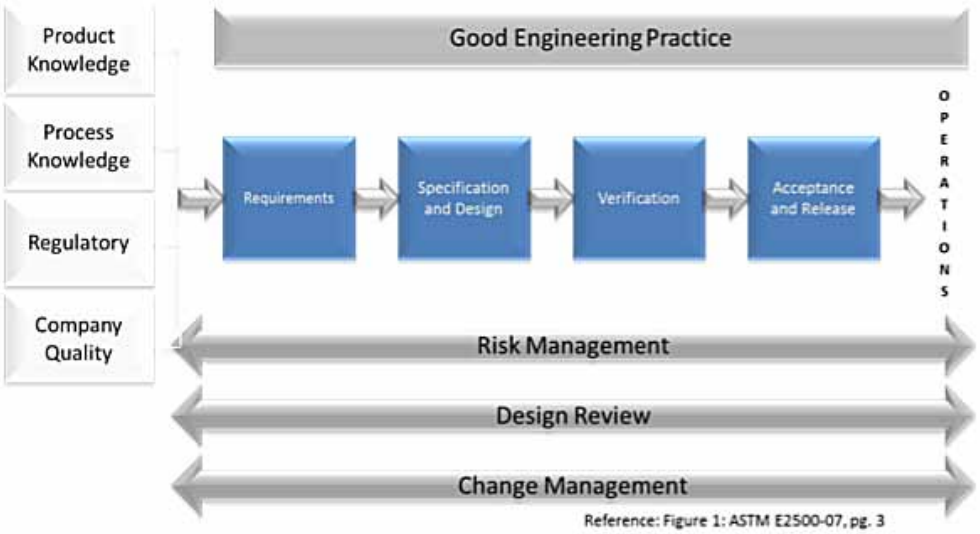

Figure 1: ASTM E2500-07 Lifecycle Phases

To implement an effective risk program, two distinct elements must be cohesively integrated and functioning: Risk Management and Risk Assessment. As defined in ICH Q9, Risk Management is a systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating and controlling Risk. This is the overall risk program which defines the processes to coordinate, facilitate and improve science-based decision making with respect to risk. Senior management is accountable to be informed and make acceptance decisions on the overall risk profile, and individuals are accountable to manage the risk processes and results to drive awareness, implementation of identified actions, and ongoing updates to the risk documentation. The Risk Management program also defines the criteria for accepting or rejecting risk evaluations, or triggering further design or process evaluation before such a determination can be made, as shown in Figure 2 (right).

Risk Assessment, as defined in in ICH Q9, is a systematic process of organizing information to support a Risk decision to be made within a Risk Management process. These are specific, point-in-time events consisting of the identification of harms, and the evaluation of risks associated with exposure with those harms. These events utilize subject matter experts with deep technical knowledge of the manufacturing system or product, and produce documents reflecting the current risk evaluation from a perspective of "what is the risk to the patient". To facilitate this process, there should be a clearly defined boundary for the system being evaluated, focus on harms, hazards and causes of patient risk, identified controls for the risks and any risk mitigation actions that might be required. However, it is important to clearly differentiate the discussion on "does it present a risk to the patient?" from "do we have controls in place to mitigate the impact?" To complete this process, it may be beneficial to first use a qualitative tool to evaluate hazards and then utilize a quantitative tool to rank the risk profile and establish the control strategy. Also, clearly defined risk categories should be used to define risk rankings consistently within risk assessments conducted at the site or within a company.

Numerous tools exist to facilitate risk assessments. As stated in the ICH Q9 EWG Briefing Pack, "*It is important to note that no one tool or set of tools is applicable to every*

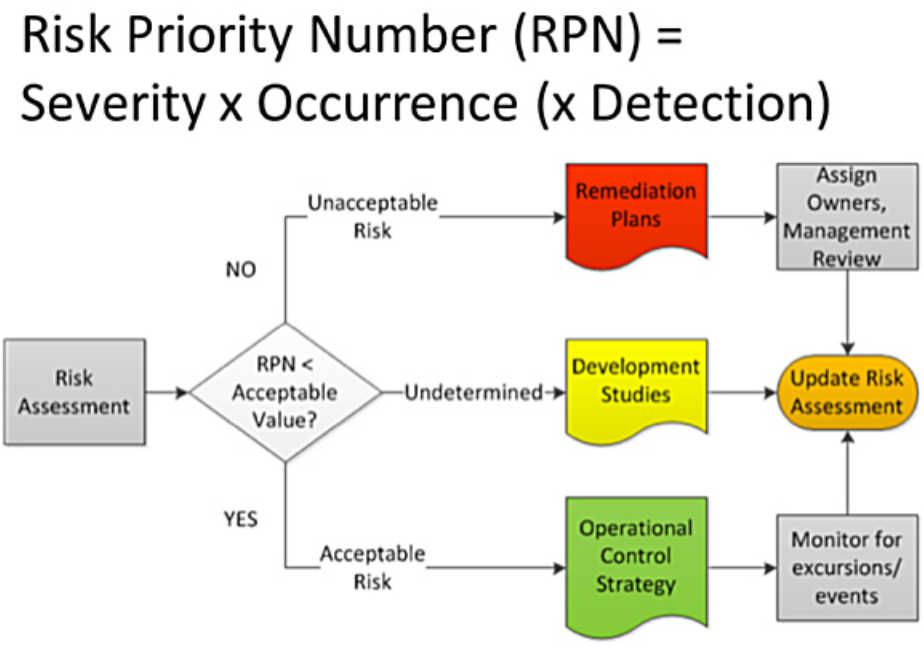

Figure 2: Risk Acceptability

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situation in which a quality risk management procedure is used." Tool selection is discussed very effectively in the article "Quality Risk Management (QRM) Tool Selection: Getting to Right First Time" by Kristen Murray and Stephen Reich from Pfizer, Inc. This was published in *Pharmaceutical Engineering*, the official magazine of ISPE, in July/August 2011, Vol. 31, No 4 and was recognized as the ISPE article of the year for 2011.

To summarize some key points, it is important to know the problem statement and intent of the risk assessment to pick a tool, and the tool selected can impact the usefulness, ease of execution, quality, and the validity of the risk assessment. Some tools are designed to be qualitative such as Fault Tree Analysis (FTA) or Fishbone Diagrams (Ishiwaka Diagrams) while others are quantitative like Failure Modes and Effects Analysis (FMEA) and Hazards Analysis and Critical Control Points (HACCP). Depending on the intent of the risk assessment, one or more of these tools may be needed to develop an appropriate risk profile.

Risk Management is a multi-faceted program that can serve to meet multiple purposes including developing deeper process understanding, identifying continuous improvement initiatives, facilitating effective validation efforts, and communicating risk profiles to senior management for awareness and acceptance. Having the organizational structure with defined responsibilities, experts familiar with risk tools, and document systems in place to manage this continually evolving program is critical to delivering an effective Quality Risk Management program at your site.

About the authors

Mike Porter is a Compliance Consultant for Commissioning Agents, Inc. (CAI), with over 24 years of diverse experience in regulated environments across product development and manufacturing operations in pharmaceutical, medical device, laboratory and medical diagnostic business areas, providing leadership in quality, operations, and project management. Since joining CAI, he has been involved in numerous projects related to risk management, risk assessment and process validation. Mike can be reached at michael.porter@cagents.com or 435-714-1974.

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Update Your Calendar!

DATE	DETAILS
February 12, 2013	Therapeutic Tuesday at California Dreaming, Charleston, SC
February 22, 2013	CaSA Leadership Symposium at McKimmon Center, NCSU Campus
February 23, 2013	5th Annual Casino Night, Capital City Club, Raleigh, NC
March 14, 2013	Sparians Bowling Event at Sparians, Raleigh, NC
March 26, 2013	20th Annual Biotechnology Show at the Raleigh Convention Center
April 6, 2013	BEST Fest (Biotechnology, Engineering, Science, and Technology) at the NC Museum of Natural Sciences, Raleigh, NC
May 6, 2013	Annual CaSA Golf Outing at Prestonwood Country Club, Cary, NC

Highlights From Therapeutic Thursday at Boylan Bridge Brew Pub

By Jon Doyle, Young Professionals Chair

On January 24, the ISPE Casa Networking and Young Professionals committees held "Therapeutic Thursday" at Boylan Bridge Brew Pub in downtown Raleigh. Over twenty Members, as well as a few non-members, attended. At least 12 different life sciences companies were represented.

Appetizers (hot sourdough pretzels!) were provided by CRB and PCI. Andrew, the owner of the Brew Pub, gave personal tours of not only the brewery operation but also the store room, refrigerated keg room, and the master carpentry operation that is also managed out of the same building.

It was a great evening which was enjoyed by all in a new Therapeutic Thursday location. Boylan offers one of best views in all of Raleigh and it has incredibly good craft beer.

If you are interested in other networking events please attend the March 14 event, which will be held at Sparian's, a premier bowling and entertainment center in North Raleigh!

City view from the brewery

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