



ISPE®

New Jersey Chapter

Celebrating 30 Years

VOLUME 24 ISSUE 1

2017 1st Quarter Newsletter

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Chapter**
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ISPE NJ—Your Membership, Your Chapter

The ISPE NJ Chapter strives to provide support for new professionals, challenge seasoned engineers, scientists, and managers, cultivate a spirit of continuous learning for all members, and maintain an open atmosphere.

Benefits

ISPE is a global organization which offers members a variety of resources. Visit www.ispe.org for a more detailed description of Membership Benefits.

Some of the items offered are listed below:

- Educational Training
- Guidance Documents
- Pharmaceutical Engineering Magazine
- Knowledge Briefs
- Regulatory Updates
- Communities of Practice

On a local level, we offer affordable programs that focus on learning industrial principles, building your technical knowledge base, professional development, and networking. Communities of Practice provide an avenue for you to connect with subject matter experts in fields that interest you, contribute to the creation/revision of guidelines, and work with a team of highly knowledgeable people.

We are very happy to welcome new members. Your energy and enthusiasm are noticed and we encourage you to participate. We look to our loyal, seasoned members to provide mentorship to our new members. Your presence and active participation makes our chapter a strong organization. We know that you will extend a helping hand to newer members by introducing yourself to them and promoting a welcoming atmosphere.

It is a good idea to maintain relationships and networking connections. However, there is always room for growth within a strong network. We are challenging you to meet one (1) new person at each program.

Please share your experiences, lessons learned, and goals. Our moments of sharing can quickly turn into a favorable circumstance. Someone that you haven't met yet may be looking for someone with your expertise. They may also be able to provide a service that will give you a strategic advantage.

Thank you for joining ISPE NJ Chapter.



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President's Message

By Harry Segner

A belated Happy New Year to all the members and friends of the New Jersey Chapter of ISPE!!! We are off to a great start to the 2016/2017 chapter year with very successful chapter events in October, November and December of 2016. As we reported in our last newsletter, the 30th Anniversary Celebration held at Beneduce Vineyards was a terrific success and a very enjoyable opportunity to socialize and celebrate 30 years of service to the life sciences community with many friends and associates. The event was even recognized by Mike Arnold, International Chairman of ISPE, in the November/December 2016 issue of *Pharmaceutical Engineering* magazine, along with his congratulatory comments and a photo of the event!!

On November 3rd, the Student/Young Professionals Committee held their first ever Think & Drink event in Florham Park. These events are intended to provide our Student/YP community an opportunity to network with each other, as well as meet and network with more seasoned pharmaceutical industry professionals in a casual, fun atmosphere. About a dozen students and YP's (and yours truly!!) enjoyed the inaugural event and all provided very positive feedback. We thank Christine Farnier and Mike Kelliher for organizing and leading this committee and for developing this event.....we understand that they have another similar event in planning for early 2017. Stay tuned for that announcement and please come out and participate in this most enjoyable and valuable opportunity to help mentor and grow the future of ISPE and our chapter!!!

A full house audience was in attendance on November 16th at Pfizer Peapack to hear presenters from BMS and HDR speak to the issues surrounding Site Master Planning, a topic both timely and critical to the continuing success of many of our operating company members now and into the near term future. And we closed out the year with our annual holiday party at the Nassau Inn in Princeton, where much fun and camaraderie was enjoyed by all. Further coverage of these events will be found throughout the balance of this newsletter.

One of the issues the NJ Chapter Board, as well as the International board of IPSE, intends to focus on this year is increased engagement of our current and future membership. In the first few months of this chapter year, we have seen an impressive level of volunteerism amongst both the regular membership (particularly relatively new members or those relocated to the NJ Chapter) and the Student/YP membership. We encourage anyone with an interest in serving the NJ Chapter to please contact Donna Petro, who has taken the lead with membership and volunteers, and she will coordinate your engagement in an area of interest to you.

I certainly welcome any feedback you may have about the NJ Chapter of ISPE.....this is your organization and we all wish for great success moving ahead into 2017. I look forward to seeing you at an upcoming Chapter event!!!



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Events Schedule

February 9, 2017	ISPE Pfizer Facility of the Year Sanofi 55 Corporate Dr. Bridgewater, NJ 08807
March 15, 2017	Professional Development Day Rutgers Piscataway
April 19, 2017	Student Poster Competition and Industry Presentation Johnson & Johnson New Brunswick, NJ
May 15, 2017	Golf Outing & Winery Tours Neshanic Valley, NJ
June 2017	Joint Event w/Delaware Valley Chapter TBA

Register for Facility of the Year event

<https://www.eventbrite.com/e/ispe-nj-foya-event-tickets-30091165486>

Risk Management through cGXP Compliance Audits

By Nick Andrews, Director of Operations, Life Sciences
CP Professional Services

In FDA regulated industries risk management is present throughout every facet of a successful organizations operations extending from the operational SOPs utilized by operators to the high level Quality Risk Management (QRM) policies and SOPs ultimately arising from the core principles of ICH Q9: Quality Risk Management:

- *The evaluation of the risk to quality should be based on scientific knowledge and ultimately linked to the protection of the patient*
- *The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk*

No matter how robust an organizations policies and procedures may be the performance of audits is the key to ensuring that the policies and procedure are be utilized in an appropriate manner and avoiding the costs associated with noncompliant, and inefficient practices.

Effective compliance audits are a critical tool to ensure that organizational leadership, operational procedures and policies, and business objectives are fully aligned. The alignment of these three elements in FDA regulated industries is critical to minimizing operational risk by ensuring that each individual element is aligned with the requirements and expectations necessary to function successfully in FDA regulated markets.

Organizational leadership will have a high level expectation for how an organization will operate which is often described in the business mission statement of similar documents. Simultaneously the members of the organization executing the actual functions of the business at all levels, from managers to equipment operators collectively give rise to the policies and procedures by authoring SOPs, creating work procedures etc. Collectively the first two elements generally determine how successful an organization is at meeting business objectives, which are commonly focused on meeting customer needs in a regulated FDA market while generating value for shareholders and owners.



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Risk Management through cGXP Compliance Audits

The primary source of risk for most organizations is lack of feedback within the organization such that each aspect of the business believes it is meeting expectations even though critical risk gaps may exist. Management may believe that the mission and expectations of the business are clear and well communicated. The members of the organization executing the primary activities may believe they are meeting management and regulatory expectations. All while both groups believe they are meeting the business objectives in a manner fully compliant with regulatory and industry expectations. A well executed audit performed in an open manner with a clear objective, scope and criteria provides objective feedback to each level of an organization. This feedback is critical for the identification of risk identification and risk management.

While the exact methodology utilized in executing an audit may vary the core principles are the same across the major types of compliance audits. The core principle of each of the three main types of compliance audits, internal, external, and supplier/vendor audits, is to ask 3 primary question:

- *Are we doing what we say we are doing?*
 - A. *Is an organization doing what it claims to be doing, are policies, procedures, and SOPs being followed as they currently exist?*
- *Are we doing what we need to be doing?*
 - A. *Do existing policies, procedures and SOPs align with the relevant regulatory expectations and with industry best practices?*
- *What can we do better?*
 - A. *What can be done differently to be more compliant and more effective?*

These three questions may be applied to any compliance audit across any portion of an organization and utilized to identify risks. “Are we doing what we say we are doing?” is often one of the most critical questions and one of the most effective at identifying risks. Regulatory expectations are generally well understood throughout the majority of organizations however, ensuring that the actual practices fully align with the existing policies and procedures is where a majority of risks arise. The root cause of many common FDA observations ranging from data mishandling, to potential cross contamination in a multi API facility, to labeling errors potentially resulting in recalls, all commonly have human error in common. Either human error in execution of policies and procedures or human error in the creation of policies and procedures.

Risk Management through cGXP Compliance Audits

The regulatory landscape in FDA regulated industries is complex and any organization, despite rigorous efforts, may fall victim to the second question, “Are we doing what we need to be doing?”. Because of the dynamic nature of FDA regulated industries even minor changes to regulations in industry or to an organization processes can generate a risk due to how even small changes can cause unexpected impacts in complex systems such as those seen in pharmaceuticals and healthcare. While systems such as change control and document management are intended to address such risks as part of their core functions, compliance audits offer the opportunity to identify potentially unexpected risks prior to these risks having organizational impact.

An example of the sort of situation the second question may identify is a change in regulatory approaches such as in cleaning validation. Over the last several years the industry and regulatory expectation has been that companies begin to utilize Acceptable Daily Exposure / Permissible Daily Exposure (ADE/PDE) as part of the tool set for determining acceptable residual levels. An organization that is not fully aware of the more recent expectations may believe that their existing cleaning policies are robust when even though the policies may have been robust initially, due to changes in regulatory expectations a gap and hence a risk has developed.

The third question “What can we do better?” is critical for the growth and success of any organization. The policies and processes within any organization may always be improved upon. The improvement of existing policies and processes inherently reduces risk by making processes and policies more effective and more robust.

Compliance audits at any and all levels of an organization should be seen as a collaborative tool which allows an organization to utilize constructive feedback to ensure that the organization is operating effectively and meeting the common goal of providing a quality product and creating value.

About the Author:

Mr. Nick Andrews is currently the Director of Operations, Life Sciences for CP Professional services based in Sparta NJ. Mr. Andrews serves as CP's Director of Operations, Life Sciences. Nick has over 13 years of experience leading cross-functional teams to plan, facilitate, and execute all phases of validation including cleaning, process, equipment & facilities. In addition, Nick has experience leading cross-functional teams to plan, facilitate, and execute all phases of process engineering for pharmaceutical and biologic solid dosage, liquids, sterile and medical devices. Nick is a results driven individual with extensive experience working with companies ranging from big pharmaceutical to virtual companies and managing multiple clients in an aggressive contract manufacturing environment.

Member Spotlight—Jim Brinkman, Pfizer

**When did you first join ISPE?**

I've been a member of ISPE for about 13 years.

Why did you join?

I joined the society to become better connected with industry peers and to stay current with the business.

Do you regularly attend meeting and events?

Yes, I look forward to attending Chapter meetings and events. I especially like the balance that the Programs Committee has established between technical education and social events. By attending technical education events, my knowledge base continues to grow in addition to providing the networking opportunities. The social events provide that bit of "fun" that is a necessary ingredient in any organization.

What do you get out of them?

In addition to growing my technical knowledge base, I enjoy the networking opportunities that are part of every meeting and event. These professional relationships among peer operating company and supplier colleagues open the door to a vast array of opportunities including: information sharing, problem solving, resourcing, etc.

Do you attend the Annual Meeting?

Yes, I have been a regular attendee of the Annual Meeting since 2010.

Why do you attend?

I attend for a variety of reasons... As the chairman of the ISPE Guidance Documents Committee, I lead a face to face meeting of this important group as part of the Annual Meeting. As an executive board member within the NJ Chapter, I also try to attend the Affiliate Council meeting to get the pulse on happenings across the other Chapters and affiliates globally. I enjoy meeting with suppliers in the exhibition hall and finally, I get value of attending the educational sessions for both my professional growth and for meeting my continuing professional competency requirements for my NJ Professional Engineering License.

Do you serve as a volunteer or board member?

Yes, I have been on the Board for several years. This year I hold the office of Vice President of the Chapter.

What benefits accrue to you or your company from this service?

I am fortunate to have been elected VP of the NJ Chapter and consider it an honor to serve the Chapter. I had been a member for eight or nine years before being encouraged to seek a leadership position. Since that time, I find myself better connected to the chapter and its members. I enjoy working with the other Board members. We really have a great team and have a bit of fun while carrying out our leadership responsibilities. From a company perspective, Pfizer is very supportive of ISPE and my continued service both at the Chapter and International level.

What are the key benefits of being a member of NJ ISPE Chapter for you?

From my perspective, the benefits of being a member of the NJ Chapter are very straightforward:

- Professional growth through technical education
- Networking with industry peers
- Fun social events
- Support of our future industry leaders through the Chapter focus on student chapter and young professional development
- Great people to associate with

Member Spotlight—Rohan Bhaumik, Merck

What is your full name?

My full name is Rohan Kush Bhaumik.

Where did you grow up?

I grew up in Warren, NJ.

Tell us something unique or interesting about yourself.

In a parallel universe, there's a version of me that owns a restaurant and plays semi-pro soccer in a tiny French village. In other words, I enjoy cooking, love soccer and hope to be fluent in French one day.



Where did you attend college?

I attended the University of Illinois at Urbana-Champaign, from which I graduated in May 2016.

What degree(s) did you earn?

I have earned a Bachelor's of Science in Bioengineering.

What is your current position?

Currently, I am an Associate Scientist, Engineering in the Biologics Process Development and Commercialization group of Merck & Co. in Kenilworth, NJ.

What do you like most about your job?

Working in a commercialization group at Merck, I enjoy supporting projects that have been approved and had success in clinical trials. It helps me understand how strategic decisions flow down to the experimental level.

Why did you join ISPE?

I joined ISPE because I saw the value of networking and education about industry that the organization had. Undergrad didn't teach me much about pharma, so I grabbed the opportunity to learn more.

Which ISPE activities have you participated in? Please describe the activities and your opinion of the experience.

I attended the 2016 annual conference in Atlanta and loved it. It was the first time I had seen many motivated people sharing ideas on their successes and interests in industry. I learned about a variety of topics spanning from industry innovation and data integrity to career development and networking.

What advice do you have for students who are considering a career in your field?

First of all, know that your skills (technical or otherwise) are needed in the industry. There's certainly room for bright and creative minds that bring a fresh perspective to the biotech/pharma fields. Take the opportunity to speak to and work with people who have long careers in industry as their expertise can teach you more than any textbook in college can. Plenty of people in our organization are willing to tell their stories and give valuable advice on how you can make the right decisions in your career.

NJ Chapter Students Young Professionals

By Ross Udod

Attendees met at the Wyndham Hamilton Park Hotel for food, drinks, and a few games of pool while they got to know other YPs in the industry.

The event attracted YPs of all backgrounds - students, Masters and Ph.D graduates, and YPs working in manufacturing, engineering and research in the Pharmaceutical industry.

At the beginning of the event, a lively crowd of students met with the ISPE YP Committee Co-Chairs (Christine, and Mike) and the Chapter President (Harry); who helped introduce us to one another.

As the event progressed, we became more comfortable with one another and started talking about our interests, careers and plans for how we could be more involved in ISPE.

This was the first exclusively YP event in years and we hope to hold up to four events per year exclusively for YPs!

**Wyndham Hamilton
Park Hotel
Florham Park, NJ**





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Holiday Party 2016 at Nassau Inn, Princeton

By: Debra Bahr



On Wednesday, December 14th, the ISPE New Jersey Chapter joined to celebrate at its 2016 Holiday Party at the Nassau Inn in Princeton, NJ. Nestled in the heart of Palmer Square in Princeton Borough, directly across from Princeton University, the Nassau Inn was built in 1756. This year we held a holiday gift exchange for all attendees at the end of the evening, generously sponsored by industry companies. The event was well attended by owner and vendor companies as well as students and young professionals. Our President, Harry Segner, welcomed guests and members alike, and the holiday festivities commenced with food, drink and networking for all!





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ISPE NJ Fall Educational Program: Site Master Planning

By: Monique Sprueill

The Site Master Planning educational program took place in November 2016. Pfizer hosted the program at the beautiful Peapack facility. The program was preceded by a networking session with food and beverages, providing an opportunity for members and friends of the chapter to catch up, discuss hot topics, and meet new people.



The speakers are highly skilled in the subject matter and provided different perspectives. Felix Martinez and Brian Larson presented an outline including strategy and business alignment planning, gap analysis, evaluation of options. They also walked the attendees through a process simulation which gave the audience a tangible example of how to use modeling tools. Allison Arnone demonstrated how to develop the plan, align on strategy and use analytical tools to execute a site master plan.

The speakers were very knowledgeable and the audience was engaged. This topic is an important one for the Life Sciences industry and was well received by the attendees.



Benefits of Membership

Networking Opportunities - Whether networking at face-to-face events or collaborating online, the value of ISPE is in the links forged between industry professionals with common work challenges, connecting professionals and companies to practical guidance and dialogue between industry and global regulators.

- Membership Directory
- Affiliates and Chapters
- CoP Online Discussion Forums
- Networking Events

Technical Resources - ISPE Guidance Documents, industry-leading publications and on-demand training courses and webinars provide practical information and solutions to real-world problems.

- ISPE Guidance Documents
- Review and Comment on Regulatory Guidance
- Pharmaceutical Engineering Magazine

Professional Development - Industry-leading education and training, global volunteer opportunities and industry-focused career solutions allow ISPE Members to grow their professional knowledge and skills.

- Education and Training
- ISPE Career Solutions
- Volunteer Opportunities

Who We Serve -

Traditional Pharmaceuticals/Biotechnology/Generics/CMOs/Global Regulators/Suppliers and Service Providers/



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Welcome New Members

Zach	Anhorn	Rite-Hite
Amy	Babeu	Regeneron Pharmaceuticals
Dennis	Belanger	Emerson Reliability Consulting
Yijun	Chen	Stevens Institute of Technology
Steven	Cohen	Steven S. Cohen, Architect P.C.
Gary	D'Alonzo	Bristol Myers Squibb
Jaclyn	Docs	Acuitive Technologies
Jamie	Gajeski	The Venetian Group
Steven	Gayanilo	West-Ward Pharmaceuticals
George	Khoury	Kedrion Melville Inc.
Darlene	Kuykendall	M+W Group
Rayon	Levy	
Maritza	Morales	New Jersey Institute of Technology
Anthony	Mui	Merck & Co Inc
Manuel	Patino	Climet Instruments
Sameer	Pradhan	Pentec Health
Margaret	Prendergast	BioBots, Inc.
Thomas	Self	
Donald	Shoemaker	Synovos
Fernando	Velez	Aplicare
Wendy	Zhao	NYU-Lutheran Medical Center

2017 ISPE NJC CHAPTER SPONSORSHIP AND ADVERTISING PROGRAM*

Advertising and sponsorship represent an excellent opportunity to be identified as an industry participant and a supporter of the ISPE New Jersey Chapter's Professional Programming. It is a cost effective means of increasing your firm's visibility to the Chapter membership and beyond. ISPE NJC has many exciting sponsorship and advertising opportunities in 2017. These include:

Chapter Sponsorship: \$1,650

Chapter Sponsorship has many benefits, including:

- Recognition as a Chapter Sponsor at all ISPE NJC events in 2017
- Name and Logo on announcements for all ISPE NJC events in 2017
- 1/2 page Advertising space in the ISPE NJC newsletter for 2017 (A \$800 value!)
- 12 month Advertising space on the ISPE NJC website in 2017 (A \$500 value!)

Advertising

Advertising opportunities are available for the Newsletter and Website "a la carte":

Newsletter Advertising (2017-2018) – The Chapter publishes a newsletter 4 times a year, highlighting recent and upcoming events, educational programs, technical articles and general interest to the members. The newsletter is published electronically to all current ISPE NJC members and others on our circulation list. (5000+ recipients). Advertise for 1 issue or 4 consecutive issues:

- | | | |
|----------------------|---------------------------------------|-------------------|
| Business Card size - | \$100 per issue or \$350 for 4 issues | (a \$400 value!) |
| 1/4 page- | \$150 per issue or \$525 for 4 issues | (a \$600 value!) |
| 1/2 page - | \$200 per issue or \$700 for 4 issues | (an \$800 value!) |

Website Advertising – Your ad is visible to everyone who visits the ISPE NJC website.

Event/Program Sponsorship-

Event Sponsorship has many benefits, including:

- Name and Logo on all Announcements for designated event
- Recognition at Event during session
- Complimentary Tickets for Two Attendees¹
- Select Event(s)- Vendor Table/Display (Professional Development Day and Golf

To become a sponsor please visit - <https://www.eventbrite.com/e/2016-ispe-njc-chapter-sponsorship-advertising-program-tickets-19824345150> or contact manager@ispenj.org

¹Golf outing complimentary tickets are limited to Clubhouse Outing activities only. Excludes Holiday Party

*CHANGES TO PROGRAM COMING SOON FOR 2017