June 2015

IPPH NEWSLETTER

INDUSTRIAL & PHYSICAL PHARMACY

PURDUE
COLLEGE OF PHARMACY

GREETINGS from the department head

Dear Alumni and Friends,

We're rolling into summer here at Purdue. We have flowers, we have birds, we have green grass, we have construction, we have prospective students touring the campus with their parents and guides walking backwards – all clear signs that summer is finally here! The old ENAD building has been torn down and a new Active Learning Center is going up in its place; it'll have lots of classroom space, some library facilities and a great view of the bell tower. A new residential honors college is also under construction. At the same time, we're working hard to control affordability and accessibility to higher education, a real priority for President Mitch Daniels.

We're delighted to share the latest IPPH happenings with you in this newsletter. You'll meet Jainik Panchal, a graduate student from Ahmedabad, India, who's working on protein drugs. You'll learn about research in my lab on the immunogenicity of protein aggregates, a common impurity in biologics. You'll find a summary of our 2015 Peck Symposium, which had record attendance, fabulous speakers and a celebration of Dr. Kinam Park's career. You'll also learn about the many awards received by our students and faculty; it just wouldn't be summer if we didn't brag about them.

Thanks for catching up on the IPPH news. If your travels bring you to West Lafayette this summer, do stop by – we'd love to see you. Boiler up!

Liz Topp
Dane O. Kildsig Chair and Department Head

In Memoriam:

Dr. Kenneth R. Heimlich (1932-2015)

The Department of Industrial & Physical Pharmacy shares the passing of College of Pharmacy Distinguished Alumnus Dr. Kenneth R. Heimlich, on March 17, 2015.

"Dr. Heimlich was a friend of IPPH and of the Center for Pharmaceutical Processing Research (CPPR)," said Dr. Rodolfo Pinal, CPPR Director. "For the first ten years of the Center, Dr. Heimlich served as the NSF appointed evaluator of this I/UCRC (Industry/University Cooperative Research Center). Subsequently and until his retirement, Dr. Heimlich continued his valuable contributions as Center Evaluator and as a champion for the (NSF-graduated) CPPR. He will be missed with sorrow but remembered with respect and gratitude."

Dr. Heimlich received a BS (1954), MS (1956), and PhD (1958) as well as an honorary doctorate of science (1990) from Purdue University and the College of Pharmacy. He was a past member of the Dean's Industrial Council, and during his career he also worked at GlaxoSmithKline and Merck until he retired in 1995. He was named a Purdue University College of Pharmacy Distinguished Alumnus in 1984.

"Ken was a fine gentleman and a terrific, proud alumnus," said Dr. Greg Knipp, IPPH Associate Professor. "This is a big loss for our department."

Dr. Heimlich's Life Celebration service took place on April 18 at Christ Memorial Lutheran Church in Malvern, PA, followed by a private interment.

In lieu of flowers, memorial contributions can be made in his honor to: Neighborhood Hospice, 400 East Marshall St., West Chester, PA 19380, or Christ Memorial Lutheran Church, 89 Line Road Malvern, PA 19355.

Obituary

HIGHLIGHTS from the department

FACULTY HIGHLIGHTS

Dr. Liz Topp's proposal entitled "Advanced Lyophilization Technology Consortium for Manufacturing of Food, Pharmaceuticals and Biotech Products" was funded by the National Institutes of Standards and Technology (NIST). The award started in June 2015 and provides two years of support to develop a new industry-led consortium and conduct technology

roadmapping. More

Dr. Yoon Yeo received the first-ever Chaney Family Early Scholar Award from Purdue's College of Pharmacy. She also received a Challenge Award from the Purdue University Center for Cancer Research and was recognized for this award at the 2015 Purdue Challenge® 5K Walk/Run on April 18. And her research on novel drug delivery systems was featured in the Jan. 27 issue of Purdue Today. More

Dr. Rodolfo Pinal was elected to the Purdue University Innovator Hall of Fame for developing new technologies for precision compounding of drugs commercialized through his company, BioKorf, LLC. Read about this in MedCity News, and watch a video about the company. More

Dr. Liz Topp's group received funding from MedImmune for a project entitled "Solid-state Hydrogen/Deuterium Exchange with Mass Spectrometric Analysis (ssHDX-MS) for a Lyophilized Monoclonal Antibody (MAb)". The award provides two years of funding. Research Scientist S. Moorthy Balakrishnan of the Topp group will help direct the work. More

Dr. Keith Chadwick received a Research Starter Grant in Pharmaceutics from the Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation for his project entitled "Controlling Crystallization on Polymeric Excipients for the Advanced Manufacture of Drug Formulations". He also received a Summer Faculty Grant from the Purdue Research Foundation for his project entitled "Heterogeneous crystallization in polymeric microspheres: The advanced manufacture of oral dosage forms in four steps". More

Dr. Greg Knipp's project entitled "SaliPhe, a promising broad spectrum antiviral for alphavirus infections" received funding from Omm Scientific to develop various formulations of SaliPhe and evaluate their pharmacokinetics in rats and mice. More

Congratulations to Dr. Kinam Park for 30 years of research on Drug Delivery! He also recently established a partnership with Chong Kun Dang (CKD) Pharmaceutical Company, a leading pharmaceutical company based in Seoul, South Korea. Dr. Andrew Otte, an IPPH alum, will serve as Manager of the CKD Laboratory at Purdue University. More

Dr. Liz Topp's group received a Pfizer, Inc., award to support a four-year research project entitled "Biotherapeutic aggregation and immunogenicity". IPPH graduate students Jainik Panchal and Ehab Moussa will be involved in the project. Her group also received an award from MedImmune, Inc., that will support a contractual research project entitled "Pyroglutamate Formation in Lyophilized Powders" over a three-year period. Graduate student Anshul Mishra will be primarily responsible for the work. More

More Faculty Highlights

GRADUATE STUDENT HIGHLIGHTS

Venecia Wilson (Taylor group) received a Teaching Academy Graduate Teaching Award from Purdue University's Center for Instructional Excellence (CIE). This award recognizes Venecia's many contributions as a TA in IPPH 562, in the mini-tableting labs and in the Molecular Basis of Manufacturing course. She was honored at the Annual Celebration of Graduate Student

Teaching Excellence on April 29. More

Jing Ling (Chadwick group) received a research grant from the Purdue Research Foundation for her proposal entitled "The Rational Design of Excipient Surfaces for Controlling the Crystallization and Physicochemical Properties of Drug Compounds". The grant provides partial support for one year. More

Senior graduate student Ehab Moussa (Topp group) received a a research grant for one year from the Purdue Research Foundation for his proposal entitled "Analytical Characterization and Formulation of Monoclonal Antibodies in the Solid and Liquid State". He also received a travel award from AMGEN to attend the 2015 AAPS National Biotechnology Conference in San Francisco, California, June 8-10, 2015. More

Two IPPH graduate students, Joonyoung Park (Yeo group) and Arjun Kalra (Li group), were chosen with three other students (out of 48) to present their posters to the 2015 Peck Symposium on Feb. 27. More

Senior graduate student Sara Ahmed (Yeo group) received an award from the Purdue University Center for Cancer Research Hasson Graduate Travel Fund. She plans to use it to attend the Cancer Nanotechnology Gordon Research Conference on "Nanomedicines from Laboratory to Clinical Reality" this summer in Vermont. More

Senior graduate student Bo Sun (Yeo group) received a travel award from the Purdue University Center for Cancer Research Hasson Graduate Travel Fund. The award provides partial reimbursement for research-related travel in 2015. More

More Graduate Student Highlights

SPOTLIGHT IPPH graduate student

Meet Jainik Panchal

Jainik Panchal (Topp group) knows about protein drug delivery, and wants his research to help make safer drugs with longer shelf lives. Initially interested in medicine, he chose to go into pharmaceutical research instead because he wanted to impact health care by doing new drug research.

Jainik Panchal injects a sample into the LC-MS to characterize the mass of a protein molecule

After graduating from the L.M. College of Pharmacy (LMCP) in Ahmedabad, India, Panchal worked for 10 months at Zydus Cadila, the fifth-largest pharmaceutical company in India and a major generic drug manufacturer. Zydus Cadila is a USFDA-approved plant that manufactures oral solid dosage forms, including Lipaglyn, the world's first drug to be approved for the treatment of diabetic

dyslipidemia. Panchal then did his MS at Butler University and came to Purdue in 2010 to start his PhD. While at Butler, he heard about IPPH's Dr. Steve Byrn and his work in Africa.

"I always knew Purdue was a very good school," says Panchal. He applied to IPPH and was accepted. Because Dr. Byrn was not taking new PhD students that year, Panchal talked to other IPPH professors and decided to join Dr. Liz Topp's lab to work with proteins. "She explained to me the challenges in delivering protein drugs and her research goal," he says. "I found it very challenging and exciting to work on something new."

Now finishing his fourth year in the IPPH program, Panchal works in the Topp lab on understanding the aggregation process by developing high-resolution methods based on mass spectrometry. His current project is collaborating with the FDA to understand the effect of various stresses on aggregate morphology.

"One of the most exciting aspects of Jainik's work is his use of hydrogen deuterium exchange with mass spectrometric analysis (HDX-MS) to identify changes in protein structure that lead to aggregation", says Dr. Topp. "These quantitative measures of aggregate structure may help us design better formulations."

Panchal thinks the IPPH program is the best one around because of the:

- excellent quality of professors
- camaraderie between different research groups
- quality of diverse & high-impact research

"Most of the labs have their own niche and this gives an excellent environment of critical thinking and researching new ideas while having expertise in many areas," he says. "I would tell other students to definitely apply to Purdue to become a part of the IPPH family."

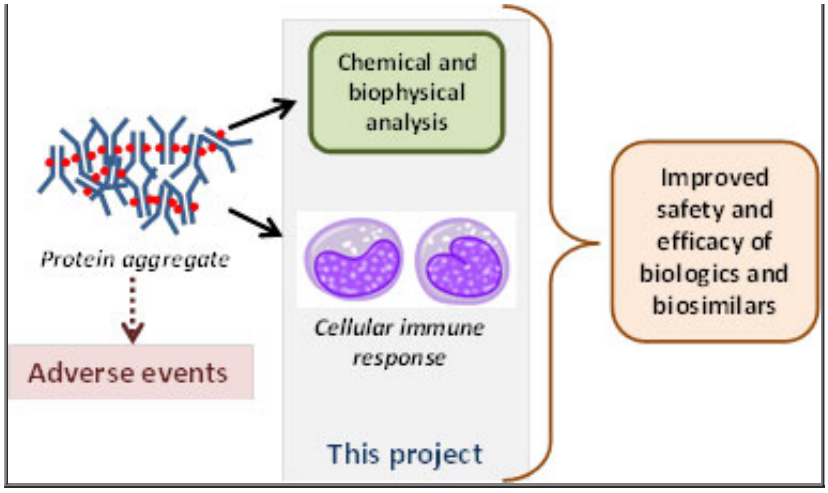
This summer Panchal has an internship at Amgen in South San Francisco. His analytical group there is working on developing mass spectrometry based methods for biologics. He hopes to finish his PhD by the summer of 2016, and then work in formulation development/analytical development at a biotech company.

Panchal is married to Lavanya Iyer, a PhD student in the Topp lab, whom he met at LMCP. He is a "big fan" of science and technology, loves math and physics, and is an avid movie buff.

Dr. Liz Topp: Immune response to protein aggregates

Recombinant proteins are a

rapidly growing class of drugs. These large, complex molecules can degrade in many ways, complicating formulation and manufacturing. Arguably, the most important type of degradation for protein drugs is aggregation. Aggregates have been associated with decreased potency and an increased potential for adverse immune reactions in patients. The properties of the aggregates that cause these adverse events aren't well understood, though. As a result, it's unclear which aggregates are "bad" and so need to be detected, quantified and controlled.



Dr. Liz Topp and her group are trying to improve the way protein aggregates are monitored. The group is evaluating different analytical methods for protein aggregates and trying to relate aggregate properties to immune responses in cells. The group is comparing methods like dynamic light scattering (DLS), resonance mass measurement (RMM), analytical ultracentrifugation (AUC) and nanoparticle tracking analysis (NTA) for their ability to detect standard-sized particles and antibody aggregates. So far, the results have shown that the methods can differ in the working ranges for both particle size and particle number, and that different methods can give conflicting results.

The group is also using various different human macrophage and monocyte cells, including primary peripheral blood mononuclear cells (PBMCs) and THP-1 and MM6 cell lines as in vitro indicators of immune response, based on the release of cytokines from these cells in response to aggregated protein. Results have shown that the cytokine response depends on how the aggregates were prepared (e.g., shaking, stirring, heating) as well as particle size and number. Blocking receptors on the cell surface affects cytokine release, suggesting that the cells respond to the pattern of amino acids on the aggregate surface and not just aggregate size and number. This may be important because the surface properties of protein aggregates are not usually measured.

The project is a collaboration involving the Topp lab, an immunologist at the Indiana University School of Medicine (Dr. Janice Blum) and scientists at the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration (FDA). The project is sponsored by the FDA (HHSF223201310233C).

Watch Topp lab video

Topp lab website

NEWS & EVENTS
department happenings

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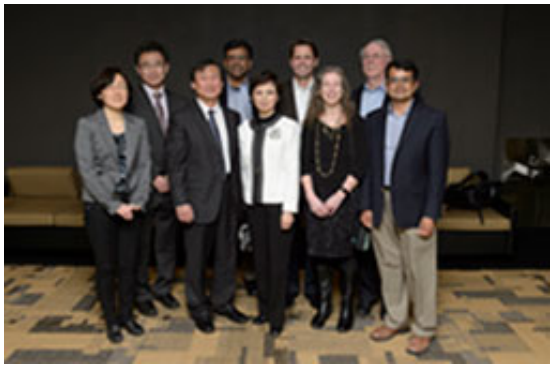
SAVE THE DATE: 2016 Peck Symposium

The 2016 Peck Symposium will be held on March 30 & 31, 2016, at Purdue University. More details TBA, or contact the IPPH Communications Coordinator.

Record numbers attend 2015 Peck Symposium



Kinam & Haesun Park (center) with friends and alumni

194 partipants attended the two-day 12th Garnet E. Peck Symposium on Feb. 25-27, 2015! The symposium featured 21 outstanding speakers who discussed moving new drug delivery technologies into pre-clinical and clinical development, launching their drug delivery technologies to market, and developing transformative ideas likely to affect clinical translation in the future. Two round table discussions, 48 posters with five poster contest winners, two receptions, and a "Celebration Dinner and Roast of Dr. Kinam Park" gave opportunities for scientific exchange and networking with Purdue Boilermaker hospitality. See photos.

IPPH Renovation: Phase 3

IPPH anticipates a renovation project for Dr. Lynne Taylor's labs in G57 and G59. Funding has been provided by the College of Pharmacy and Purdue's Discovery and Learning Laboratory Renovation Program (DL^2). The Taylor lab group met in March with Kay Townsend of Synthesis, Inc., to start working on lab design. Renovation should begin in the fall of 2015.

Chao Center update

The Chao Center for Industrial Pharmacy and Contract Manufacturing will increase its pharmaceutical development and production to include other drugs for niche markets in addition to its current manufacturing of Cycloserine Capsules USP, a global drug developed by Eli Lilly and Company used to treat multidrug-resistant tuberculosis. More

New spray dryer

Read about our new Buchi B-290 Spray Dryer.

May 2015 IPPH Graduate

Congratulations to May 2015 IPPH PhD graduate Biplob K. Mitra! Biplob works at Eli Lilly & Co. in Indianapolis.

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