



President's Message



Wendy Haines

Winter has arrived, and we have survived several snow storms. Even though it has been cold outside things are heating up in the CaSA Chapter. We held another successful CaSA Gala on February 10, 2018. Everyone looked beautiful and the night was filled with connections between old and new friends. This year marks a special year in our Chapter with the 25th Annual Technology Conference on March 13, 2018. The Technology

Conference Committee has been hard at work for many months to ensure that they deliver high quality education, keynote address, product demonstrations, vendor exhibits and networking opportunities. Lastly, we have our Annual CaSA Golf Event on May 21, 2018 and our Durham Bulls Game Event on August 23, 2018.

This month's newsletter's theme is "Things we love about our Chapter." What I love most about the CaSA Chapter is our people and the relationships that I have made over the years. I started as a student member and gained mentors who have helped me become the person I am today. Eventually, those mentors became peers and dear friends. I feel blessed to be in the CaSA Chapter with so many knowledgeable people who are willing to mentor, listen and share their wisdom and life with others. I challenge all of you to think about what you love about the CaSA Chapter and come to our events and get involved to help us make our Chapter the best it can be.



Wendy Haines, PhD
President, ISPE CaSA Chapter

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Connecting a World of Pharmaceutical Knowledge

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Connecting a World of Pharmaceutical Knowledge

Membership Corner

2018 Technology Conference - Where Pharmaceutical Manufacturing Meets Revolutionary Technology!

By Chris Small


The Carolina-South Atlantic Chapter (CaSA) of the International Society for Pharmaceutical Engineering (ISPE) is gearing up for the 25th Annual Life Sciences Technology Conference, at the Raleigh Convention Center, 500 S Salisbury St, Raleigh, NC 27601. The 2018 Conference will feature more than 200 exhibitors, multiple tracks of continuing education programming, and a special education session for students and young professionals.

This year's keynote speaker will be Paul McKenzie, Ph.D., Biogen - Executive Vice President - Pharmaceutical Operations & Technology. Paul will address the attendees and highlight some of the new and innovative products in the Biogen pipeline! We're looking forward to hosting Paul!

In recognition of our 25th year, ISPE-CaSA is inviting all pharmaceutical manufacturer employees to attend free of charge. Additionally, there will be enhanced networking pavilions to engage industry experts, service providers, and product reps. Program high-

lights include a day-long series of continuing education programs in a variety of disciplines, including Biomanufacturing and Process Development, IP COP, Manufacturing Operations, Women in Pharma, Devices and Equipment, and the Facility of the Future. In addition, the conference offers a special career development track for students and young professionals.

The conference opens its doors at 9 a.m. and the public is invited to attend. Registration fees are \$65 for members and \$75 for nonmembers. Employees of pharmaceutical manufacturers are invited to attend free of charge. Registration at the door on the day of the event is \$85. Student registration fees are \$15 for members and \$25 for nonmembers. Registration includes food, parking, and beverages throughout the day.

For more information about attending, exhibiting, or sponsorship opportunities visit www.ispecasa.org 

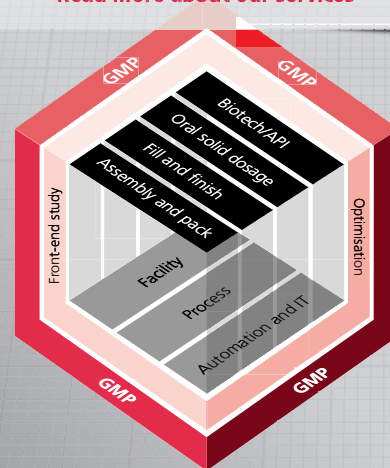
Education Committee

By Rachel Leahy, PhD, RAC

The Education Committee of ISPE-CaSA is working diligently to finish planning our 2018 events! We have some exciting topics in mind for a myriad of event types – from Talk & Tours to state-of-the-art Seminars and even Trivia Nights. We're also developing a new type of event where new or expanding pharmaceutical facilities host a forum to seek expert advice from the industry experts (AKA you, the members of ISPE-CaSA). If you are interested in speaking at one of these events, please reach out to the Education Committee (education@ispecasa.org) with your name, company, and topics of interest. We are open to most topics pertaining to pharmaceuticals, but hot topics such as state-of-the-art advancements, gene therapy/personalized medicine, and manufacturing regulations are specifically requested. And as always, a big "thank you" to our past Partners from 2017 and our current 2018 Partners for supporting our cause. 

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Membership Corner

Student Affairs Committee

By Catherine Bays

The **2018 ISPE-CaSA Local Student Poster Competition** will be held at the Raleigh Convention Center in downtown Raleigh on Monday, March 12, 2018 from 6:00 PM to 8:30 PM.

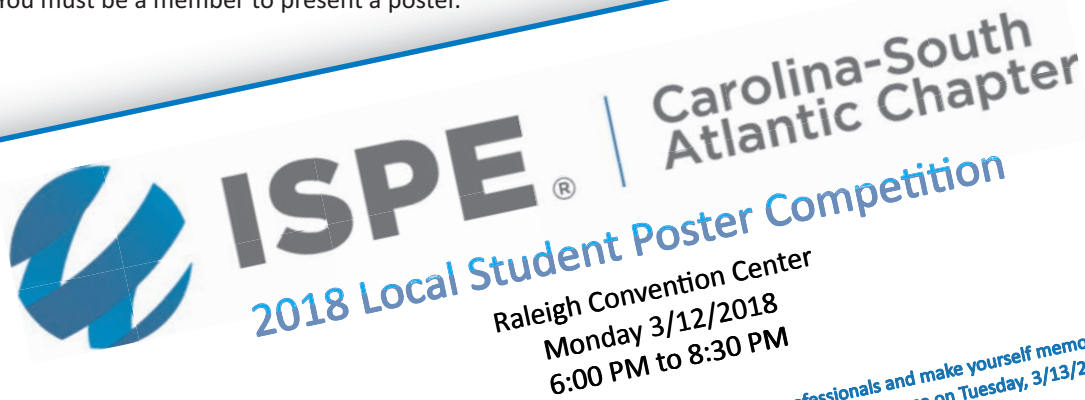
Posters will be displayed at the 25th Annual Life Sciences Technology Conference on Tuesday, March 13, 2018.

- Rules for competing are found here: <http://www.ispe.org/students/poster-competition-rules>
- Creating a poster is a great opportunity to show off your work to industry professionals and to make yourself memorable.
- The poster can be on any life science-related topic.
- All presenters will be eligible to present at the 2018 Annual Meeting & Expo to be held in Philadelphia in November.
- Graduate and undergraduate winners receive an all-expenses paid trip to the Annual Meeting & Expo.
- You must be a member to present a poster.

Abstract submissions are due to ispecasasac@gmail.com on Friday, March 2, 2018 by the end of the day.

Join the Student Affairs and YP Committees for a **Resume Review Session** from 2:00 to 2:45 PM at the 25th Annual Life Sciences Technology Conference in Room 402. Bring your resume with you for a critique by industry professionals and/or recruiters, or get help from the ground up if you're just getting started. THIS SESSION IS LIMITED TO 30 Students/Young Professionals - select the Resume Review Session when you register for the conference.

Volunteers are needed to review resumes and judge posters. Please email ispecasasac@gmail.com if you'd like to get involved. ▲



This is a GREAT opportunity to show off your work to industry professionals and make yourself memorable. Posters will be displayed at the 25th Annual Life Sciences Technology Conference on Tuesday, 3/13/2018.

Competition Rules : <http://www.ispe.org/students/poster-competition-rules>

- ☐ The Poster can be on any life science related topic.
- ☐ All presenters will be eligible to present at the 2018 Annual Meeting in Philadelphia in the fall.
- ☐ Graduate and undergraduate winners get an all expense paid trip to the annual meeting.

Send Abstract Submissions to:
ispecasasac@gmail.com
Before End of Day Friday, 02 March 2018

SAVE THE DATE

March 6 - 7, 2018

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Membership Corner

CaSA Member Spotlight: Charlie Dick, EAS

Interviewed by Newsletter Committee

Q: What is your full name?

A: Charles (Charlie) Milton Dick

Q: Birth Place?

A: Greensboro, North Carolina

Q: College?

A: North Carolina State University;
B.S. Biological & Agricultural Engineering, 1979

Q: Tell me a little about your personal life.

A: I'm a Christian & I like most any type of water sport and spending time on a lake, especially Lynwood Lakes, Lake Tillery, and Badin Lake. One time I attached a lawn lounge chair to a pair of water skis and pulled my kids around the lake on it. It was a little scary and looking back now that I am older I wonder why I thought this was a "good idea" to risk my kids' safety by bouncing them around the lake on this flimsy contraption.

Q: How long have you been with your current employer?

A: 21 years at Environmental Air Systems

Q: What is your present position? What do you do at your job?

A: I'm the Director of Business Development; Client Development / Maintenance for Industrial HVAC / Mechanical Construction, most of which is in Pharmaceutical / Medical Device Manufacturing; and Off Site Manufacturing / Modular nationally for MEP Infrastructure for industry.

Q: Tell me about your career path, and how you ended up where you are today.

A: I started off my career working right out of college for Carolina Byproducts (now known as Valley Protein) as a Plant Manager Trainee, then worked for another mechanical contractor for a year. In the years to follow, I worked as a Technical Services Engineer for a raised floor manufacturer in Maryland, a Sales Engineer for a national modular clean room manufacturer for laboratory animal housing and medical device manufacturing, and then after returning to North Carolina I worked 8 years for a regional and then later for a national geotechnical and environmental engineering consultant firm.

Q: What is your favorite part of your job?

A: Starting off in engineering in my career, I learned quickly the most satisfying and motivational part of who I am is to identify and develop new business. Consulting with owners, construction management and engineering firms on modular construction for MEP systems is extremely satisfying and rewarding.



Charlie Dick

Q: How long have you been a member of ISPE/when did you first join ISPE?

A: About 21 years I believe, in the 1996 time frame.

Q: What benefits have you realized from being a member of ISPE, and why are you still involved with ISPE?

A: The organization is great for helping me stay current with the trends and being exposed to new equipment. I typically attend events at the CaSA level, an occasional Therapeutic Thursday, and occasionally the National ISPE Conference when they are being hosted at an East Coast location. Networking among my peers and prospective customers is extremely important to me.

Q: Any Mentors/Role Models that have helped to shape your life?

A: Jim Horneff, who held several patents for clean design for laboratory animal housing. He was patient and kind to me when I was a young "pilgrim" learning the business and took time to explain the technology to me. I still use some of the sales language to this day that he taught me as a young man in my early 20's.

Q: If you weren't involved in pharma/biotech, what business do you think you'd be in?

A: Not sure, I am involved with a variety of industries currently, with pharma being the primary.

Q: Any hobbies? What are they?

A: Boating, skiing, tubing, coaching basketball for 3rd / 4th grade boys, pistol shooting, and banjo playing

Q: Finish this sentence – "I need more...."

A: Time with neighbors and friends. I enjoy having meals together and doing activities with them, inviting them to spend time on the lake with my wife and me.

Q: Favorite Food?

A: Country cooking

Q: What is something that people would be surprised to learn about you?

A: I love cheesy Kung Fu movies. Without question, my favorite actors within the genre are Jet Li and of course, the man, Tony Jaa in his Ong Bak movie series. Tony Jaa is a Muay Thai practitioner and tended to be on his opponent's knee and elbow joints, if you know what I mean.

Q: Last movie you saw?

A: Jumanji and, of course, The Last Jedi

Q: For those in the early stage of their careers, what advice would you give them?

A: Being involved with professional trade organizations that represent your client base, spend 1 night / day a month being involved in a professional networking event that involves your industry focus. 🏠

Membership Corner

Golf Tournament

The Golf Tournament is scheduled for Monday, May 21 at Prestonwood Country Club in Cary, NC. Registration is open.

Please visit the registration site to select a sponsorship or to register players. [▶](#)

<https://www.eiseverywhere.com/ehome/index.php?eventid=264698&>

Monday, May 21, 2018



Prestonwood Country Club, Cary, NC

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Membership Corner

Networking Committee

By Kevin Debbs

On behalf of the ISPE CaSA Board and Networking Committee, we would like to thank our Sponsors and all the Attendees for making the 2018 edition of the ISPE CaSA Gala a success. We are fortunate to have a beautiful night at a wonderful and interactive venue. We had great food, great music and plentiful conversations to go along with the benevolent efforts to raise money for the ISPE CaSA Jane Brown Scholarship Program.

Next, I would like to thank the entire Networking Committee and our Chapter Manager for all the time and effort to plan this

event. This event was a terrific start to 2018. We have multiple high quality networking events planned for our members throughout the remainder of the year, so stay connected and take advantage of the ISPE CaSA networking opportunities.

In closing, I would like to thank all of our sponsors again. Without your dedication to our chapter and the continued financial support you provide, these types of events, in the way that we do them, could not happen. Therefore, I'd like to highlight and individually recognize all of our sponsors for this year's Gala. ▲



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Membership Corner

Upcoming Therapeutic Thursdays

Join colleagues and friends for an evening of networking and enjoyment on Therapeutic Thursday! And yes, we are hosting two Therapeutic Thursday events in North Carolina next month – in Raleigh and Greenville – and then two events again in Florida in

March – in Fort Lauderdale and Gainesville! The mix & mingles run from **5:30 to 7:30 p.m.** There's no need to register in advance. Just walk in the door and start networking. Sponsors will provide appetizers. Cash bar. 

February 22



North 30th Sports Pub & Grille



**Raleigh Times
Downtown Raleigh, NC**



**Winslow's
Greenville, NC**

March 29



**Location: TBD
Atlanta, GA**



**Location: TBD
Fort Lauderdale, FL**



**Blackadder Brewing Company
Gainesville, FL**

Many Therapeutic Thursday sponsorship opportunities remain for 2018.
Contact networking@ispecasa.org to sponsor an event.

Membership Corner

Young Professionals

By Mariessa Perez

Being part of the YP committee isn't just about being young, social, and new to the professional world. Some of our committee members say being a part of this group has transformed their careers. Here's what they have to say:

"What I love best about our chapter/ISPE is being part of an organization with people of various ages that have a lot of the same goals and interests. I really enjoy going to events, having a beer, and either talking shop or about topics outside of work. It's also nice that a lot of the people involved in the chapter are around my age." -Tony Le

"The technical experience I've gained with the chapter members that attend events is unparalleled. Which, transfers through conversations with members and topics at events to enhance the overall experience of being a part of the chapter." -Damien Wassell

"By being a brand new ISPE member and Young Professional this year, the experience and gratitude I have to be a part of this organization is unprecedented. I not only have the ability to network with other young professionals but also with seasoned professionals from all different areas. I make at least one new connection every event and continue to build my network." -Katherine Gibbins


**Why you will
LOVE to
be part of the
YP Committee!
Let's hear from
some of our
members!**



In the next few months we have a lot of exciting social and educational events planned and you should get involved! Come network, meet new professionals, volunteer (FOR THE TECH SHOW), come step out of your comfort zone to further your career, or come and try something new! We look forward to having you – YOU ARE GOING TO LOVE IT.

We are also looking for volunteers for the 25th Annual ISPE Tech Show. We are in need of the following:

- Speaker Escorts
- Registration and Information Desk
- Resume Reviewers

If you are interested in volunteering for this event, future events, or being part of the YP committee please contact casayoungprofessionals@gmail.com. As an incentive we offer registration reimbursement for all volunteers. Come be part of what we LOVE to do in this month of February! 

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Membership Corner

Social Media Committee


By Daniel Santarsiero

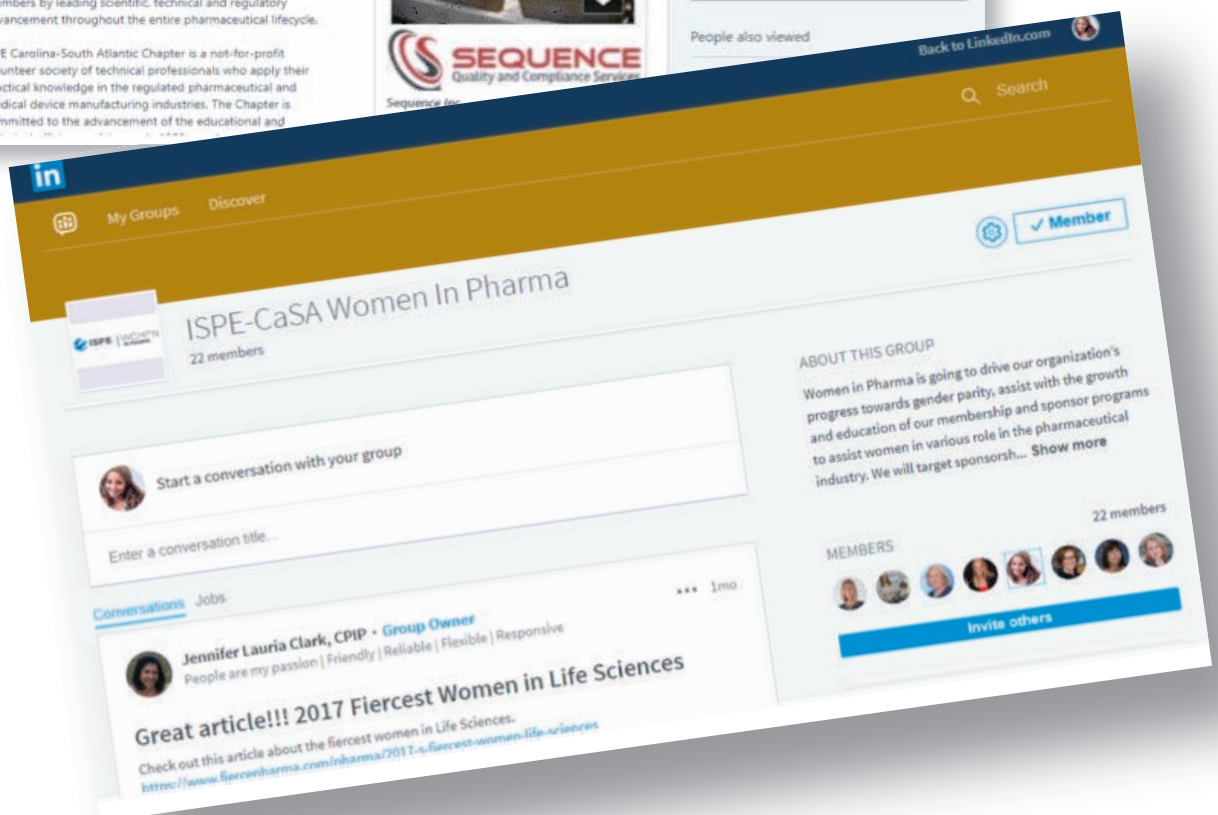
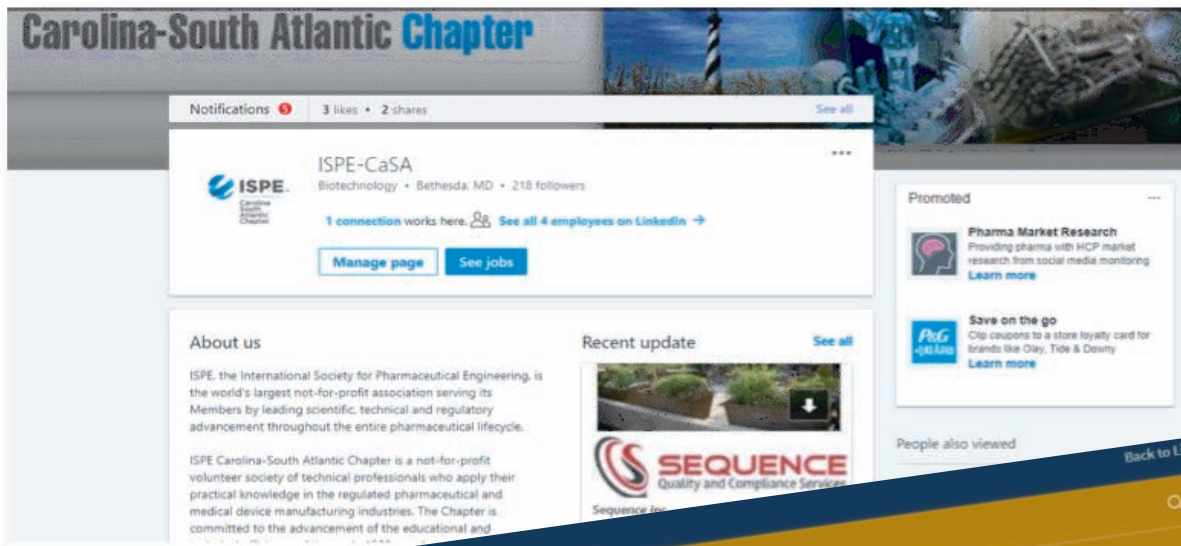
Attention! Attention! LinkedIn Update! Follow Us On LinkedIn

For better LinkedIn communication, ISPE CaSA will begin using the [ISPE-CaSA Company](#) page for the posting of exciting upcoming events, industry news, and other relevant information related to the Chapter and Organization. This change does two things for the Chapter:

1. It puts our page in compliance with LinkedIn security policies.
2. It provide more opportunity for our chapter to add additional ISPE-CaSA groups, such as the already added "[ISPE-CaSA Women in Pharma Group](#)" to our company page for more member involvement and recognition.

Unfortunately, this switch will cause us to lose a few followers who were solely connected to the older ISPE-CaSA group. Therefore, we are asking all members to make the switch by electing to join and follow our [ISPE-CaSA Company](#) page. Our goal is 1000 members connected by the end of 2018.

Follow this [link](#) to join the ISPE-CaSA page for updates! And follow [Women in Pharma Group](#)! 



Technology Corner

This month in the newsletter, we're discussing things we love about our chapter. Perhaps it isn't surprising that we of the Newsletter Committee love stories about the talented people who live and work in our region! Tanvi Joshi, now at Aurobindo USA, won the Student Poster Competition (Graduate Level) at the 2017 ISPE Annual International Meeting for work performed at Campbell University.

We've asked Tanvi to share a summary of her award-winning poster for those of us who weren't able to attend the International Meeting.



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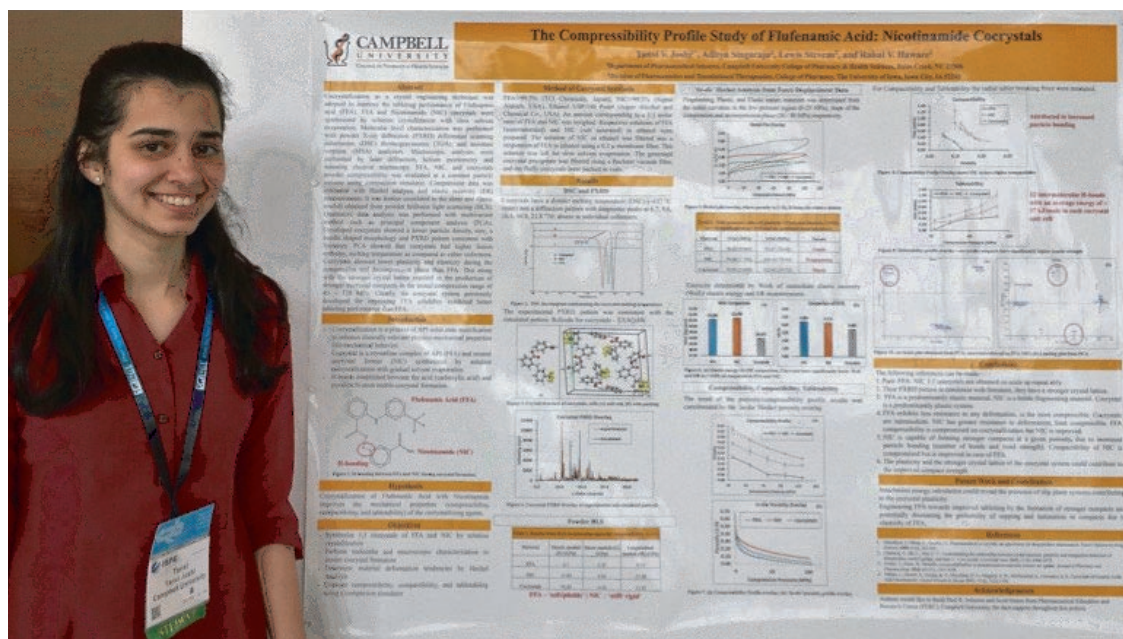


BUILDING A SMARTER ENERGY FUTURE™

Structure-Mechanics and Compressibility Profile Study of Flufenamic acid: Nicotinamide Cocrystals

By Tanvi V. Joshi
Aditya Singaraju
Lewis Stevens
Rahul V. Haware

Most of the crystal engineering techniques are designed to overcome limitations like solubility, stability within the API rendering their suitability to pharmaceutical processes resulting in the production of a patient friendly dosage form. Cocrystallization was the focus of this study and the effect on powder mechanics on a molecular and macroscopic level were investigated.



Tanvi Joshi (Campbell University Student Chapter) wins the Student Poster Competition at the 2017 ISPE Annual International Meeting

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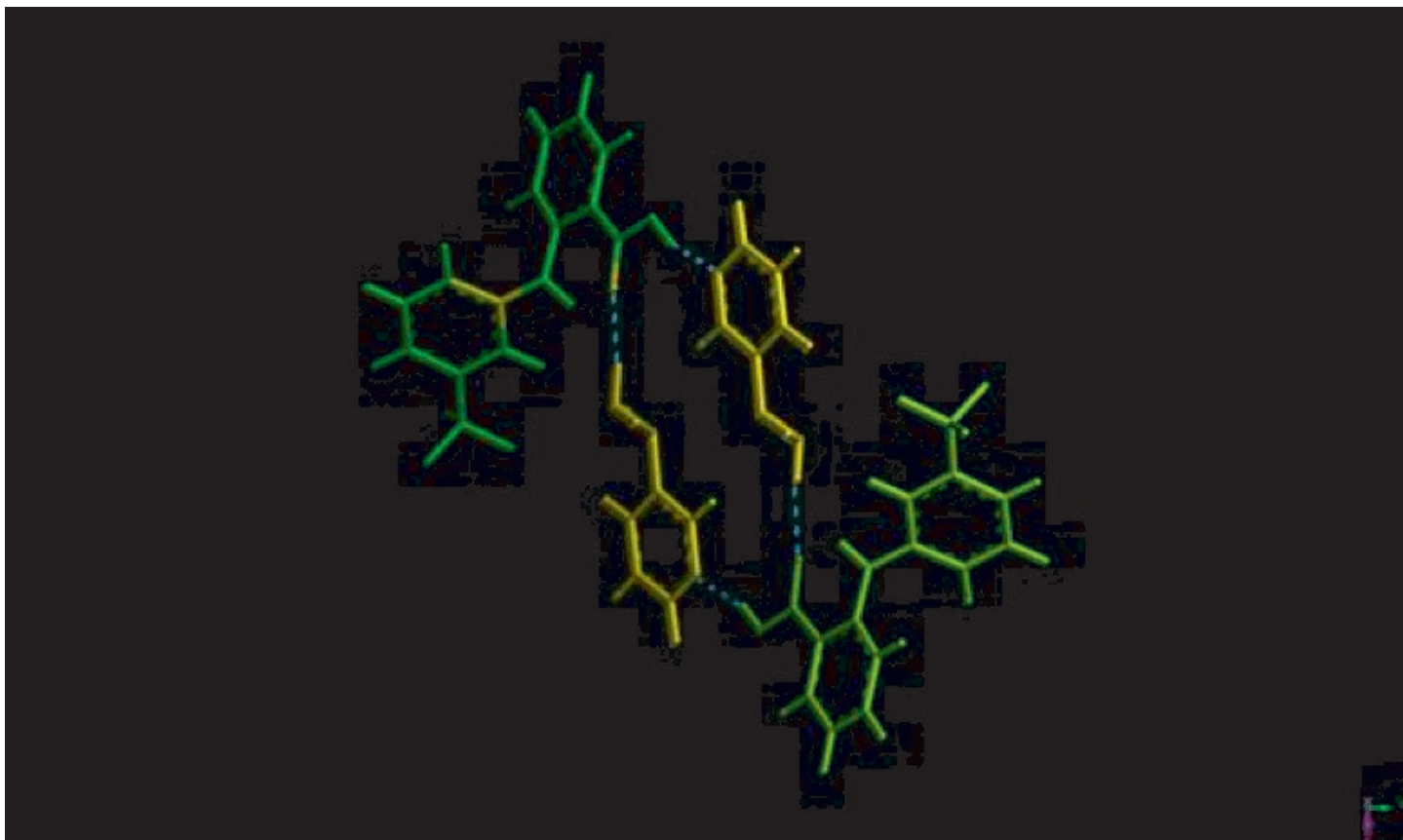


Figure 1 Acid pyridine heterosynthon during cocrystal production

Cocrystals of Flufenamic acid (FFA) were made using Nicotinamide (NIC) as the conformer using the process of solution cocrystallization with slow solvent evaporation. A robust acid pyridine heterosynthon (intermolecular H-bond between the carboxylic acid of FFA and N-atom of pyridine ring of NIC as can be seen in Figure 1) enabled the cocrystal production. Various techniques including X-ray diffraction, infrared spectroscopy and hot-stage microscopy were employed to characterize the individual coformers and establish the unique identity of the newly formed crystalline complex. The cocrystals had improved thermal stability (as identified from their reported higher MP) and a stronger crystal lattice (identified due to its higher fusion enthalpy) as compared to the coformers.

The ability of the materials to undergo deformation was studied using p-BLS and in-die Heckle analysis. This deformation capability under the applied compression pressure is important to result in volume reduction and compact formation. Results from both these studies were in agreement and the nature of the material could be identified as NIC – stiff/ rigid, FFA – soft/ ductile and cocrystals as intermediate. This meant that FFA deformed easily (easily compressible) and formed compacts of the least thickness due to highest volume reduction. The tablets formed at every compression pressure for all the three materials were evaluated for their tensile strength as a part of the tabletability study. Here compacts of FFA were found to have the lowest tensile strength, followed by NIC and the

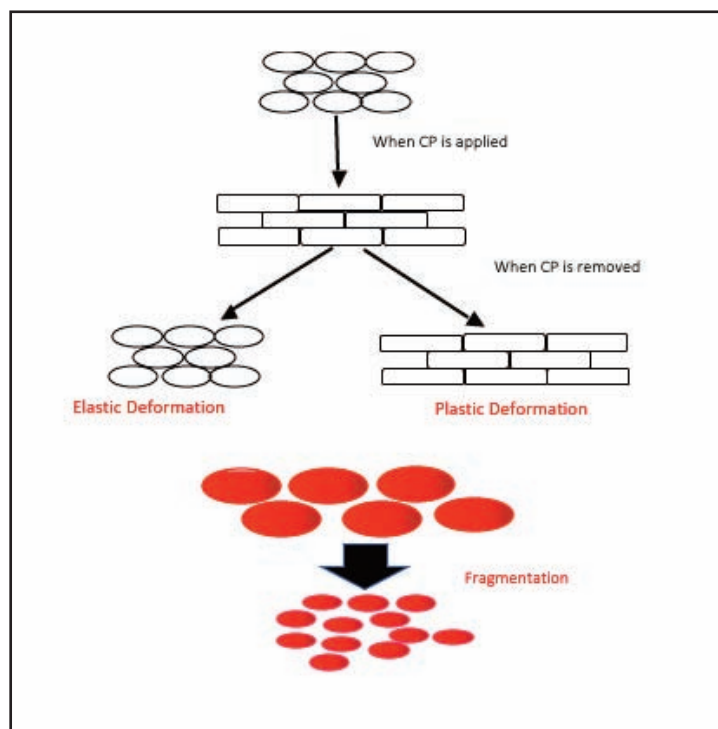


Figure 2 Different deformation mechanisms, where CP is compression pressure

(continued next page)

Technology Corner

cocrystals. An understanding into this trend using the elastic recovery measurement data as a secondary reference reported the same trend; the deformation mechanisms were suspected to be, FFA – elastic, NIC – fragmenting and cocrystals – plastic as can be understood visually in Figure 2. In case of an elastic material the deformation that the material undergoes during compression is not retained after the removal of compression pressure producing weaker tablets. Being a non-permanent deformation, the bonds are broken upon the removal of compression pressure compromising compact strength. Plastic materials on the contrary are bond favoring materials, the established interparticulate bonds are retained even upon ejection from die cavity. This causes them to produce stronger tablets. This strength conferred to the tablets helps them withstand the attritional forces likely to be experienced during manufacturing and handling. Cocrystals exhibited superior and favorable properties compared to the coformers, due to the deformation mechanism involved making them better suited for tablet manufacture. This tensile strength data is independent of the material particle size as the same trend was observed for both the sieved and the unsieved material and the generated data is also statistically significant. The larger particle size of FFA, causing a decrease in the available bonding surface area is not

responsible for the diminished tablet strength. The reason behind the differences in the material deformation tendencies and macroscopic tableting performance can be postulated to be due to differences in the crystal structure, attachment energies, crystal packing, H-bonding networks and the slip plane systems. In conclusion a basic understanding of the crystal structure in the early development phase could help predict the material performance during large scale manufacturing processes.

Effectiveness of this technique can be exemplified as follows. It may decrease the need for bulk excipient usage to confer desirable properties to the tablets. Example, the use of binders like starch, and wet granulation process to confer strength to the tablet. Secondly the crystal structure and macroscopic tableting performance can be used to predict certain defects that may occur; capping and lamination in the tablets due to the elastic nature of the material. This technique may be used to alter the deformation mechanism and avoid tablet defects.

Lastly the work on this project continues. Here we try to explore an alternative approach of wet grinding in a ball mill to synthesize the cocrystals. This technique was chosen as it requires very low quantities of organic solvent making it large scale production environmentally and economically favorable. ▲

SAVE THE DATE

Join ISPE-CaSA and your colleagues for the

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Monday, May 21, 2018

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ISPE Carolina-South Atlantic Chapter Newsletter

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EDITORIAL POLICY

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Manuscripts should be submitted with a brief, three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment.

Would you like to see your name in the newsletter?

Contribute content! We're looking for the following:
Reviews of ISPE-CaSA Events

Did you meet someone inspiring, find a job, or just have a great time at one of our events? Let us know!

Lessons Learned

Have you learned an interesting lesson at work recently? Write it up and share it! Our members are always interested in improving their skills.

Pharmaceutical Funnies / Biotech Bloopers

Did something entertaining happen at work? Tell us about it! If we laugh, we'll publish it and give you the credit.

Your contributions help us keep the newsletter fresh. You'll get full credit, and bragging rights, when we publish them. We love to hear from you, and our members do, too!

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

A word to the ISPE CaSA Newsletter advertisers:
Thank you all for your continued support. Without it we could not have the wonderful support staff to get our ISPE CaSA Members the news in such a timely and professional fashion. If you have updates to your advertisements or find any other error, please contact us so that we can serve you better.



ISPE®

Carolina-South Atlantic Chapter

Advertising Opportunities in ISPE CaSA 2018 Electronic Newsletter

The ISPE CaSA Chapter produces **six** e-newsletters per year. ISPE CaSA sends out the newsletters via e-mail and via Web link to all of our Chapter Members throughout the Southeastern U.S., which reach top-notch pharmaceutical, biotechnology, and bio-science professionals and managers. These newsletters are also posted on our **Web site** so your ad can be accessed by interested visitors to our site.

The cost for a full color business-card-sized ad is \$1000 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional \$1000 per year for six issues. Space limits the number of front page to only **four**, and is offered to the first four paid advertisers on a first-come, first-served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad, a hot-link can be added to your submitted ad file for an additional \$500 for the entire year.

You may choose one of the special offers below (pro-rated for partial-year advertising):

SOLD OUT ~~Full-color ad for six issues on the front page of each newsletter (\$333/issue)~~

- ☐ \$2,000 Full-color double-sized ad for six issues (\$333/issue)
- ☐ \$1,000 Full-color ad for six issues (\$167/issue)
- ☐ \$500 Adding a hot link for directing customers to your website by a simple click

We hope you will take advantage of these opportunities and advertise in the 2018 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2018 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. **Deadline for 2018 advertisements, to start in the February 2018 issue is January 19th, 2018.**

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE-CASA Newsletter Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5" x 2") or double-sized ads (3.5: x 4") may contain your logo or other artwork. Artwork should be sent directly to newsletter@ispecasa.org.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!


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Atlantic Chapter**

2018 Newsletter Advertisement Order Form

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Billing Address:	
Contact Email:	
Contact Phone:	

Check all that apply:

Note: Ads are business card size- 3 5/8" (w) X 2" (h)
Double-Sized Ads are 3 5/8" (w) X 4" (h)

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