



ISPE NJ Newsletter

Coming Events

May 15, 2017

ISPE NJ Annual Golf Outing
and Winery Tours

Neshanic Valley Golf Course

Neshanic Station, NJ

June 8, 2017

Joint Meeting NJ/DelVal

*Expedited Shutdown Case
Study—BMS*

HDR

1000 Lenox Drive

Lawrenceville, NJ

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Volume I, Issue I

May 8, 2017

President's Message

In what is becoming an annual tradition for the NJ Chapter, our 2017 Facility of the Year event was held on February 23rd at the Sanofi Bridgewater site. Again this year, we participated in a joint meeting with the Construction Round Table of NJ and our respective members had the opportunity to network and collaborate prior to a most interesting presentation by representatives of Pfizer, GEA and G-CON Manufacturing. That team presented the 2016 FOYA Category Winner for Equipment Innovation.....the PCCM Development and Manufacturing for Solid Oral Dosage platform at Pfizer's Groton site. Thanks to all the participants for sharing this exciting new technology with our groups!

The first and only significant snowfall in the NJ Chapter region in mid-March forced us to postpone our Professional Development Day event from the normal date and site at Rutgers University Busch campus (which is only available during the one week window of spring break) to be conducted on the same date as the Student Poster Contest and Continuous Manufacturing event. BMS New Brunswick generously agreed to host both events at their site on April 19th and both were very well attended and successful. Congratulations to our 2017 undergraduate and graduate school level Student Poster Contest winners, both of whom will be joining us at the 2017 ISPE Annual Meeting in San Diego, with hopes of winning the overall ISPE Student Poster contest!!!

Please consider joining us for one or both of the remaining 2016/2017 NJ Chapter events, the Golf Outing and our annual Joint Event in collaboration with the Delaware Valley (DelVal) Chapter. The Golf Outing will be held on May 15th again at Neshanic Valley Golf Club and an optional vineyard tour is available for those who wish to participate on that day, but who may not be golfers. This year's Joint Meeting with the DelVal Chapter will include a presentation entitled "Expedited Shutdown Case Study - BMS" and will be held at the HDR offices on Lenox Drive in Lawrenceville on the evening of Thursday, June 8th. Speaking of the DelVal Chapter, I am sure many of you are aware that the DelVal Chapter will again be hosting the ISPE Annual Meeting in Philadelphia in the fall of 2018. A few weeks ago, I was approached by several members of the DelVal leadership team about assisting with the planning of this event and have accepted their invitation to help out. I am sure that they would welcome additional support and assistance from NJ Chapter members, and I would be pleased to facilitate introductions for any NJ Chapter members interested in volunteering to help. Please contact me if you have this interest and I will make the connection to the DelVal team.

I look forward to seeing you very soon at an upcoming event and, as always, certainly welcome your questions or comments at any time.

Harry Segner

President, ISPE NJ Chapter



Records and Data Integrity & Continuous Manufacturing



ISPE/CRT Joint Meeting—FOYA Event

By Christine Farner, ISPE NJ Board Member

The ISPE NJ FOYA program took place in February. The Sanofi, Bridgewater campus hosted 95 attendees. The night was filled with networking, learning, and great food.

Pfizer's Valentin Tarasenko, Fred Furman, and Jeffrey Moriarty provided an overview of their featured project which was the recipient of the Facility of the Year award for equip-

ment innovation. Their presentation included a video that demonstrated the concerted effort, talent, and expertise that resulted in this amazing achievement.

The speakers are sharing a copy of the presentation on the ISPE website at <http://www.ispe.org/new-jersey/past-events-presentations>.

Professional Development Day 2017 and Continuous Mfg

By Jim Brinkman, ISPE NJ Vice President

A “two-fer” event at BMS New Brunswick

Members converged at BMS New Brunswick for the Chapter's annual Professional Development Day (PDD) and Student Poster Contest (SPC) event on April 19th. These were originally planned as two separate events spaced about a month apart. However, due to an ominous forecast for a late season snow, the event was shifted to April. All told, there were approximately 75 attendees including 9 students in attendance. The PDD topic was Records and Data Integrity (RDI), which has become an increasingly sensitive compliance topic of late. All PDD attendees received continuing education credits for attending the event.

We were fortunate to have Mike Rutherford (Lilly), Lorrie Schuessler (GSK), Chris Jacobson (EY), and our own Jamey Canterbury (EY) as the event speakers. Mike led the ISPE

RDI document development team and recently returned from Barcelona, Spain where the publication was launched and first presented earlier that month. The NJ Chapter members were the first to receive this technical presentation in the U.S. Subsequent presentations are planned at other US venues over the course of 2017. Chris Jacobson and Jamey Canterbury provided very interesting parallels from Pharma Data Integrity to compliance with the Sarbanes-Oxley Act of 2002 brought a similar focus on financial data integrity 15 years earlier.

While the PDD event took place, the student poster contest judging was occurring in adjoining rooms. At the conclusion of both activities, meeting attendees enjoyed refreshments and then received two continuous manufacturing presentations from Catherine MacConnell of Merck, and Doug Hauser of Rutgers. Our 2017 student poster contest winners are: M. De Abreu Pinada (undergraduate) and Kunnath

Kuriakose (graduate). Both will be attending the International ISPE Student Poster Contest to be held during the 2017 Annual Meeting during September in San Diego.

As always, we thank our event sponsors Informetric Systems, Azzur, Genesis, Eastern Controls, and HSO, and BMS for hosting this very successful event.



Student Poster Competition 2017

By Christine Farner, ISPE NJ Board Member

The ISPE NJ Annual Student Poster Competition was held at Bristol-Myers Squibb's beautiful New Brunswick facility.

The event was a raging success with 11 posters submitted from three colleges/universities: New Jersey Institute of Technology, Stevens Institute of Technology and Kingsborough Community College - in both categories -

Undergraduate and Graduate. Nine industry judges split their skills between judging the graduate and undergraduate posters. They had a tough time getting to the actual winners with all the engineering talent available! Somehow they managed to carve out the numbers to allow for the winners. The winners receive a trip to the ISPE Annual Meeting in San Diego this year from ISPE NJ Chapter - where they will be exposed to industry experts and all the education that our industry has to offer.

They will also be able to present their winning posters for further recognition. The NJ ISPE 2017 Student Poster Competition Winners are:

Graduate Category: Kuriakose Kunnath of NJIT

Undergraduate Category: Maria DeAbreu Pineda of Stevens

Congratulations to the winners - please be sure to look them up in San Diego!

The NJ ISPE 2017 Student Poster Competition Winners are:

Graduate Category: Kuriakose Kunnath of NJIT for his poster enabling direct compression at High Drug Loading.

Undergraduate Category: Maria DeAbreu Pineda of Stevens for her poster regarding Brian Pulsatility.



Drug Dissolution Testing—An Engineering Perspective

By Piero Armenante

Dissolution testing of solid dosage forms is routinely conducted in industry to provide critical in vitro drug release information for both quality control purposes, i.e., to assess batch-to-batch consistency of solid oral dosage forms, and for drug development, i.e., to predict in vivo drug release profiles. Several dissolution apparatuses are listed in the USP, but the most commonly used is the USP Dissolution Testing Apparatus 2, simply referred to here as “Apparatus 2”, shown in Figure 1. The Apparatus 2 vessel itself is an unbaffled, cylindrical, hemispherical-bottomed, glass vessel with a nominal volume of 1 L. Unlike most cylindrical vessels used in industry, this vessel does not contain “baffles”, i.e., the rectangular vertical plates, typically four, commonly placed next to the cylindrical wall of vessels to dissipate energy, reduce the tangential component of the fluid velocity in the vessel, promote vertical fluid recirculation, and achieve a more uniform distribution of fluid velocities in the vessel. The agitation system is a simple two-blade paddle. A typical dissolution test consist of adding the dosage form, e.g., a tablet, to one of the dissolution vessels, turning on agitation, and sampling the liquid at intervals to determine the percentage of drug dissolved over time. One can think of Apparatus 2 as just a simple piece of analytical equipment, but since failed dissolution tests can often be the cause for expensive drug recalls it is worth examining the test, and the device, in a more systematic way and using an engineering approach. This is precisely what has been in done in recent years at NJIT and elsewhere. In order to analyze Apparatus 2, we have used experimental tools such Laser-Doppler Velocimetry (LDV) and Particle Image Velocimetry (PIV) as well as computational tools such as Computational Fluid Dynamics (CFD) to map the fluid velocity in the dissolution vessel and determine how the system’s hydrodynamics can affect the dissolution process (1,2). Just to show that CFD is now reliable enough to predict the correct velocities inside Apparatus 2, Figure 2 shows the tangential velocity on a horizontal plane just below the paddle at different agitation speeds. The good match between experiments and prediction shows that we can rely on CFD to examine more in general what happens inside this system. For example, Figure 3 shows the velocity intensity (velocity magnitude) in Apparatus 2 at different impeller agitation speeds. It is easy to observe that in general, when the speed is increased, the velocity magnitude increases accordingly, as one would intuitively imagine. However, in the inner core region below the shaft near the vessel bottom, the velocity is still very low (blue color), even when the agitation speed is increased from 50 rpm to 75rpm or even 100 rpm. This core region is where the lowest velocity magnitudes in the entire vessel can be found, independently of the agitation speed, but is also the region where the dissolving tablet can be found during a test. The velocities in this region change rapidly depending on the exact location at the vessel bottom, as shown in Figure 4, where the arrows are the velocity vectors and the paddle lower edge is visible at the top. Clearly, a tablet located just a bit off the vessel bottom center would experience a very different flow around it that another one located at the very center. Similarly, a smaller tablet would be more likely to find itself fully immersed the low-intensity core region than a larger one. Therefore, a careful engineering analysis of an apparently simple device such Apparatus 2 can help understand how the system operates and shed some light on the high variability of dissolution test results.

References

- Bai, G., Armenante, P. M., Plank, R. V., Gentzler, M., Ford, K., and Harmon, P., Hydrodynamic Investigation of USP Dissolution Test Apparatus II, *J. Pharm. Sci.*, 2007, **96**(9): 2327-2349.
- Bai, G., Wang, Y. and Armenante, P. M., Velocity Profiles and Shear Strain Rate Variability in the USP Dissolution Testing Apparatus 2 at Different Impeller Agitation Speeds, *Int. J. Pharmaceutics*, 2011, **403**: 1-14.

Drug Dissolution Testing (cont.)

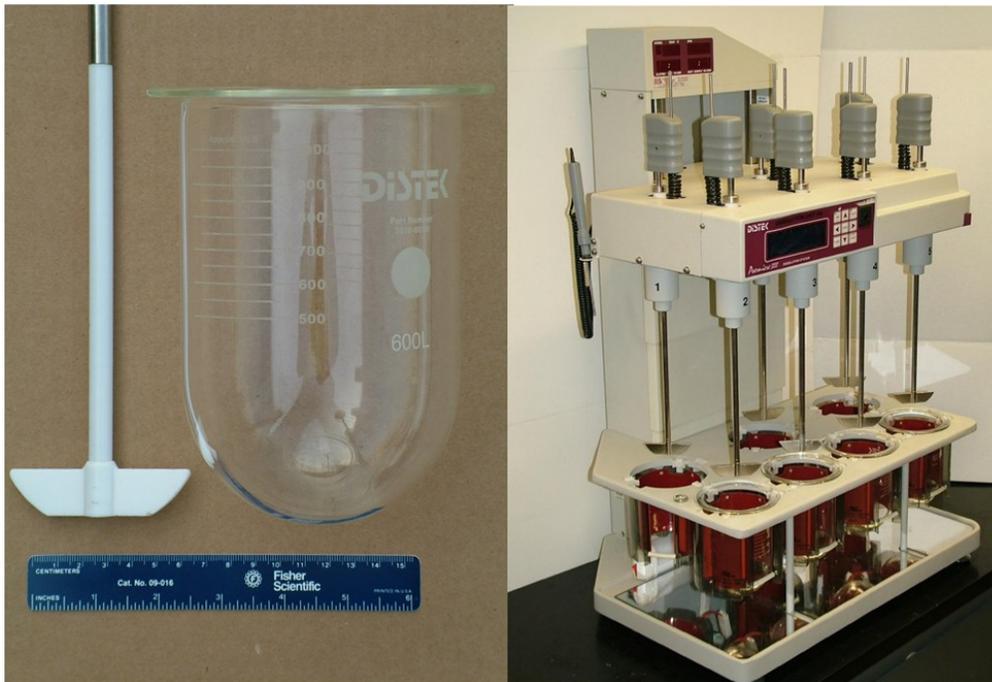
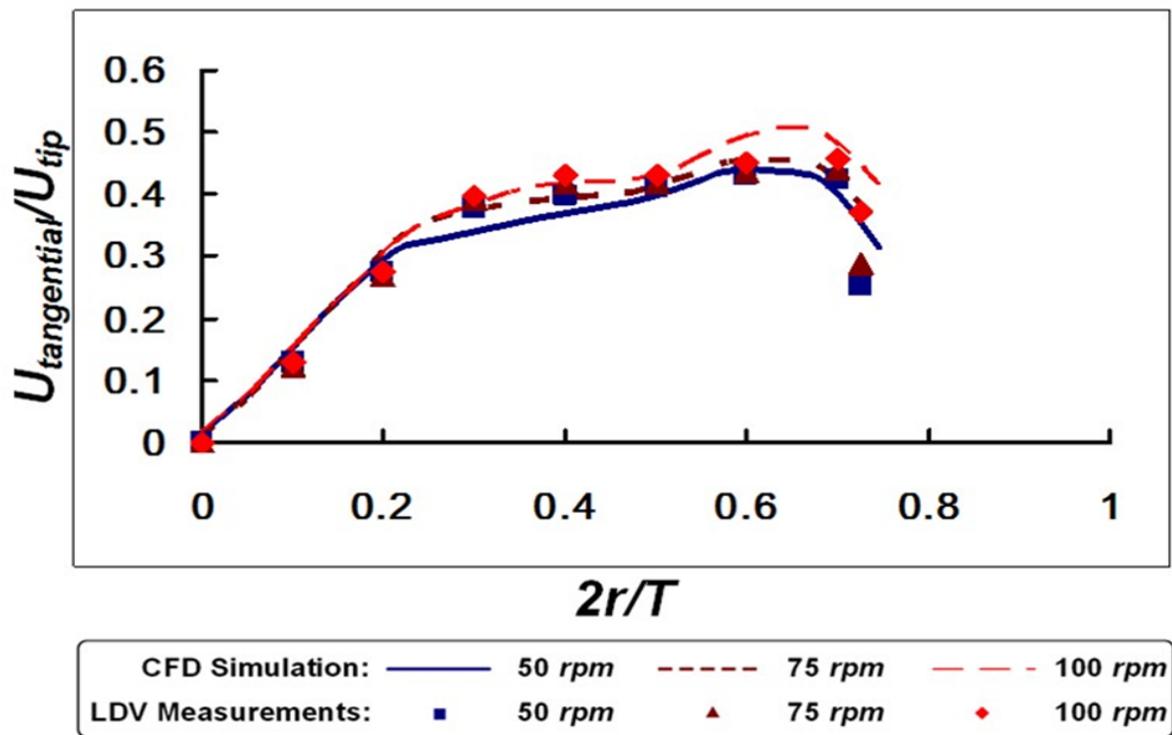


Figure 1. USP Dissolution Testing Apparatus 2: paddle impeller and glass vessel and typical commercial dissolution testing system (Distek Premiere 5100 Bathless Dissolution System) [1].
 Figure 2. Comparison between experimental LDV data and CFD predictions for the tangential fluid velocity $U_{tangential}$ (with respect to impeller tip speed U_{tip}) vs. radial position r (with respect to vessel radius $T/2$) on a horizontal plane just below the paddle Apparatus 2 at different agitation speeds [2].



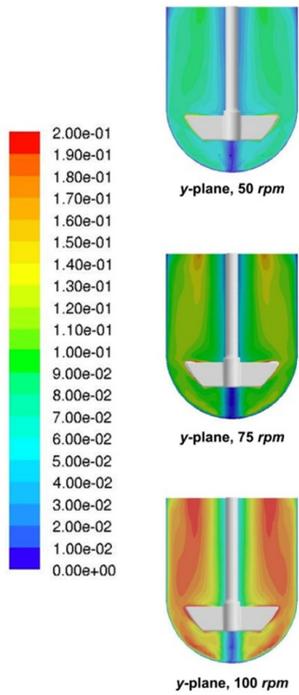


Figure 3. CFD predictions of velocity magnitude on a vertical cross section through the impeller shaft (y-plane) Apparatus 2 at different agitation speeds [2].

Drug Dissolution Testing (cont.)

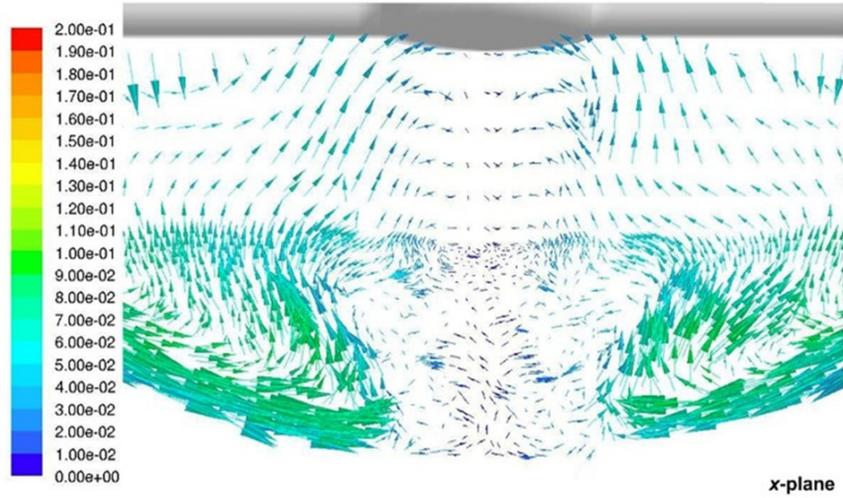


Figure 4. Expanded view of bottom region of Apparatus 2 showing CFD the impeller shaft [1]. Predictions of velocity vectors (in m/s) colored by velocity magnitude on vertical cross section through

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Academic Member Spotlight —Piero M. Armenante

What is your full name?

Piero M. Armenante

Where did you grow up?

I grew up mainly in Rome, Italy, before moving to the US for my Ph.D. (a long time ago)

Tell us something unique or interesting about yourself.

Having lived in Italy and in different European countries as well as in the US (for more the 35 years now), having an Austrian wife and children living in the US and in Europe, speaking different languages, advising students literally from all over the world, I find myself at ease in an international setting, and I like it. Besides, I love baroque music.

Where did you attend college?

I received my BS/MS degree from the University of Rome, "La Sapienza", Italy, and my Ph.D. from the University of Virginia, both in Chemical Engineering.

What degree(s) did you earn?

See above.

What is your current position?

I am currently Distinguished Professor of Chemical Engineering in the Otto H. York Department of Chemical, Biological and Pharmaceutical Engineering at New Jersey Institute of Technology (NJIT), as well as Director of Pharmaceutical Engineering Program at NJIT. I am also the academic advisor for the ISPE Student Chapter at NJIT.

What do you like most about your job?

I like mainly the academic freedom to study, teach, and research in any engineering areas of interest to me but also of industrial relevance, and to do so with students, who are eager to learn and progress in their academic career and transition to industry/academia.

Why did you join ISPE?

I interacted with the pharmaceutical industry for most of my professional life, as an employee at a pharma company, as a consultant, as a researcher involved in pharmaceutical engineering projects, as instructor of pharmaceutical engineering courses, and as developer of the Pharmaceutical Engineering program at NJIT. Therefore, it made a lot of sense for me to join ISPE, i.e., a professional organization that serves the pharmaceutical industry in general and the engineering profession within the pharmaceutical industry in particular. In addition, I always try to expose NJIT students to different aspects of the pharmaceutical industry and ISPE offers a great opportunity for our students to interact with industry professionals at all levels.

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

I have been involved in all activities related to the organization and the operation of the ISPE Student Chapter at NJIT, and therefore I have interacted at all levels with ISPE officials and members. I have attended countless events, professional meetings, annual conferences, and so on. In addition, I serve on the ISPE Students Affairs Committee of the NJ ISPE Chapter, and I served in the past in the ISPE Professional Certification Commission.

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

Given that the need for medicines can only grow in the future, there will always be a need for a solid pharmaceutical industry capable of developing, testing, and manufacturing new and old drugs. Therefore, this is a good industry to be associated with in my opinion. In addition, I personally like the idea of contributing to an industrial sector such as the pharmaceutical sectors, which contributes to humanity's welfare on a global scale. Engineering is one of the most rigorous and, at the same time, hands-on discipline that one can pursue. Therefore, if a student has the interest and the ability to pursue it, a career combining "pharmaceutical" and "engineering" can be professionally attractive, highly stimulating, international in scope, and also financially rewarding. Therefore, I can sincerely recommend a career in this field, also having seen many of my former students entering and successfully progressing within the industry. I always advise students pursuing this career to become highly technically/scientifically competent first (i.e., they really need to study to acquire the technical/scientific proficiency that they will use for life), but also to be curious, ready to learn new skills, and quick to embrace new approaches if they see the advantage. Finally, interpersonal and "soft" skills will always be in great demand, and absolutely essential for a successful and rewarding career.



Industry Member Spotlight —Peter C. Studer

What is your full name?

Peter C. Studer

Where did you grow up?

My hometown is Mankato, MN.

Tell us something unique or interesting about yourself.

I started my career as a R&D chemist in Italy.

Where did you attend college?

University of Wisconsin – Madison 1990

What degree(s) did you earn?

BS in Organic Chemistry

What is your current position?

Program Manager for Pharmaceutical and Environmental Industries

What do you like most about your job?

Working with customers on their processes and solving chemistry and engineering problems. Lately, I have really enjoyed sharing my knowledge with my young colleagues, then watching them taking that knowledge and succeeding.

Why did you join ISPE?

Initially for networking opportunities in the Pharmaceutical industry, but I continue to my membership to keep up on the changes and innovations in our industry.

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

Mostly networking functions, trade shows, conferences and ISPE forums, where I have found the best ways to keep current and learn about possible changes and innovations in our industry. I find these events to be great for many reasons, but mostly for the exchange of ideas and experiences that help me improve my skills on multiple levels.

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

I never believed that my choice to study organic chemistry and work in the pharmaceutical industry would lead me through so many aspects business. I started as an R&D chemist in Italy, where I developed a passion for chemical engineering and production. Then, I took a position as a Production Manager back in the US at a fine and specialty chemical plant in South Carolina, where I managed over 130 operators. Five years later, I was asked to lead that company's process equipment business in North America, a position in which I honed my commercial and business skills, and expanded my industry application knowledge. Now, I am a Program Manager for the Chemistry, Energy and Environmental Industry team at Linde, where I focus on the Fine & Specialty Chemical, Pharmaceutical & Biopharma and Water Treatment industries.

I believe my experience just goes to show that once you finish your formal education, the pharmaceutical industry offers many careers in many different aspects from R&D, through production, business management and sales. Keep your options open and explore all aspects of the pharmaceutical industry, and it will give you a rewarding career. In the end, the pharmaceutical industry is all about helping people, which has made my career worthwhile.



Young Professionals Member Spotlight —Ross Udod

What is your full name?

Rostislav Udod. I go by Ross.

Where did you grow up?

In Orange County, New York.

Tell us something unique or interesting about yourself.

In my spare time I like to go for a run. Running really helps me relax.

Where did you attend college?

University of California, Berkeley

What degree(s) did you earn?

Chemical Engineering

What is your current position?

Systems Solutions Engineer

What do you like most about your job?

There is always a lot to learn. The role has a lot of elements of different disciplines of engineering. It is an exciting role that lets me step out of my comfort zone to tackle new challenges.

Why did you join ISPE?

I want to help solve problems in the pharmaceutical field through engineering. Right now I am working for Xyntek Inc and we provide serialization solutions for the FDA regulation coming in November 2017.

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

I have attended the ISPE 30th Anniversary Celebration, Site Master Planning, Chapter Holiday Party, YP Think and Drink and the Facility of the Year Award. I think the experience of meeting new people and learning about their roles in the Pharmaceutical industry is exciting. I have attended two presentations given by ISPE - one was about Site Master Planning and the other was on Continuous Manufacturing - were very well done and well presented. I learned a lot from the experts in these areas. Overall, I think the ISPE events are very positive because everyone in the organization is very approachable.

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

I would suggest to take as many electrical and mechanical engineering lab classes as you can. A lot of the work is hands on and having practical troubleshooting experience really helps. I would also suggest to value your non-engineering skills such as communicating your thoughts clearly, being open to new ideas and working with other people in a pleasant and collaborative way. I think having good engineering and social skills is good advice for students who want a career in any field.



**To become a
member of ISPE
go to
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and select New
Jersey Chapter!**

Member Message by Donna Petro, Membership Chair

Thank you for participating as a member of the ISPE New Jersey Chapter! We want to make sure that all members are aware of the benefits that are available to them. A short overview is provided below. Full details can be found at: www.ISPE.org/Membership

Networking Opportunities – Member Directory (Members represent all facets of the industry), Affiliates & other Chapter events (local and national), CoP (Communities of Practice) online discussion forums, various scheduled networking events.

Technical Resources – ISPE Guidance Documents, Complimentary subscription to the Pharmaceutical Engineering Magazine, Review and Comment on Regulatory Guidance through your input.

Professional Development – Save on a variety of targeted Education and Training programs, Volunteer Opportunities to gain professional experience and recognition in the industry, ISPE Career Solutions by posting your resume or job opportunity.

As our New Jersey Chapter continues to grow and thrive, we are always interested in introducing new individuals to the benefits of membership, and who better than our current members to spread the word. We encourage each existing member to bring along an associate with them to an upcoming meeting. Be sure to let one of the board members know that you have a guest attending with you, in order for us to welcome them properly and answer any questions they may have during or after the meeting.

Please remember to check out our Chapter website often to take advantage of any newly announced membership benefits. As always, we very much appreciate members who offer their time to volunteer for the Chapter in various roles. Volunteering gives you the opportunity to mentor our Young Professional and Student members, help shape the organization and give back to the industry. If you are interested in learning about the many ways that you can become further involved in the organization, reach out to myself or another board member directly.

Also, visit the main ISPE website to view both National and International upcoming events. www.ispe.org

We look forward to seeing you at the next event!

Donna V. Petro
Board Member/Membership Chair

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Pharma Headlines

Bristol-Myers Squibb and Nordic Bioscience Announce Collaboration for Fibrosis Biomarker Technology (source: <http://www.biospace.com>)

Bristol-Myers Squibb Company and Nordic Bioscience, a Danish company specializing in biomarker technologies, announced a collaboration agreement to develop biomarker technology to potentially aid in the diagnosis and monitoring of fibrotic diseases including Non-alcoholic steatohepatitis (NASH). Under the

terms of the agreement, Bristol-Myers Squibb and Nordic Bioscience will collaborate in the development of translational biomarkers and diagnostics for the evaluation of NASH in pre-clinical models of fibrotic diseases and in clinical settings.

Samsung Biosim Nod sets J&J's Remicade Up for Tough Fight with Merck and Pfizer

(source: <http://www.fiercepharma.com>)

Samsung Bioepis won FDA approval for its Remicade substitute, Renflexis, becoming the second biosimilar to threaten that brand in the U.S. The med is already marketed as Flixabi in the EU. The rivalry looks interesting as Merck & Co. has Remicade marketing rights outside the U.S. and rights to Renflexis in the U.S. at the same time. Pfizer has its biosimilar version in both the U.S. and Europe.

Drug Firms Call for Next UK Government to Set Sights High for NHS and Life Sciences

(source: <http://www.pharmaceutical-journal.com>)

The trade body representing medicines manufacturers has called on the next government to bring current healthcare spending of 9.9% of GDP into line with the G7 average of 11.3%, in order to help the NHS become one of the best

health services in the world.

FDA Warning Letter Says Teva China Plant Has More work to do on API Issues

(source: <http://www.fiercepharma.com>)

For nearly two years, Teva struggled with impurity issues for an API manufactured at a plant in China, problems that affected about 20% of the product's production. While the drugmaker has been work-

ing for months to get on top of the problems, the FDA said in a warning letter to the generics giant that it has yet to be convinced Teva has solved all problems.

Pharma News

Bristol-Myers

Squibb

Nordic

Bioscience

Samsung Biosim

J&J

Merck

Pfizer

Teva

Job Opportunities

Are you looking for your next career challenge? Did you know that the ISPE website contains a list of job opportunities? Visit www.ispe.org to find more information for the job postings below and more.

Manager, Global Quality Supply Chain Security

Company: Bristol Myers Squibb
Location: New Brunswick, New Jersey
Job ID: 34260479

Senior Fire Protection Engineer

Company: Arup
Location: New York, New York
Job ID: 33817215

Manager- Validation, Technology & Engineering

Company: Eisai
Location: Exton, Pennsylvania
Job ID: 34415089

Validation Scientist

Company: GSK
Location: King of Prussia, Pennsylvania
Job ID: 34378101



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- Regulatory Compliance & Permitting
- Solid Waste Management

CP Architecture

CAPABILITIES INCLUDE:

- Feasibility Studies & Building Analysis
- Egress Studies
- ADA Solutions
- Schematic & Design Development
- Sustainable Design
- Master Planning
- Historical Renovations
- New Buildings, Facades & Additions

CP Construction Management

CAPABILITIES INCLUDE:

- Design Build/General Contracting
- Program Management
- Value Engineering
- Planning & Coordination
- Procurement
- Estimating
- Scheduling
- Permitting

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Chapter Sponsorship has many benefits, including:

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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!) Two complimentary tickets for all 2016 NJC Events¹

A vendor/display table at one event per year – excluding Holiday Party

<https://www.eventbrite.com/e/2016-ispe-njc-chapter-sponsorship-advertising-program-tickets-19824345150>