

Peck Symposium Speakers

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The 2019 Peck Symposium information will be posted soon!



Dr. Ruben Carbonell

Frank Hawkins Kenan Distinguished Professor of Chemical Engineering, North Carolina State University, Raleigh, NC

Ruben G. Carbonell is the Frank Hawkins Kenan Distinguished Professor of Chemical and Biomolecular Engineering at NC State University. He is on temporary leave as Executive Director of the Biomanufacturing Training and Education Center (BTEC) to serve as Chief Technology Officer of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). He is also Director of the Kenan Institute for Engineering, Technology & Science, which supports multi-disciplinary and multi-institutional research, educational, entrepreneurial and public policy programs.

Dr. Carbonell was elected to the National Academy of Engineering in 2014. He is a Fellow of the National Academy of Inventors, the American Institute of Chemical Engineers, and the Industrial and Engineering Chemistry Division of the American Chemical Society. Dr. Carbonell is a Foreign Member of the Slovenian Academy of Sciences and the Academy of Sciences of the Institute of Bologna. He has published over 240 technical papers and is an inventor in over 30 patents. Prof. Carbonell received his BS degree in Chemical Engineering from Manhattan College in 1969 and his PhD from Princeton University in the same area in 1973.

Challenges and Advances in Downstream Purification of Biopharmaceuticals

The biopharmaceutical industry is facing demands for cost reductions in medications in developed countries with aging

populations, as well as in developing countries with growing middle classes. The advent of biosimilars has led to increased competition from other countries. In addition, regulatory constraints require enhanced potency, efficacy and safety while there is a need for rapid approval and deployment of life-saving vaccines, and novel gene-based and stem cell-based therapeutics.

There is a great deal of interest in the development of novel downstream processes to accelerate production, reduce process steps, process footprint, buffer and energy use, and regulatory burdens. Single use devices, low cost affinity media, membrane chromatography, process intensification, in-line validation and other approaches are being explored. Our group has pioneered the use of synthetic peptide libraries for the identification of low cost ligands with high affinity and selectivity for a wide variety of protein targets. In addition, we are pursuing inexpensive, high-throughput, high binding-capacity non-woven membranes as solid supports for product or contaminant capture. These developments might enable “truly continuous” purification strategies based on flow-through separation steps relying completely on disposable membranes.



Dr. Robert (Bill) Williams

Division Head and Professor of Pharmaceutics, Johnson & Johnson Centennial Chair in Pharmacy, University of Texas at Austin

Dr. Robert O. (Bill) Williams III is the Johnson & Johnson Centennial Chair and Division Head of Molecular Pharmaceutics and Drug Delivery at the College of Pharmacy, The University of Texas at Austin. He is an inventor on over 35 patents and patent applications and is the co-founder of several pharmaceutical companies. He received the *Inventor of the Year* award from the University of Texas at Austin in 2017. He was elected Fellow of the American Association of Pharmaceutical Scientists in 2006 and Fellow of the American Institute of Medical and Biological Engineering in 2008. He has published over 450 peer-reviewed research articles, reviews, abstracts and book chapters, and has co-edited two books, including [Formulating Poorly Water Soluble Drugs](#), Second Edition (AAPSPRESS and Springer). Dr. Williams is Editor-in-Chief of *AAPS PharmSciTech* since 2014 and was Editor-in-Chief of *Drug Development and Industrial Pharmacy* from 2000 to 2014. He is on the Editorial Advisory Board of *The Journal of Drug Delivery Science and Technology*. He earned a B.S. in Biology from Texas A&M University, a B.S. in Pharmacy from the University of Texas at Austin and Ph.D. in Pharmaceutics in 1986 from UT Austin. Dr. Williams worked 9 years in the pharmaceutical industry.

Thermal Processing Enhances Drug Delivery of Poorly Water Soluble Drugs – Process Selection

Thermal processing, including hot melt extrusion and KinetiSol® Dispersing, are useful processes for formulating drugs with low water solubility in order to improve their properties, such as wetting, dissolution and bioavailability. Polymers are typically employed in these processes to formulate the drug as an amorphous solid dispersion. Thermally labile drugs and drugs that have a high melting point (e.g., greater than ~200°C) are often not suitable for processing by hot melt extrusion. KinetiSol® Dispersing, a high energy fusion process not requiring an external heat source, offers a suitable alternative to these difficult to formulate drugs. Processing times differ in terms of minutes versus seconds, for hot melt extrusion and KinetiSol® Dispersing, respectively. This talk will discuss hot melt extrusion and KinetiSol® Dispersing in terms of process selection and limitations, and will include examples of formulations exhibiting enhanced properties.

Dr. Nithin Raghunathan

Staff Scientist, Birck Nanotechnology Center, Purdue University

Nithin Raghunathan received his Ph.D in electrical engineering from Purdue University, West Lafayette, IN, USA, in 2014. His dissertation focused on the development on micro-machined g-switches for impact applications typically in the ranges of 100 – 60,000 g's. He worked as Post-Doctoral Research associate from 2014 to 2015 and was involved in the development of wireless radiation sensors for dosimetry applications. He is currently a Staff Scientist at the Birck Nanotechnology Center at Purdue University. His current research focus is in the development of sensors for pharmaceutical lyophilisation and aseptic processing. His other interests include novel MEMS inertial devices, development of new microfabrication techniques, wireless and flexible sensors and Internet of things (IOT) and also sensors for industrial and harsh environments.

Low-power battery-free wireless sensors for industrial process monitoring

Lyophilization or freeze-drying is a \$30B industry in the global food and pharmaceutical manufacturing sectors today. A wide variety of protein-based drugs, live virus vaccines, probiotics as well as high-value foods such as preservative-free dried fruits, cheese and bread cultures are manufactured by lyophilization/freeze-drying process. About 46% of the approved biological drugs are manufactured by freeze-drying. Despite its wide application for a growing number of biotech products, the current lyophilization technology is a slow batch process with an energy efficiency below 5%. A key bottleneck in advancing lyophilization is lack of in-process product sensors which leads to overly conservative cycles and preclude closed-loop controls and continuous operation. This talk focuses on wireless process-monitoring sensors for dramatically improving lyophilization technology as employed in pharmaceutical and biotech product manufacturing. These multi-point sensing devices are wirelessly powered and require no batteries. They accurately monitor the temperature of the product in the vial with a resolution of less than 0.1 C. They can also monitor an entire lyophilization cycle and can survive standard FDA-mandated sterilization processes. Furthermore up to 2^{32} sensors to be networked together.

**Dr. Nien-hwa Linda Wang**

Maxine Spencer Nichols Professor of Chemical Engineering, Purdue University

Dr. Nien-Hwa Linda Wang is the Maxine Spencer Nichols Professor of Chemical Engineering at Purdue University. She received her PhD in Chemical Engineering from the University of Minnesota in 1978. She is internationally known for her research contributions in separations, adsorption, ion exchange, multi-component chromatography, and simulated moving bed technologies.

Fundamental Principles and Enabling Technologies for the Design of Batch and Continuous Chromatography Processes

Chromatography methods are highly selective separation methods, which are required for manufacturing of many biochemicals and biopharmaceuticals. Advanced chromatography methods for manufacturing, however, are not taught in conventional science or engineering curricula. Many chromatography processes in industry are designed empirically, with poor yield, productivity, and solvent efficiency. In this talk, the fundamental principles of batch and continuous chromatography will be explained. Enabling technologies and tools, which will help understand, analyze, simulate, design, and optimize various types of chromatography processes, will be discussed. The knowledge and the advanced computer tools are useful for improving the efficiency of existing processes or designing more efficient processes to reduce manufacturing costs.



Dr. Mukerrem (Miko) Cakmak

Reilly Professor of Materials Engineering & Mechanical Engineering, Purdue University

Dr. Cakmak received his BS in Chemical Engineering from Technical University of Istanbul and MS and PhD in Polymer Engineering from University of Tennessee, Knoxville.

He was one of the founders of Polymer Engineering Department at University of Akron where he was named Harold A. Morton Chair and Distinguished Professor of Polymer Engineering. He recently was the founding director of the National Polymer Innovation Center where he developed roll to roll manufacturing lines for functional polymer films for a range of applications including membranes for batteries, biomedical devices such as artificial pancreas, slow drug release platforms, flexible transparent electrodes for flexible electronics and flexible sensors.

Dr. Cakmak's current research includes modeling and experimental studies on processing–structure property relationships in polymer films and moldings and polymer/metal/ceramic hybrid systems.

Design and Modeling of Roll to Roll Continuous Lyophilization System

Authors: Miko Cakmak. Alina Alexeenko

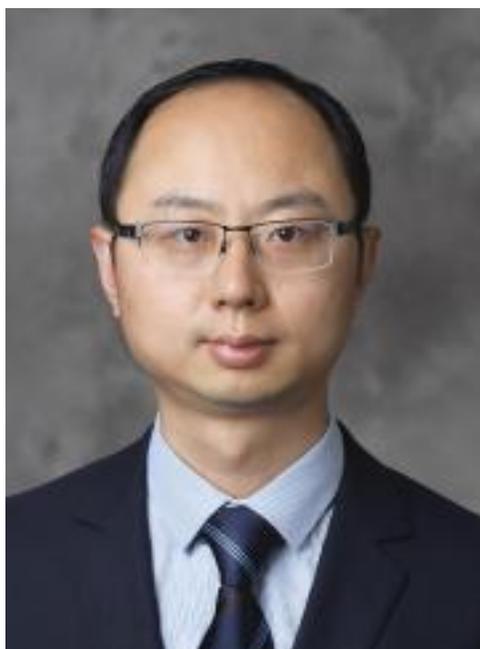
Abstract: In this talk we will present a novel design of continuous roll to roll Lyophilization System and metrology tool. The machine designed has dual purpose. One is to produce thin layers of lyophilized materials and laser packaging. In the second function it was designed with metrology tool that will track weight loss, thickness during lyophilization. A basic modeling of the process was developed help predict the thickness changes and extent of lyophilization.



Dr. Ali Shakouri

Mary Jo and Robert L. Kirk Director of Birck Nanotechnology Center, Professor of Electrical and Computer Engineering, Purdue University

Dr. Ali Shakouri is the Mary Jo and Robert L. Kirk director of the Birck Nanotechnology Center and professor of electrical and computer engineering at Purdue University. He received his doctoral degree from the California Institute of Technology in 1995 and his bachelor's degree in engineering from Telecom ParisTech in France in 1990. He was a faculty member at the University of California, Santa Cruz from 1998 to 2011 where he directed a multi university research center focused on direct conversion of heat into electricity. He also initiated a sustainability curriculum and a California-Denmark summer program in renewable energies in collaboration with colleagues in sociology, political science and environmental studies. Ali's major initiative at the Birck Center focuses on nanomanufacturing and printing smart films. This involves two dozen faculty from colleges of engineering, science, agriculture and pharmacy. Ali received a Packard Fellowship in Science and Engineering in 1999, an NSF CAREER Award in 2000 and the Thermi Award in 2014.

**Dr. Qi (Tony) Zhou**

Assistant Professor of Industrial and Physical Pharmacy, Purdue University

Dr. Qi (Tony) Zhou joined the Department of Industrial and Physical Pharmacy as an Assistant Professor in 2015. He obtained his PhD from Monash University of Australia in 2011, and received postdoctoral training at the University of Sydney. As a junior faculty, he has published 51 journal articles and secured >\$4M research funding from Governments and industry, including NIH R01 and Bill & Melinda Gates Foundation grants. Dr. Zhou's contributions to the field of pharmaceutical sciences have been recognized by many awards including 2013 Australian Early Career Fellowship, 2014 Australian Endeavour Fellowship, 2015 AAPS Postdoctoral Fellowship, 2016 IPEC Excipient Emerging Researcher Award and 2017 New Investigator Award in Aerosol Medicine. Dr. Zhou is an Editorial Board Member of Journal of Pharmaceutical Sciences, and Guest Editors of Current Pharmaceutical Design and Pharmaceutical Research.

Innovative technologies for spray drying and characterization of pharmaceutical solids

Abstract: The 21st century has seen many innovations in manufacturing of pharmaceutical solid, with purposes to improve production efficiency, formulation performance and product stability. As an example, spray drying has been increasingly employed for production of both small- and large-molecule pharmaceutical solids, attributed to the superior production efficiency and formulation flexibility. Over the past decade, there are some innovative technologies have been developed for spray drying. Also, some cutting-edge techniques have been applied to characterize physico-chemical properties of spray-dried solids, aiming to optimize the manufacturability, stability and therapeutic efficacy of the spray-dried products. This talk will summarize some advances in spray drying and characterization of pharmaceutical solids.

**Dr. Rodolfo Pinal**

Associate Professor of Industrial and Physical Pharmacy, Director of Center for Pharmaceutical Processing Research, Purdue University

Pharmaceutical Manufacturing in the Era of Patient-Centric Medicine

Biomedical advances are making it possible to quantitatively understand why is it that the same medication does not work the same in every patient, thus rendering the long-standing drug therapy practice of “one-dose-fits-all” outdated, for an increasing number of drugs. The pharmaceutical industry faces the challenge of how to apply the latest advances in process understanding achieved in recent years, along with the accompanying high standards of product quality achieved, as it moves into the era of patient-centric medicine (PCM). Namely, the “retooling” needed to create a product that instead of being a blockbuster, is a large collection of “mini-busters.” This requires the ability to cost-effectively produce product variations, covering an arbitrary number of different doses, and with a range spanning roughly two orders of magnitude (based on metabolic variability). Similar challenge arises for the manufacture of patient-specific, non-fixed combination products, bound to change over time even for the same patient, involving different number and APIs.

A platform for the design and manufacture of oral dosage forms (“pills”), developed to satisfy the patient-tailored (or subpopulation-tailored) requirements of PCM is presented. The approach is a paradigm shift, whereby pills are conceived as Integrated Systems, rather than as traditional compacts of powder blends. The manufacture of this new type of multiplexed pill (“3 D Pill”) is analogous to the manufacture of 3D Integrated Circuits. The oral dosage forms, modular in design, are made by assembling prefabricated components in 3 D stacks, where each prefabricated component performs a specific, pre-determined pharmaceutical function. Each prefabricated component is a polymer composite wafer, whose particular function in the assembly is determined by the type of material embedded with the polymer (active pharmaceutical ingredient, solubilizer, disintegrant, absorption enhancer, pH modifier, ID/anti-counterfeiting element, etc.). The Integrated Systems approach to drug manufacturing makes it comparatively to traditional manufacturing, a much simpler task to add or refine performance attributes of the pill, and/or quality related attributes to the dosage form by incorporation of additional/different functional composite wafers. The 3D Pill concept is fully patient-centric, such that precise dose adjustment, as well as drug release characteristics, can be achieved within the same platform, in order to meet the therapy requirements of the individual patient. The Integrated Systems approach to pharmaceutical manufacturing fully exploits the advantages of things like continuous manufacturing and QbD, provided that a slight but important shift in focus is adopted, thus suggesting that the “retooling” needed in industry to fulfill PCM needs, is rather one of “mindset,” and not so much one of facilities, processes or know-how.



Dr. Zoltan K. Nagy

Professor of Chemical Engineering, Purdue University

Dr Nagy is a Professor of Chemical Engineering at Purdue University. Dr Nagy has 20 years of experience in advanced process control, process analytical technologies, crystallization modeling and control approaches and advanced control of particulate systems. His current research focuses on the application of systems approaches and tools in the design and robust control of batch and continuous crystallization systems, process analytical technologies and integrated particulate manufacturing processes. Dr Nagy is the Founding Editor of the Pharmaceutical Engineering Subject area of Chemical Engineering Research and Design, and associate editor of another four international journals in the area of process control. Dr Nagy is member of the American Association for Crystallization Technologies, and the Crystallization Working Party of the European Federation of Chemical Engineers. He received awards and best paper prizes for his work in the areas of crystallization and control from IEEE, IFAC, European Federation of Chemical Engineering, Institute of Chemical Engineering, Council of Chemical Research, Royal Academy of Engineering and the European Research Council.

Process Intensification via Continuous Crystallization of Pharmaceuticals

Continuous crystallization has the benefits of better controllability and improved product uniformity compared to the batch process. The presentation will describe the application of continuous crystallization technologies for the separation, purification and particle design in pharmaceutical manufacturing. Both the cascade continuous stirred tank as well as plug flow crystallization systems will be presented. The use of novel oscillatory flow and dynamic baffled crystallizers will be illustrated, which can provide improved particle suspension, heat and mass transfer. The role of rigorous mathematical modeling in the systematic optimal design, start-up and control of continuous crystallization processes will be illustrated through examples for both cascade of mixed suspensions mixed product removal (MSMPR) as well as plug flow crystallization systems. Anti-fouling control (AFC) will be presented as an illustrative example demonstrating how active feedback control can be the key enabling technology for the implementation and smooth operation of continuous crystallization processes. Novel control approaches for integrated continuous crystallization and wet milling systems will be presented that can produce crystalline materials with tailored material properties with excellent consistency. A novel view for implementing continuous drug manufacturing processes will be presented, which is based on spatially distributed control of various particle formation processes including nucleation, growth and agglomeration, within a single continuous plug flow crystallization system. The system uses spatially distributed antisolvent addition, heating/cooling cycles and/or binder/excipients addition to control the individual mechanisms of nucleation, growth and spherical agglomeration to produce particles with controlled internal and external size and micromeritic properties. The talk intends to provide motivating examples of the next stage of innovation in pharmaceutical manufacturing, illustrating the potential benefits of the new quality-by-control (QbC) framework in improving product quality and process efficiency while reducing costs and time-to-market.

