

IPPH NEWSLETTER

INDUSTRIAL & PHYSICAL PHARMACY



GREETINGS
from the department head



Dear Alumni and Friends;

It was one of the most contentious presidential elections in history, and the outcome has been called a victory of the common man over the educated elite. Higher education, of course, is what we do here in IPPH. Our mission is to educate students to become leading pharmaceutical scientists and pharmacists, to advance scientific discovery, and to contribute to society through outreach and public service. Our mission is rooted in Midwestern practicality, embraces the land grant idea of fostering opportunity and economic development, and aspires to create new medicines that improve human health. Are we elite in the quality of our faculty, our graduates and our scientific contributions? You bet. Are we elite in our rarefied isolation from the real world? Not on your life.

Take a few minutes to catch up with us in this newsletter. Meet graduate student Aimable Ngendahimana, a native of Rwanda studying the blood-brain barrier. Learn about Dr. Qi “Tony” Zhou’s work to improve inhalation therapies for life-threatening lung infections. Catch up on our latest pharmaceutical manufacturing initiatives in CPPR and in LyoHUB. Find out about our upcoming Garnet E. Peck symposium celebrating the life and work of Dr. Steve Byrn; we’re calling it “Outside the Box”. And allow us to brag about our faculty and graduate students, whose accomplishments help to make better medicines for us all.

Happy holidays from all of us here at IPPH! Boiler up!

A handwritten signature in black ink, appearing to read 'L. Topp'.

Liz Topp

Dane O. Kildsig Chair and Department Head



FACULTY HIGHLIGHTS

Dr. Steve Byrn received the AAPS Dale E. Wurster Research Award in Pharmaceuticals. The award recognizes individuals who have made significant research contributions to pharmaceuticals, and is among the most prestigious of the AAPS awards. The Wurster award consists of \$10,000, an engraved plaque, and travel expenses and meeting registration for the 2016 AAPS Annual Meeting and Exposition in Denver.

Dr. Greg Knipp was appointed as the new Chair of the IPPH Ph.D. Admissions Committee.

Dr. Rodolfo Pinal was appointed as the new Director of the IPPH Ph.D. Program.

Dr. Lynne Taylor and **Dr. Qi "Tony" Zhou** received a new award from the Bill & Melinda Gates Foundation to support the project entitled, "CMC Pilot Project to Evaluate Novel Drug Product Manufacturing Technologies".

Dr. Lynne Taylor received a new award from Pfizer to support her project entitled, "Improved Mechanistic Understanding of Salt Disproportionation in Solid Oral Dosage Forms".

Dr. Yoon Yeo received a research grant from the Purdue Research Foundation (PRF) for her proposal entitled "Particle Engineering for Intracellular Delivery for Vancomycin"

Dr. Yoon Yeo was appointed as the new Associate Department Head of IPPH.

Dr. Yoon Yeo received notice of award for the following patent:

Yeo, Y., Bajaj, G., Xu, P., Liu, K., and Cho, E.J. 2016. Chitosan derivatives for inactivation of endotoxins and surface protection of nanoparticles. United States Patent 9,393,262.

Dr. Qi "Tony" Zhou was selected to receive a 2016 Emerging Researcher Award from the International Pharmaceutical Excipients Council-Americas Foundation. This award is for \$15,000 over two years and was formally presented at the 2016 AAPS Annual Meeting and Exposition in Denver.

Dr. Qi "Tony" Zhou has been appointed to a three-year term on the editorial advisory board (EAB) of the *Journal of Pharmaceutical Sciences*. EAB members advise the editors on the scientific direction of the journal and contribute significantly to reviewing submitted manuscripts.

GRADUATE STUDENT HIGHLIGHTS



Anura Indulkar (Taylor group), **Laura Mosquera-Giraldo** (Taylor group) and **Ehab Moussa** (Topp group) were each awarded a McKeehan Graduate Fellowship in Pharmacy by the College of Pharmacy. The McKeehan Fellowship provides partial stipend support for graduate students with research interests in the physical sciences, and is awarded on the basis of a competitive application.

Anura Indulkar (Taylor group) was selected to receive the 2016 Graduate Student Research Award in Physical Pharmacy and Biopharmaceutics from the AAPS. The award was conferred at the 2016 AAPS Annual Meeting and Exposition in Denver this November.



Monika Lavan (Knipp Group) received the Kienly Award as the outstanding graduate teaching assistant in the Department of Industrial and Physical Pharmacy. The award was presented at the Graduate Student Awards Ceremony on Tuesday, November 8th in the South Ballroom of the Purdue Memorial Union.



Laura Mosquera-Giraldo (Taylor group) received a 2016 Graduate Student Scholarship from the International Pharmaceutical Excipients Council-Americas Foundation which included a certificate and a \$1500 monetary award.

Laura Mosquera-Giraldo (Taylor group) has been selected to continue her research under a 2016 AAPS Foundation Graduate Student Fellowship for a second year. The award provides \$10,000 in support of Laura's research through August of 2017.



Ehab Moussa (Topp group) received a 2016 BIOTEC Section Travelship to attend the 2016 AAPS Annual Meeting and Exposition in Denver this November. The award provides up to \$750 to be used toward travel and lodging.

Ehab Moussa (Topp group) received the Jenkins-Knevel Award for Outstanding Graduate Research from the College of Pharmacy. The award was presented at the Graduate Student Awards Ceremony on Tuesday, November 8th in the South Ballroom of the Purdue Memorial Union. At the ceremony, Ehab and other awardees gave brief presentations on their research.

GRADUATE STUDENT HIGHLIGHTS (continued)



Joonyoung Park (Yeo lab) received a Baxter Young Investigator Award. The award includes an unrestricted honorarium of \$2,000.00 and paid travel to an awards ceremony at Baxter’s North American R&D center in Round Lake, Illinois. The awards ceremony was held on Thursday, October 6th, during which Joonyoung gave a presentation on his research.

Yihua Pei (Yeo lab) received the Chaney Graduate Student Travel Award.

Yihua Pei (Yeo lab) was awarded a PRF Research Grant Fellowship for the proposal entitled, “Particle Engineering for Intracellular Delivery for Vancomycin”.

Hitesh Purohit (Taylor group) was selected to receive the 2016 Graduate Student Research Award in Formulation Design and Development from the AAPS. The award was conferred at the 2016 AAPS Annual Meeting and Exposition in Denver this November.

Hitesh Purohit (Taylor group) received a 2016 Graduate Student Scholarship from the International Pharmaceutical Excipients Council-Americas Foundation which included a certificate and a \$1500 monetary award.



Venecia Wilson (Taylor group) is the recipient of this year’s Lieberman Award from IPPH. The award recognizes her outstanding service as a graduate student leader and teaching assistant for Dr. Byrn. The Lieberman award was funded by Mr. Bruce Lieberman to honor his late father, Dr. Herbert Lieberman, author of *The Theory and Practice of Industrial Pharmacy*. The award consists of a \$500 award to the recipient.

Jun Xu (Yeo lab) received a Lilly Endowment Gift Graduate Research Award for his proposal entitled “Engineering Leukocyte Mimetic Nanoparticles for Enhancing Extravasation at Peritumoral Endothelium”.



In June, **15 IPPH graduate students** participated in the Pharmaceuticals Graduate Students Research Meeting (PGSRM) 2016, held in Kansas City. This year’s theme was “From Benchtop to Bedside: Translational Medicine Today”. This theme focused on efforts in drug research, discovery and development coming together to achieve the common goals of curing disease and advancing therapeutics. Delegates from more than 20 pharmacy schools and several pharmaceutical companies met to learn about the latest trends in pharmaceutical research, and to meet experts from both industry and academia.

“The PGSRM meeting was a great opportunity to learn and discuss research with people from other institutions who are involved in similar fields of study,” said **Nathan Wilson (Topp Group)**.

IPPH STAFF HIGHLIGHTS

In August, **Jennifer Gray's** responsibilities were expanded to include Communications and Events Coordinator for IPPH and the Center for Pharmaceutical Processing Research. She joined the department as Communications and Events Coordinator for the new LyoHub project in IPPH in September of 2015.



Meet Aimable Ngendahimana

Fifth-year graduate student **Aimable Ngendahimana** (Knipp group) was born and raised in Rwanda. He hopes to use the research he's conducting here at Purdue to improve the process of CNS (Central Nervous System) drug discovery and development.

Aimable's father, a nurse by profession, influenced him to study pharmacy. Shortly before the Rwandan-genocide, his parents owned a small pharmacy in their home village in Rwanda. As nurses, they were actually licensed to prescribe drugs for patients! As a young boy, Aimable helped in the store and observed his parents dispensing malaria or typhoid medications to very sick patients. He himself contracted malaria twice and was treated by his parents with Fansidar or Chloroquine which according to Aimable are very bitter medications! Based on his childhood experiences, he became fascinated by how miraculously malaria medicines saved him. His family moved to Kenya in 1994, following the Rwandan conflict, in search of better educational opportunities. In Kenya, Aimable learned English. His father advised him that if he became a chemist, he would understand how medicines heal patients. Thus, while in Kenya, Aimable received his degree in chemistry and returned to Rwanda to teach chemistry and physics in English as the country transitioned from being a Francophile country to a bilingual one. Through his study of chemistry, Aimable learned how to synthesize molecules but never really learned how pharmaceutical products (tablets, capsules, etc.) were made. In 2007, he departed his country once again in search of higher educational opportunities, attending graduate school at Youngstown State University-Ohio.

In 2011, Aimable came across a story on the IPPH website about Dr. Byrn's work in Africa (Tanzania). According to Aimable, "I was highly motivated. I knew that if I became a graduate student in IPPH at Purdue, I would also have an opportunity to work with Dr. Byrn in his program in Tanzania. I could see myself one day in Tanzania, making medicines, something that I had always wanted to do. So, I applied at Purdue, got admitted and in the summer of 2015, my dream came true." Aimable travelled to the Kilimanjaro School of Pharmacy in East Africa to participate in teaching a lab in pharmaceutical unit operations with Dr. Byrn. While there, he was able to network with many pharmacy professionals from all over Africa. They were attending a course in pharmaceutical regulatory affairs, and were happy to meet a Rwandan student from Purdue.

IPPH GRADUATE STUDENT SPOTLIGHT (continued)

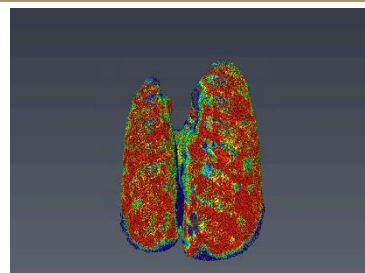
Aimable is currently doing research on drug permeation through the Blood-Brain Barrier (BBB). Currently, brain diseases such as Alzheimer have no cures. The BBB has been implicated in many such brain diseases. A novel methodology is being studied which may be used to predict whether a CNS-drug candidate can be well absorbed into the cerebral cortex at the very early stage of CNS-drug discovery or development. “I like my research on the BBB because it requires me to apply two important areas of pharmaceuticals: knowledge of physico-chemical properties of drugs and how to overcome physiological barriers of drug absorption. It is a very interesting area of research,” says Aimable.

A highlight of his time here at Purdue has been the industrial mentoring from **Dr. Royal J. Haskell** through AAPS. “Dr. Haskell has been helping me to learn more about the pharmaceutical industry, and I feel very lucky to have him as my mentor.”

When taking a break from his studies, you may find Aimable hanging out with friends from IPPH, nicknamed the “Chailu-group”, playing tennis and basketball or watching science fiction movies. Aimable plans to graduate in May of 2017.



Dr. Qi “Tony” Zhou Combating Deadly Lung Infections with an Inhalation Approach

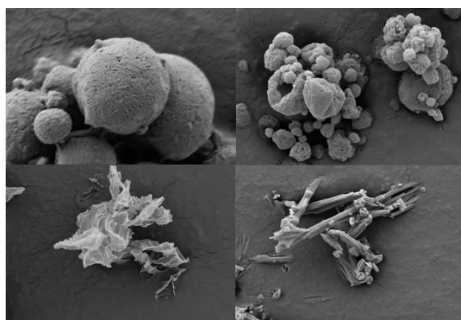


WHO has identified antimicrobial resistance as one of the three greatest threats to human health. Many clinicians worldwide have already been confronted with deadly lung infections caused by *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *Acinetobacter baumannii*, which are resistant to all current antibiotics except for the last-line defense, colistin. Colistin became available in the clinic in the late 1950s; but has rarely been used since the 1970s largely due to its nephrotoxicity. As a result of the emergence of MDR Gram-negative pathogens and the dry antibiotic pipeline, colistin has been brought back into clinical use over the last decade, demonstrating very effective bacterial killing activity against Gram-negative ‘superbugs’.

Lung infections are the fourth leading cause of death globally, and those caused by MDR Gram-negative pathogens are very dangerous and particularly difficult to treat. Colistin is often the only option but parenteral therapy has very limited efficacy in the treatment of lung infections due to limited drug exposure at the infection sites. Simply increasing the dose of parenteral colistin is not feasible because of the dose-limiting nephrotoxicity. Nebulized colistin has been used in the clinic for the treatment of lung infections in an attempt to circumvent the limitations of the parenteral route, but current inhaled colistin therapies have very poor delivery efficiency (typically <40% of drug is delivered to the lungs) and, thus, exhibit compromised efficacy and significant pulmonary adverse effects (e.g. cough and throat irritation). Although FDA has never approved inhaled colistin products, off-label use of injectables is common in the clinic. Surprisingly, such off-label use is entirely empirical and no systematic evaluations have been conducted on potential pulmonary adverse effects and clinical effectiveness of inhaled colistin. The lack of key safety and efficacy information significantly limits their clinical utility. Thus, there is an

urgent need to develop optimized inhalation therapies of colistin.

A research program led by Dr. Qi “Tony” Zhou will develop much safer and more efficacious inhalation therapies of colistin for better treatment of deadly Gram-negative lung infections. This multidisciplinary project will first design innovative inhaled formulations with superior delivery efficiency by novel particle engineering techniques. The project will then determine the disposition and potential toxicity of colistin in the lungs using systems pharmacology. Finally, dosage regimens for inhaled colistin will be optimized based on the pharmacokinetics (PK)/pharmacodynamics (PD) in animal lung infection models. The project will be performed through collaborations with an international leader in colistin pharmacology, Prof. Jian Li at Monash University of Australia and a world-leading antimicrobial pharmacometrician, Prof. Alan Forrest at the University of North Carolina. Eventually, Dr. Zhou hopes the success of this project will save many lives from dangerous Gram-negative lung infections.



Novel particle engineering techniques can manipulate particle properties and produce ‘smart’ particles with superior drug delivery efficiency for inhalation therapies.



NEWS & EVENTS
department happenings

CONGRATULATIONS IPPH GRADUATES!

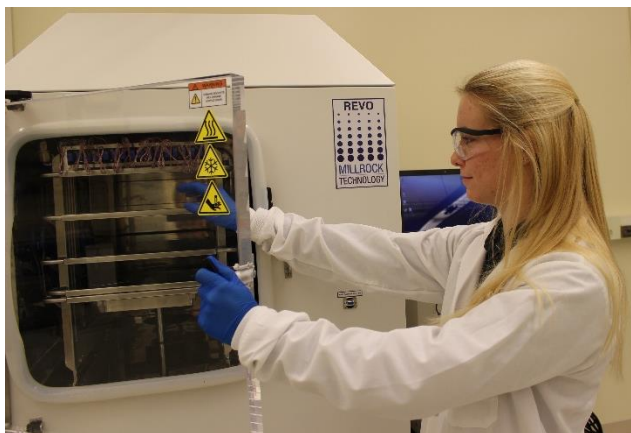
August 2016

- Jainik Panchal
- Rubayat I. Khan, MS

December 2016

- Christopher D. Kulczar
- Haichen Nie

LyoHub Opens New Demonstration Facility in Birck Nanotechnology Center and Continues Work on the Lyophilization Technology Roadmap



The new LyoHUB demonstration facility, located in Purdue's Birck Nanotechnology Center, currently houses three lab-scale lyophilizers: LyoStar 1 with Millrock Controlled Nucleation, Millrock Revo and SP Scientific LyoStar 3. It is also equipped with an Inficon Mass Spectrometer and a McCrone Freeze Dry Microscope.

Managed by two trained superusers, the LyoHUB demonstration facility conducts a wide spectrum of lyophilization research in areas such as operational qualification of lyos, wireless temperature sensor characterization (Purdue ECE), therapeutic protein stability,

freeze drying of gelatin foam, BPA antigen, and biologic sample preparation for X-ray photoelectron spectroscopy.

LyoHUB offered its first LyoHUB member training workshop in October of this year.



LyoHUB Members met in Chicago for the Annual LyoHUB meeting in April 2016

The new consortium, led by **Dr. Liz Topp**, IPPH Department Head, and **Dr. Alina Alexeenko**, Professor in Aeronautics and Aerospace Engineering, also continues to develop and refine a lyophilization technology roadmap. In recent months, meetings were held in Chicago, Washington DC and at Purdue in order to further these efforts. Visit the LyoHUB website (www.lyohub.org) for additional information on this growing consortium.



Jeff Browne of Catalent provided the keynote speech for CPPR Conference at Purdue in October 2016

Dane O. Kildsig
CPPR Center for
Pharmaceutical
Processing Research

The Center for Pharmaceutical Processing Research met in October 2016 at Purdue University for its biannual conference and to review proposals for the next two years. One such proposal from Purdue University was selected for funding. The proposal, submitted by Dr. Gregory Knipp, is entitled “Development of a Pediatric Platform Mini-Tablet Formulation for Expedited Preclinical Studies”. According to Dr. Knipp’s proposal, a paradigm shift is taking place in pediatric formulation. “Traditional views over the last couple of decades have been to protect children **from** clinical research. – However, the current regulatory paradigm shift is to now protect children **through** clinical research.” The new challenges identified, based on the paradigm shift, are predicated on the fact that children are not miniature adults. Deficiencies in child safety and efficacy in preclinical models need to be addressed and should allow for pediatric patient age classification and age appropriate formulation (formerly made primarily through compounding). Dr. Knipp’s project will address these challenges by developing a “flexible mini-tablet formulation capable of incorporating a variety of active pharmaceutical ingredients for adjustable pediatric dosing”, and by testing their pharmacokinetic profiles in the juvenile porcine model. Dr. Knipp’s laboratory has published several papers demonstrating the potential of the porcine model as preclinical surrogates for children and adults.

CPPR will next meet at the University of Minnesota in May of 2017.

Faculty Openings: IPPH is Seeking Qualified Applicants for Two Positions:

Assistant Professor of Industrial and Physical Pharmacy (Pharmaceutical Solids)

This position is for a full-time tenure-track Assistant 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 should have expertise in fundamental and applied research related to the development, design, analysis and manufacturing of drug products. Representative areas of expertise include:

- *Pharmaceutical materials science*
- *Pharmaceutical engineering*
- *Crystallization and particle technology*
- *Solid state chemistry of pharmaceutical systems*
- *Unit operations/continuous manufacturing associated with drug substance and drug product*

Assistant Professor of Industrial and Physical Pharmacy (Pharmaceutical Biotechnology)

This position is for a full-time tenure-track Assistant 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 should have expertise in fundamental and applied research related to the development, design, evaluation and manufacturing of biopharmaceutical products. Representative areas of expertise include:

- *Formulation and manufacturing of peptide, protein, and/or nucleic acid-based therapeutics*
- *Analysis, processing and engineering of therapeutic proteins*
- *Vaccine formulation development*
- *Formulation of immunotherapeutics*
- *Preclinical drug disposition (PKPD), in vitro in vivo correlations*
- *Gut pharmacomicrobiomics*

For information on applying for either position, please visit the IPPH website at www.ipph.purdue.edu or e-mail Mary Ellen Hurt, Assistant Professor Search Committee at mhurt@purdue.edu

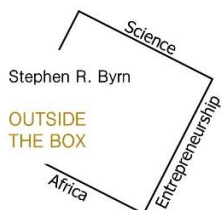
FOURTEENTH ANNUAL GARNET E. PECK SYMPOSIUM



March 28 & 29, 2017

Purdue University - West Lafayette, Indiana

“Outside the Box: Celebrating the Life and Work of Stephen R. Byrn”



Co-chaired by:

- **Dr. Lynne Taylor**, Retter Professor of Pharmacy
- **Dr. Elizabeth Topp**, Dane O. Kildsig Chair and Department Head

The Peck Symposium is hosted by the Department of Industrial and Physical Pharmacy, the Dr. Garnet E. Peck Graduate Scholarship Fund, the College of Pharmacy and the Varro E. Tyler Lectureship Fund.

Registration will be available online in early 2017. Questions? Email ipphcomm@purdue.edu

*The annual Peck Symposium honors the late **Garnet E. Peck, Ph.D.**, Professor Emeritus of the department of Industrial and Physical Pharmacy at Purdue University. Dr. Peck left a record of enduring contributions to the pharmaceutical sciences, including the development of latex-based tablet coatings that have been used in the industry for more than thirty-five years. The goal of this event is to stimulate interest in the symposium's focus areas and to identify opportunities for new research.*

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Department of Industrial & Physical Pharmacy

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