

# IPPH NEWSLETTER

December 2019

Professor Elizabeth (Liz) Topp now dons an additional cap by joining Ireland's National Institute for Bioprocessing Research and Training (NIBRT) as their Chief Scientific Officer. Liz maintains her appointment in IPPH and continues to guide her research group and participate in other activities here at Purdue. At NIBRT, Dr. Topp joins a group of investigators focused on biopharmaceutical manufacturing research, particularly in the upstream and downstream processing of recombinant protein drugs and other biologics. Areas of ongoing research at NIBRT include cell engineering, bioanalysis, glycan profiling, data analytics, and single cell analysis. Manufacturing cell and gene therapy products (CGT) is becoming increasingly important for NIBRT as well. Liz brings expertise in drug product formulation and manufacturing to this growing team.



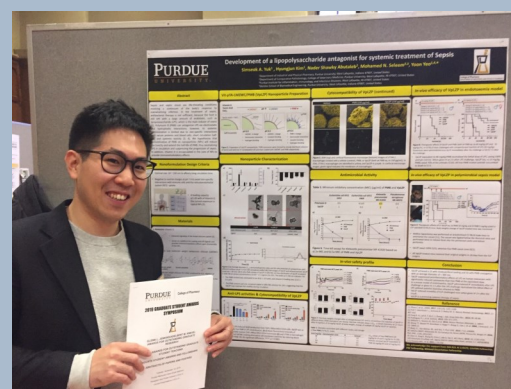
"NIBRT is internationally recognized as a leader in biopharmaceutical manufacturing research," Topp said. "I'm honored to become a member of a team with world-leading expertise in this field." Liz's dual role presents exciting opportunities for IPPH to develop new research collaborations, courses and student exchange programs in pharmaceutical biologics. "NIBRT's world-class facilities in biopharmaceutical manufacturing provide a way for IPPH to expand its traditional strengths in pharmaceutical manufacturing into the biologics area. At the same time, research strengths in IPPH and across Purdue offer new research opportunities for scientists at both institutions," Topp said. NIBRT is based on an innovative collaboration between University College Dublin, Trinity College Dublin, Dublin City University, and the Institute of Technology, Sligo. NIBRT was founded by funding from the Government of Ireland through its inward investment promotion agency, IDA Ireland (Industrial Development Agency). NIBRT supports the biopharmaceutical industry by providing training in biopharmaceutical manufacturing and by conducting leading edge research in biopharmaceutical manufacturing in collaboration with industry and academia. The NIBRT facility is a purpose-built, multi-functional building which replicates the most modern industrial bioprocessing facility. The total building area is approximately 6,500 m<sup>2</sup> over two floors. At the heart of the NIBRT building is the bioprocessing pilot plant, consisting of extensive upstream, downstream, fill-finish and the associated analytical facilities. These facilities are all operated in a realistic GMP simulated, operational manufacturing environment.

**Continued on page 3**

## IPPH Holds First Recruitment Open House



## IPPH Graduate Student Awards



## GREETINGS FROM THE HEAD



Dear Alumni and Friends,

The end of the calendar year is always a special time for the department as things slow down at the end of fall semester. It allows us to spend more time with family and friends, enjoy the snow here in West Lafayette (or sun for those traveling further south), and reenergize for the upcoming spring semester. It is also a great time to catch you up on the latest happenings with the department.

One of the questions that I have often heard from administrators at Purdue has been "Is Liz Topp still part of the IPPH faculty?" The answer is a resounding YES! We are very fortunate to be able to share her with NIBRT in Dublin, Ireland. We are excited about the great synergies already emerging between Purdue and the biological formulation groups in Europe, and more specifically in Ireland. IPPH already has very close contacts with universities in Ireland, especially the University of Limerick, where IPPH professor Lynne Taylor continues her invaluable work as a Scientific Advisory Board member of the Science Foundation Ireland Research Centre for Pharmaceuticals. We are looking forward to continuing to build these relationships in the future.

This coming year we will be having two Peck Symposia at Purdue University. The first is a more traditional Peck Symposium being held on March 25, 2020 and is entitled "New Therapeutic Frontiers: Immunotherapies from Genes to Cells". It will be hosted by our newest faculty member, Sandro Matosevic. The focus will be on the breakthrough of immunotherapies as emerging treatment modalities. We encourage you to attend if you are interested in these areas.

The second Peck Symposium will be held on October 29, 2020, and will be an alumni focused event. We view this as an opportunity to highlight the success of our alumni. More information will be shared soon, but mark the date on your calendar now!

We are continuing our search for a new faculty member in pharmaceutical biotechnology. The search remains open, and we are always interested in potential candidates for this position. If you know someone who may be interested, please let me know.

I also want to highlight some of our faculty and student achievements, including Liz Topp being awarded the 2019 Michael J. Pikal NIPTE Distinguished Scholar in Pharmaceutical Processing Award, Yoon Yeo's election to Fellowship status in AAPS, and Tony Zhou receiving an NIH R01 grant. Our students have also received national recognition, including the 2019 Baxter Young Investigator Award given to Simseok Yuk, and the 2019 AAPS Best Abstract Award to Yue Li at the AAPS PharmSci 360 conference. Sidhi Hate and Dana Moseson received 2019 IPEC Foundation Graduate Student Awards. Please make sure to check out the rest of the faculty and student updates that are found in the newsletter!

As the department head, one of the most important jobs that I have is to determine the future needs and directions of the department. In academia, we usually do this through a strategic plan. Our current strategic plan ends in 2020, so we need to think about the new plan for the next five years. This coming year, the faculty, staff, students, alumni, stakeholders and I will work to define the future direction for the department, and will be seeking your input. Please look for and respond to communications from the department as we solicit your input.

Finally, I would like to continue to thank the friends and alumni of the department. I am continually impressed by the passion that you have for the department and Purdue. During my many travels, I have had the opportunity to talk to many of you, and I always enjoy hearing the stories of your time at Purdue. Please reach out to me if you haven't already to help create these new relationships.

Happy Holidays and Boiler Up!

Eric Munson  
Dane O. Kildsig Chair and Department Head

## IPPH Hosts Recruitment Open House



Students interested in graduate school and a career in the pharmaceutical sciences were invited to explore IPPH at an

open house on November 13<sup>th</sup> in the College of Pharmacy's Collaborative Commons. IPPH faculty were on hand to discuss research areas with prospective students. Current students displayed lab posters and shared their experiences with the attendees.

IPPH plans to hold a similar event in September of 2020, and welcome alumni to attend!



<ul style="list-style-type: none"> <li>• Advanced Methods of Analysis</li> <li>• Drug Delivery</li> <li>• Drug Stability</li> <li>• Drug Transport</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturing Science</li> <li>• Materials Science</li> <li>• Modeling</li> <li>• Nanomedicine</li> <li>• Pharmaceutical Biotech</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmaceutical Engineering</li> <li>• Pharmacetics</li> <li>• Pharmacokinetics and Metabolism</li> <li>• Solid State Chemistry</li> </ul>
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**Purdue University  
Industrial & Physical Pharmacy  
Recruiting for the Ph.D. Program**

### OPEN HOUSE

Are you considering graduate school and a career in PHARMACEUTICAL SCIENCES? Come discover a valuable area of translational research from molecule to clinical formulation

- ◊ Careers
- ◊ Areas of Studies
- ◊ Steps to applying to the Ph.D. program

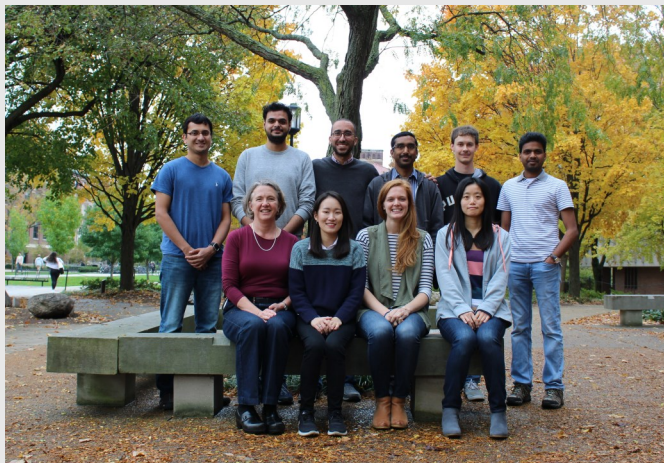
**11. 13. 2019**  
5:00 pm – 7:00 pm  
College of Pharmacy Collaboration Commons,  
2<sup>nd</sup> Floor, Heine Building (RHPH 277)

**FOOD & REFRESHMENTS PROVIDED**

**Learn more about IPPH at**  
<https://www.ipph.purdue.edu>

## Faculty Spotlight: Elizabeth Topp

(Continued from front page)



As a Professor at Purdue, Dr. Topp is the advisor for a group of seven students and postdocs, and continues her involvement as Co-Director of LyoHUB, an industry-led consortium to advance lyophilization technology.

Dr. Topp was the recipient of two National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) grants this year. One of the grants funded the development of an online **“Lyophilization Short Course.”** This course is broken into (8) modules presenting an introduction to pharmaceutical lyophilization, with each module ending in a self-assessment. A virtual lab exercise is also available. The course was developed and recorded with the help of several leading lyophilization industry experts including IPPH alumni, **Steve Nail (1975)**, **Greg Sacha (1999)** and **Ehab Moussa (2017)**. These modules are available to the public at no cost through [www.lyohub.org](http://www.lyohub.org).

The second NIIMBL grant is titled, **“Improving Lyophilization of Recombinant with ssHDX-MS.”** Over the past ten years, Dr. Topp and her group at Purdue have developed solid-state hydrogen deuterium exchange with mass spectrometric analysis (ssHDX-MS) as a novel analytical method to “see” proteins in the solid state. A challenge in developing lyophilized protein formulations is that there are very few high resolution analytics for proteins in the solid state. As a result, the formulations and drying processes that produce them are developed largely by trial-and-error, a time consuming and expensive approach. ssHDX-MS provides information on protein conformation and matrix interactions in the solid state, achieving peptide-level resolution. Dr. Topp and her group have shown that deuterium incorporation measured in ssHDX-

MS is highly correlated with the stability of the protein on storage. This suggests that ssHDX-MS can be used to accelerate formulation and process development, reducing our reliance on time-consuming stability studies.

“I’m excited about this NIIMBL project because it specifically explores the use of ssHDX-MS for manufacturing changes, including scale-up and tech transfer in lyophilization. Currently, any changes in manufacturing processes must be validated using stability studies, which can take months or years to complete. Results from this project, as well as other studies from my lab, suggest that ssHDX-MS can provide comparable information in a couple of weeks.”

**Dr. Topp** is also thrilled to be a part of an NIH SBIR Phase I/II grant worth \$1.4M that was awarded to Monon Bioventures, LLC, to **develop better rescue kits for hypoglycemia**. This grant supports the pre-clinical development of novel derivatives of glucagon, the drug used in diabetes rescue kits.

The current rescue kits for hypoglycemia are cumbersome and difficult to use. The kits require someone to reconstitute dried glucagon in a vial using a solution in a syringe, draw up the reconstituted solution back into a syringe, and then properly administer it to the patient. “That’s a lot of mixing and liquid handling,” Topp says, “particularly for people who may not be trained health care professionals, and in an emergency situation besides”. Because more than 100 million adults in the United States live with diabetes or prediabetes, the need is great to find better solutions to treat hypoglycemia effectively.

Topp and her group at Purdue are working with Mark Heiman, the chief science officer for Monon Bioventures and former chief science officer for Lilly Obesity, to develop an easier solution. They faced a challenge when developing their technology: Glucagon is poorly soluble and unstable in solution. They solved this challenge by using derivatives of glucagon, which they have shown to be soluble and stable in solution.

The glucagon analogs created at Purdue are quickly reconverted after injection to natural glucagon by enzymes in the body. This process creates an easier and quicker alternative to delivering glucagon to a person in need.

“Utilizing Topp’s innovative approach, we will be able to significantly improve patient access to this important medicine,” Heiman said. “The new glucagon solution will enable the development of much easier delivery methods such as an EpiPen-like device. Intranasal delivery may even be possible, and the derivatives may allow for the realization of an effective, dual-hormone artificial pancreas.”



## Faculty Updates

**Dr. Stephen Byrn** and collaborators continue to utilize PDF patterns derived from Synchrotron radiation available at Argonne National Laboratory to reduce risk of formulation failure as well as accelerate development and increase formulation innovation.

**Dr. Gregory Knipp** is part of a collaborative, multi-institutional investigative team that was recently awarded U54 funding on a project entitled "Advancing Cyanide Counter Measure" from the National Institute of Neurological Disorders and Stroke-CounterACT Centers of Excellence for his role as a Co-Investigator on the Pharmaceutical Sciences Core (V. Jo Davisson-Purdue PI). In a separate project from Dr. Davisson's laboratory, Dr. Knipp will serve as a Co-PI on a R01 entitled "Antiviral Lead Identification to Treat Filovirus Infections."

**Dr. Tonglei Li** advised several students selected to receive awards. Nick Huls was awarded the Kinley award for his excellence in teaching and teaching assistance by COP; Clairissa Corpstein was awarded a research funding by PRF for her research in developing long-acting drug delivery system; Yue Li was given a travel award by AAPS for his poster presentation of modeling and simulation of tablet disintegration and dissolution; Fudan Zheng was chosen by AAPS to present her research of SC absorption modeling and simulation during a RapidFire session.

**Dr. Sandro Matosevic** was awarded a Walther Tier 2 Embedding Grant by the Walther Cancer Foundation, which will support the further pre-clinical development of a novel immunotherapy for glioblastoma using genetically-engineered natural killer cells in pre-clinical and clinical collaboration with the Indiana University School of Medicine toward future clinical evaluation. This Award followed on from a successful Tier 1 grant. Dr. Matosevic also received a Robbers New Investigator Award by the Purdue Center for Cancer Research. He will be chairing the next Peck Symposium, titled "Novel therapeutic frontiers: Immunotherapies from Genes to Cells."

**Dr. Kinam Park** has been developing injectable, long-acting formulations for delivery of naltrexone for treating opioid addiction. The work is supported by the National Institute of Drug Abuse.

**Dr. Rodolfo Pinal's** recent work addresses the pH-dependent dissolution - a problem for drugs that are weak bases. His lab developed a modular system for maintaining the same dissolution rate under acidic and basic conditions. The same controlling modules can be used for any weak basic drug, without need to reformulate.

**Dr. Lynne Taylor** is continuing her membership by invitation on the SSPC, Science Foundation Ireland Research Centre for Pharmaceuticals, Scientific Advisory Board.

**Dr. Elizabeth Topp** is the recipient of the 2019 Michael J. Pikal NIPTE Distinguished Scholar in Pharmaceutical Processing Award. This award is named in memory of Dr. Michael J. Pikal, who passed away in 2018. Dr. Topp worked extensively with Dr. Pikal beginning when she received her PhD and holds many fond memories of special times working with Dr. Pikal over the years.

Dr. Pikal was a leader in the field of freeze-drying technology and was a driving force in groups such as LyoHUB, The Center for Pharmaceutical Processing Research (CPPR), The National Institute for Pharmaceutical Technology and Education (NIPTE), and more recently The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Dr. Pikal was a member of the American Chemical Society (ACS) and the American Association of Pharmaceutical Scientists (AAPS). In 1997, Dr. Pikal was the recipient of the Ebert Prize from the American Pharmacists Association (APhA) Academy of Pharmaceutical Research and Science and the 1989 PDA's Best Paper of the Year Award. He was the Busse Lecturer at the University of Wisconsin (1983) and the Enz Lecturer at the University of Kansas (1998). Dr. Pikal was also a Fellow of AAPS and received the AAPS Research Achievement Award in Pharmaceutical Technologies in 2001 and the Crioforma Award in Freeze Drying in 2006. In 2009 he received the AAPS' highest ranking award, the Distinguished Pharmaceutical Scientist Award, an award that recognizes those that have made substantial contributions to the pharmaceutical sciences that have had a lasting impact. Fewer than 20 scientists have received this accolade.

**Dr. Yoon Yeo** was elected to Fellowship status in AAPS. The status of Fellow is in recognition of Dr. Yeo's professional excellence and sustained superior impact to global health and to the AAPS Community. Dr. Yeo is also the new Associate Editor of Americas for the **Journal of Controlled Release**.

**Dr. Qi (Tony) Zhou** was recently awarded an NIH R01 grant as the Principle Investigator with a total \$3.2M support for 5 years. The project with a title "Advancing innovative therapies against pandrug-resistant Gram-negative superbugs" aims to develop novel inhalable powder formulations of liposomes against deadly Gram-negative lung infections. This is the second R01 grant that Tony has received from NIH as a continuing effort to fight the global crisis of antimicrobial resistance. His first NIH R01 grant with \$2.4M support was awarded in 2017, with 20 journal articles being published and 3 patent applications filed since then.

**Dr. Qi (Tony) Zhou and Dr. Elizabeth Topp** received an industrial grant from Genentech with a title "Electrospray Drying for Protein Formulations". This project aims to develop new protein solid formulations using an innovative technology, electrospray drying.

# Graduate Student Highlights

**Andrea Chambers (Matosevic group)** was selected to receive the 2019-20 Logan Travel Award, providing funding for her to attend the Society of Immunotherapy of Cancer Annual Meeting. She was also the recipient of the 2020 Migliaccio/Pfizer Graduate Fellowship in Pharmaceutical Sciences.

**Ahmed Elkhabaz (Taylor group)** received a Top Three Poster Award at the 2019 Gordon Research Seminar.

**Siddhi Hate (Taylor group)** was the recipient of a 2019 IPEC Foundation Graduate Student Awards. The award provided for her to travel to the AAPS 2019 Annual Meeting in San Antonio, TX in November, 2019. She also received an Outstanding Poster Award at the 2019 Gordon Research Conference.

**Nicholas Huls (Li group)** was the recipient of a 2019 Kienly Award from the College of Pharmacy. This award recognizes outstanding graduate student teaching assistants in the College of Pharmacy.

**Yue Li (Li group)** received a 2019 AAPS Best Abstract Award for the AAPS PharmSci 360 conference. The abstract, titled an *Integrating Lattice Boltzmann and Bonded Particle Models to Simulate Tablet Disintegration and Dissolution*, was among the top 10% of abstracts ranked by AAPS Abstract Screeners.

**Chailu Que (Taylor group)** received a Top Three Poster Award at the 2019 Gordon Research Seminar.

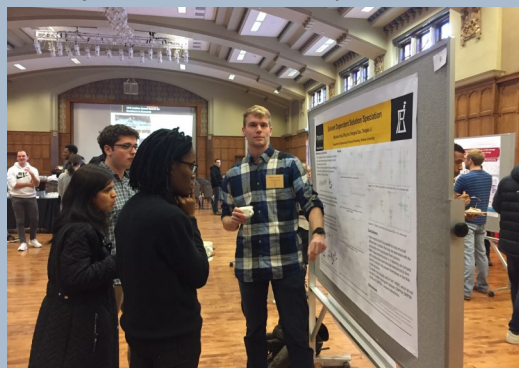
**Dana Moseson (Taylor group)** was the recipient of a 2019 IPEC Foundation Graduate Student Awards. The award provided for her to travel to the AAPS 2019 Annual Meeting in San Antonio, TX in November, 2019.

**Jianping Wang (Yeo group)** was the recipient of the 2019-2020 Ronald W. Dollens Graduate Scholarship.

**Simseok Yuk (Yeo group)** selected by the 2019 Baxter Young Investigator Awards Committee as the recipient of a 1<sup>st</sup> tier award. This award is given for outstanding research work which aligns with Baxter's mission of saving and sustaining patients' lives. Simseok was also selected by the faculty of Industrial and Physical Pharmacy to receive the 2019 Dr. Herbert A. Lieberman Award. This award recognizes Simseok's 2018-2019 leadership as the president of the AAPS Student Chapter as well as his efforts in serving as host for events such as technology presentations by representatives of national laboratories and pharmaceutical companies and completing the application work to receive a tier-one award in the Purdue Graduate Student Organization Grant Allocation (GSOGA). It is interesting to note that along with Simseok's activities here in IPPH, he is very involved on campus with activities such as conducting workshops in the Demonstration Kitchen, participating in intramural sports, bowling and more.



Award recipients, including Nick Huls (pictured below presenting his poster) and Simseok Yuk from IPPH, at the 2019 College of Pharmacy Graduate Awards Reception



Simseok Yuk is presented with the 2019 Dr. Herbert A. Lieberman Award by Dr. Eric Munson.

# Graduate Student Spotlight



## Siddhi-Santosh Hate

Fifth year student, Siddhi Hate grew up in Mumbai, India where she was passionate about two things, chemistry and

classical dance. Her journey into pharmacy was unplanned. "I joined Rutgers to pursue my Masters in Chemical Engineering. During that time, I spent six months in Austria as a research scholar in a pharmaceutical engineering center and I was working on developing a drug product from a patient compliance perspective. I was really fascinated by the complexities of overall drug product development process and intrigued by how this field impacted the society at large, which then led me to considering pharmaceuticals as a major for my PhD."

A member of Dr. Taylor's group, her research focuses on a mechanistic understanding of dissolution and absorption process for supersaturating drug delivery systems. She has developed an in vitro apparatus that can simulate the absorption process and provide simultaneous dissolution-absorption environment that exists in human gastrointestinal tract. This apparatus can give more predictive information, particularly for complex formulations that have solubilizing agents or generate thermodynamically metastable systems, based on the true amount of drug available for absorption and hence, bioavailability. What really motivates her about this work is that she can use her engineering principles to solve questions in the pharmaceutical industry.

Siddhi has this to say about her time here at Purdue, "There are great minds at Purdue and getting to learn from such pioneers is very exciting. Working in Dr. Taylor's lab has been an amazing journey. Dr. Taylor has made me an independent researcher and has constantly helped me make my way through challenging situations, be it personal or academic. I have learned quite a lot about effective decision-making from her. I also love spending time in the lab with all the group members, everyone is helpful towards each other and there is a constant exchange of ideas."

In her free time, she enjoys hiking and exploring new cities along with its food.



## Harshil Renawala

Harshil, a fifth year student in the Topp lab, also grew up in Mumbai, India's most cosmopolitan city and a melting pot of various cultures, customs and traditions. "Since my

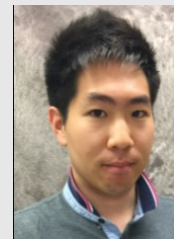
mom was a nurse at a prominent tertiary care hospital in south Mumbai, I grew up with a dream of having a career in the healthcare industry, improving lives of the sick and needy. A bachelor's degree in pharmaceutical sciences, imparting know-how of making life-saving medicines, seemed to be a step in the right direction."

His PhD research is aimed at improving stability of therapeutic peptide drugs in aqueous solution. Some peptide drugs are unstable in solution-state and form fibrillar aggregates that reduce potency and may cause life threatening immunogenic response, thus requiring lyophilized formulations. Apart from reducing higher manufacturing costs associated with lyophilization process, stable aqueous formulations can also be lifesaving in emergency situations by saving precious time spent for reconstituting lyophilized solids. "We are working towards understanding the molecular mechanism of aqueous instability of fibrillation-prone human calcitonin, a peptide hormone with therapeutic indications in postmenopausal osteoporosis and Paget's disease, and identifying structural modifications that improve its solution-state stability."

"A stable human-derived calcitonin can potentially replace the existing marketed salmon-derived calcitonin, which causes immunogenic response in some patient populations. The real-life applicability of my research is a source of great motivation," Harshil explains.

This past summer Harshil interned at Gilead Sciences, in the beach town of Oceanside, CA, where he had the opportunity to "be part of an excellent team doing meaningful research. Spending the summer at the Pacific coast, with sand, sun and salt-spray, is the highlight of my grad student life."

"When I was accepted to the Topp lab, I remember having a feeling of being on 'Topp' of the world. Dr. Topp leads by example, and I have derived immensely from her guidance and mentorship, both professionally and personally. IPPH students are a diverse group of individuals from various countries and continents, which creates a rich learning environment. I cherish their friendship, and what a rewarding journey it has been!!!"



## Simseok Yuk

While born in Salt Lake City, UT, Simseok, a fifth year student in the Yeo lab, spent his childhood in the Republic of Korea, returning to the

US for high school. After receiving his undergraduate degrees from Purdue University, Simseok originally went to a different school & discipline PhD program. The transition to the PhD program in Pharmacy was very difficult for him. However, Simseok has won 2 fellowship (**Purdue Research Foundation, Bilsland Dissertation**) and 6 awards (**1<sup>st</sup> place in podium PGSRM presentation at Minnesota, AAPS Purdue student chapter grant, College of Pharmacy Graduate Student Travel Award, Baxter Young Investigator 1<sup>st</sup> tier award, Dr. Herbert A. Lieberman Award, Dr. Jenkins-Knevel Award**) during his final PhD year.

Simseok's research involves developing a nanoparticle formulation for systemic treatment of sepsis and septic shock. Simseok was shocked to learn that overall crude hospital mortality rate of sepsis in Intensive Care Unit (ICU) is as high as 34.7%. Professor Yoon Yeo, influenced Simseok to pursue this area by teaching him how nanoformulation (with enhanced pharmacokinetics and attenuated systemic toxicities) could be used favorably to combat sepsis. Simseok proposes to develop a nanoparticle formulation of LPS antagonist that additionally includes immunomodulatory drug. The therapeutic effect of systemically administered nanoparticle formulation was evaluated in a mouse model of endotoxemia and the cecal ligation and puncture (CLP) model, a gold standard animal model of sepsis.

Of his time at Purdue he says, "Consider phase change diagram for a water ( $y = \text{Temp.}$  vs  $x = \text{Energy}$ ). For a water to change a state, there is a phase change, where temperature will not increase even with constantly applied heat. The energy added during phase changes is breaking the intermolecular forces. This is like when you are in graduate school. You won't see changes in yourself even with constant efforts you put in. But if you wait and put enough energy, you in the end will reach a different state of you."

# Alumni and Friends Focus

## Dr. Ehab Moussa



Dr. Moussa, a 2017 IPPH graduate, is a technical lead in the drug product development organization at AbbVie Inc. In this role, he is responsible for the formulation and manufacturing process development of biotherapeutics and small molecule parenteral products. He also serves as a subject matter expert on pharmaceutical freeze-drying within AbbVie. "I was at Purdue when the LyoHUB consortium started and was fortunate to be one of the first "Superusers" of the facility. I take special pride in this especially as I continue to be part of the consortium in my current role at AbbVie."

At Purdue, his research work was focused on improving and speeding up the development of therapeutic protein formulations. To this end, his thesis work was part of a larger research program in the group that was focused on developing reliable analytical methods that can accu-

rately predict long-term stability of therapeutic proteins in lyophilized and spray dried formulations. While at Purdue, Dr. Moussa was in Dr. Topp's group. "During the course of my first semester at Purdue, I talked to the different faculty to help me select a research adviser whose research interests best fit mine. When I met with Liz, it did not take long for her passion about biologics formulation to transpire to me. As more and more innovative and transformative biotherapeutic modalities are being developed, I can't be more excited about this area of work as I look forward to continuing to contribute to it."

His advise to current students is to "stay focused on the bigger picture of their work and how it can impact the way we formulate and manufacture drugs in order to deliver quality medicines to patients in need."

Jeffrey B. Rudolph received his PhD in Industrial and Physical Pharmacy and Pharmaceutical Sciences. His research at Purdue focused on long acting pharmaceutical product formulation factors for the release of medicinal agents. He continued to refine and develop his research throughout his career, a career that started in product development at Ciba. He then transitioned to formulation of pharmaceutical products at McNeil/Johnson & Johnson where he worked on the development of large-scale continuous tablet granulation for large consumer oriented pharmaceutical tablets. This was followed by 23 years at AstraZeneca where he retired after serving as the Vice President of International Pharmaceutical Development.

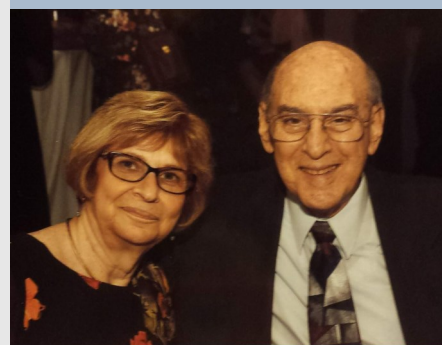
Dr. Rudolph remembers his time in Dr. Peck's group at Purdue very fondly. He appreciated the strong emphasis on industrial pharmacy and cherishes the relationships he built with faculty and fellow graduate students. In fact, he enjoyed time spent with the faculty and fellow students in IPPH so much that he and his wife, Gail invited the entire department to attend their wedding!

A fun story was shared that Dr. Rudolph was not able to attend the graduation ceremony to receive his Purdue Ph.D., so about 30 years later on May 10, 2000, he crossed the stage. The ceremony was even more special as Professor Emeritus Garnet Peck bestowed the honors. "Having Dr. Peck hood me was such an honor," comments Dr. Rudolph. "He played

such an important role in the education of many industrial pharmacy students, and having him participate in the ceremony was a small recognition for the tremendous contribution he has made over many decades."

To future and current IPPH students, Dr. Rudolph highly recommends making and maintaining contacts, including faculty, fellow students and those met through professional organizations while you are in graduate school. "Find the time to participate in and out of the department because those people will hold you in good stead for the rest of your career."

## Dr. Jeffrey B. Rudolph



*Jeff and Gail Rudolph*

*Below, Dr. Rudolph and Dr. Peck*



## Alumni and Friends Focus

Dr. Xiaorong He knows a thing or two about hard work as exemplified by the fact that she completed her PhD here at Purdue in a remarkable 2 1/2 years! Her institutional learning did not cease there though, as she also received her MBA from Western Michigan University while in the early years of her career. This career has been one of diversity including early stage formulation design at Pharmacia/Pfizer, late stage process development at GlaxoSmithKline, and building up a brand new division and doing business development at Asymchem Laboratories (close to her hometown of Beijing, China). This diverse experience in the pharmaceutical industry has given her an excellent platform to draw on when making decisions in her current position.

Today, she is the Head of Material and Analytical Sciences at Boehringer-Ingelheim (BI) in Connecticut. This department at BI supports drug substance and drug product development from early stage to launch. One of the key missions of the department is to develop cutting-edge technologies to enable efficient and effective drug development. Through her work in this area, she hopes to use these advanced predictive tools to provide innovative medicine to patients in a more cost and time effective manner. She enjoys working for BI which she claims is the best company that she has worked for with a nice work culture which allows employees to reach career goals while maintaining work-life balance.

While at Purdue, Dr. He was a member of Dr. Stephen Byrn's lab. "Purdue was like home to me. Dr. Byrn is an amazing person, academically accomplished, as well as a successful businessman. He was a father figure to those of us in his lab, hosting many gatherings in his home." Dr. He feels very privileged and fortunate to have had the opportunity of come to

the USA, and particularly to Purdue where she has such fond memories of her time in IPPH.

For the past 15 years, Dr. He has been very involved with USP ([www.usp.org](http://www.usp.org)), an organization which works "to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." She currently serves as the Chair of Physical Analysis Expert Committee, offering her scientific expertise on USP's Council of Experts.

In her free time, she loves spending time with her family, including her teenage children. The family looks forward to their annual summer trips back to Beijing where they reconnect with family and Chinese culture. Dr. He is also passionate about power yoga, not only as a way to stay fit, but also as a tool to calm the soul. To current students she emphasizes the benefits of embracing new opportunities and keeping an open mind as you never know what doors will open if you keep your options open.

Dr. Xiaorong He



## Industrial and Physical Pharmacy—Thinking of the Future

The Department of Industrial and Physical Pharmacy is well known for its expertise in pharmaceutical formulation and manufacturing. However, we also recognize that many individuals outside of our discipline have little understanding about what industrial and physical pharmacy means.

For this reason, the faculty has begun discussions about changing the name of the department to better reflect both the expansion into biologics as well as providing some clarification to people outside our discipline as to what we do as a department

I personally feel very strongly about Industrial and Physical Pharmacy, and one way to keep the name active is to form three specific divisions in the department, such as Industrial and Physical Pharmacy, Pharmaceutical Biotechnology, and Drug Delivery (titles and topics subject to change).

Regardless of what name we choose, our commitment to working with industry and maintaining our excellence in physical pharmacy remains unchanged.

If you have any thoughts on this, please feel free to email me with any thoughts or feedback on this initiative. My email is [munsone@purdue.edu](mailto:munsone@purdue.edu), and my phone is 765-494-1450.



## IPPH at Gordon Research Conference

The hills of Waterville Valley, NH were alive in June of 2019 with the sounds of science during the Preclinical Form and Formulation for Drug Discovery 2019 Gordon Research Conference (GRC). Co-chaired by Dr. Elizabeth Topp of Purdue University and Dr. Karthik Nagapudi of Genentech, this year's theme was "The Role of Form and Formulation Development in Transforming a New Era of Molecules into Therapeutics".

The conference brought together academic and industry leaders from both the small molecule and biologics areas to address challenges at the interface between drug discovery and preclinical/clinical development. Experts shared methodologies that enable the deep mechanistic insights into how different formulations and delivery systems work. Additionally, discussions focused on ways that science and technology could transform the current state in this area and identify further knowledge gaps in scientific understanding and technological capabilities that can be explored and discussed at future conferences.

Special presentations by Dr. Lynne Taylor, "Phase Behavior of Amorphous Solid Dispersions" and by Dr. Sandro Matošević, "Immunometabolic Reprogramming of Natural Killer Cells for Immunotherapies of Solid Tumors" were given and Dr. Taylor was selected to serve as the incoming Vice Chair and Co-Chair for the 2021 and 2023 conferences, respectively. According to Dr. Taylor, "The GRC meeting provides an opportunity to deliver cutting edge science at the interface of different disciplines to the pharmaceutical sciences community. I am excited to be one of the conference leaders and have the opportunity to deliver innovative programming to a broad cohort of scientists."

Out of over 81 poster presentations for the conference, nine IPPH presenters were awarded Top 25 Gordon Research Conference Poster Awards. The recipients were: Karthik Balakrishna Chandrababu, Lia Bersin, Van Tu Duong, Ahmed Elkhazab, Siddhi Hate, Dana Moseson, Tarun Mutukuri, Sugandha Saboo, as well as IPPH Adjunct Faculty from Merck & Co., Dr. Yongchoa Su. In addition, Siddhi Hate received an Outstanding Poster Award presented to the top four posters.

"It was terrific to have such a great turn-out of IPPH faculty, post docs, grad students, and alumni at the meeting. The level of science was excellent, and Purdue was very well represented among the speakers, poster presenters (and winners!) and conference organizers," says Dr. Topp.



*IPPH participants at the 2019 Gordon Research Conference*

Held in conjunction with, and two days prior to the start of the Gordon Research Conference, the Gordon Research Seminar (GRS) offers a "unique opportunity for young scientists, including graduate students, post-docs, and other early career scientists, to present unpublished cutting-edge research and to exchange ideas and experiences leading to new collaborations as well as career development." Dr. Yongchao Su (IPPH adjunct faculty member), Dr. Haichen Nie (IPPH Alumni), Nathan Wilson (IPPH graduate student) and Yihua Pei (IPPH graduate student) all presented at the seminar.

Also during this seminar, IPPH graduate students, Chailu Que and Ahmed Elkhazab received Top Three Poster Awards.

Ashley Lay-Fortenbery (Dr. Munson's student from the University of Kentucky) co-chaired this year's GRS, and Lia Bersin (IPPH graduate student) was elected to be the chair of the 2021 Preclinical Form and Formulation for Drug Discovery Gordon Research Seminar. Lia will work with co-chair, Matthew Defrese from the University of Kentucky, with guidance from the chairs for the 2021 GRC and co-chairs for the 2023 GRC, to organize the program for the 2021 GRS, which will predominately consist of presentations from other graduate students and post-docs. Additionally, there will be talks from drug development experts from academia and industry.

Of the opportunity, Lia says, "I'm looking forward to giving back to the organization and scientific community through the GRS chair position. I also see great personal growth opportunities through the planning process, from exposure to new topics in drug discovery to interfacing with exceptional scientists from both industry and academia. I am especially looking forward to working with the chairs and co-chairs of the future GRCs. I think there will be so much for me to learn from this group of all women!"

For more information about the Gordon Research Conference, visit <https://www.grc.org>

## IPPH News and Events



### CONGRATULATIONS IPPH GRADUATES!

Ahmed Elkhabez,  
PhD  
Taylor Group



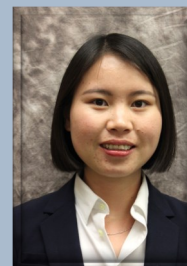
**Thesis Title:** Characterization of the phase behavior of supersaturated solutions in simulated and aspirated human fluids

Kelsey Lubin,  
PhD  
Knipp Group



**Thesis Title:** Design of experiment based optimization of a direct contact blood brain barrier in vitro model for neuroactivity screening

Chailu Que,  
PhD  
Taylor Group



**Thesis Title:** Impact of crystalline residues in amorphous solid dispersions on supersaturation

Nivedita Shetty,  
PhD  
Zhou Group



**Thesis Title:** Effects of storage humidity on physical stability and aerosol performance of spray-dried dry powder inhaler formulations

Nathan Wilson,  
PhD  
Zhou Group



**Thesis Title:** Effects of formulation and manufacturing conditions on protein structure and physical stability

## In Memorium

David Lindley, a 2009 IPPH graduate from Dr. Knipp's group, passed away on September 5, 2019. Condolences from the entire IPPH family are extended to his family and friends. Dr. Lindley's obituary can be viewed at <https://www.legacy.com/obituaries/southbendtribune/obituary.aspx?n=david-lindley&pid=193846415&fhid=8846>

## Save the Date

### Garnet E. Peck Symposium October 29, 2020

Beginning this year, IPPH will host TWO Peck Symposiums. The first, being held on March 25, 2020 will be a science symposium titled, "New Therapeutic Frontiers: Immunotherapies from Genes to Cells". The second to be held on October 29, 2020 will focus more on alumni, students and departmental issues. We hope to see you next year at the Peck Symposiums!

## Faculty Opening in IPPH: Assistant Professor / Associate Professor / Professor

The College of Pharmacy at Purdue University is seeking applications to fill a faculty position in the Department of Industrial and Physical Pharmacy in the general area of **Pharmaceutical Biotechnology**.

The position is for a full-time tenure-track Assistant Professor, Associate Professor or Professor. The faculty member is expected to establish an externally funded research program and will teach courses in the undergraduate, graduate and professional (PharmD) programs. It is expected that the individual will collaborate on various research activities within the department and in multidisciplinary, multi-institutional research throughout the University. This is a nine-month (academic year) appointment.

The candidate must have expertise in fundamental and applied research related to the development, design, evaluation and manufacturing of biopharmaceutical products. Representative areas of expertise include, but are not limited to:

- Formulation, analysis and manufacturing of peptide, protein, cell-based and/or nucleic acid-based therapeutics
- Formulation, analysis and manufacturing of vaccines and/or immunotherapeutics
- Drug/device combinations and drug/material interactions for biologics
- Preclinical drug disposition (PKPD), in vitro in vivo correlations
- Interactions of drugs and dosage forms with the gut microbiome

For instructions on how to apply, visit <https://www.ipph.purdue.edu/about-IPPH/open-positions>



## LYOHUB HIGHLIGHTS

- LyoHUB celebrated the 50th anniversary of the Apollo 11 Moon landing during **Lyo Summer School 2019**. This year's summer school focused on **Lyo 201: Characterization of Lyophilized Solids** and included a presentation on ssNMR by IPPH Department Head, Dr. Eric Munson and a ssHDX-MS tutorial by IPPH professor, Dr. Elizabeth Topp.
- In September, 2019, LyoHUB held a meeting at the National Institute of Standards and Technology (NIST) titled, Standards and Best Practices for Pharmaceutical Lyophilization. Talks included **Use of Modeling and Simulation in Drug/Device Development and Regulatory Evaluation** by Tina Morrison (FDA), **Analytical Technologies for Product Quality Measurements** by John Schiel (NIST), **Drug Substance Manufacturing** by Scott Lute (FDA) and **Regulatory Review Perspective on Lyophilization** by Steve Rhiu (FDA). The day also included a panel on the **"Use of Standards in Validation for Lyophilization and other Pharmaceutical Processes"** and one featuring organizations working in lyophilization.



**Now Available from LyoHUB**

### Online Lyophilization Short Course

Featuring eight online lyophilization 101 learning modules, together with assessment tools and instructions for a virtual laboratory exercise. There is no fee to take this course thanks to a grant from the National Institute for Innovation in Manufacturing (NIIMBL)

<https://pharmahub.org/courses/lyo101>

For the latest news from LyoHUB, you can visit their website (<http://www.lyohub.org>) and follow them on Twitter at <http://twitter.com/lyohub>.



## IPPH News

*Purdue University*

### **Seventeenth Annual Garnet E. Peck Symposium**



*“New Therapeutic Frontiers:  
Immunotherapies from Genes to Cells”*

**March 25, 2020**

Purdue University, West Lafayette, Indiana

*The Peck Symposium is hosted by the Department of Industrial and Physical Pharmacy*

<http://www.ipph.purdue.edu/peck/>

Registration questions? *Email Jennifer Gray, IPPH Communications Coordinator*  
[gray160@purdue.edu](mailto:gray160@purdue.edu)

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