Joseph Sinkule, Pharm.D.

Title: Associate Professor, Consultant, Board Member

Insitutions: UNMC, Anew Medical

LinkedIn: https://www.linkedin.com/in/dr-joseph-sinkule-10581512

Biosketch:

Dr. Sinkule has over 40 years of drug, biologic, and medical device research, development, and commercialization experience, and this serial entrepreneur is the founder and driving force behind several Companies. He has personally managed over 8 drug and biotech products successfully through FDA approval to market, 3 medical devices and 5 in vitro diagnostics. He has hired and managed both small and large teams of people in pharma and biotech organizations, and directed contract research organizations (CRO's) working on clinical and regulatory affairs for large and small clients. After serving in academia for 8 years (St. Jude Children's Research Hospital, University of Chicago, Massachusett General Hospital/Harvard University) and 38 years in the pharma/biotech industry, Dr. Sinkule has evolved into a successful businessman and serial entrepreneur. He worked on several cell-based and gene therapy programs in the mid-1990's, again in the mid-2000's, and now consults for Pfizer, Aldevron, and other concerns involved with gene and cell therapy programs. He serves on the Board of Directors of 2 drug companies and his gene therapy company, ANEW MEDICAL. Dr. Sinkule oversees and manages all licensing, financing, product development, and business development activities for ANEW MEDICAL. As a recently appointed Adjunct Associate Professor, Pharmaceutical Sciences, in the College of Pharmacy at UNMC, he will focus on novel drug delivery systems and anti-viral therapies against SARs and influenza, and support the development of Pharm.D. and post-doctoral candidates.

Helen H. Hou, Ph.D.

Title: Senior Principal Scientist

Insitution: Genentech Inc.

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Biosketch:

Dr. Helen Hou is a Senior Principal Scientist in the Department of Small Molecule Pharmaceutical Sciences at Genentech. She has over 16 years of pharmaceutical development experiences across several big Pharma companies. At Genentech, Dr. Hou leads drug product development to allow fast-entry into human and the definition of market-image formulation/process. She directs the activities of staff members in pipeline support, strategic initiatives, and research innovation. Dr. Hou specializes in development of oral solid dosage forms and sterilized ophthalmic products. She received her Ph.D. in Materials Science and Engineering from the University of Minnesota. Dr. Hou is a member of International Consortium for Innovation and Quality (IQ) Amorphous Solid Dispersion Working Group, the lead of Enabling Technologies Consortium (ETC) Solid Formulation Granulation project, and currently serves as the Industry Advisory Board (IAB) chair of Center for Integrated Material Science and Engineering for Pharmaceutical Products (CIMSEPP).

Pad Chivukula, Ph.D.

Title: Chief Scientific Officer and Chief Operating Officer

Insitution: Arcturus Therapeutics

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Biosketch:

Pad Chivukula, Ph.D., is the Chief Scientific Officer and Chief Operating Officer of Arcturus Therapeutics. Dr. Chivukula has an exceptional solid foundation in pharmaceutical development and is a member of the Executive Leadership Team and the company's Portfolio Strategy which governs major pipeline investments and strategic end-to-end R&D priorities.

Pad Chivukula oversees Arcturus' discovery, research and development of therapeutics, focusing efforts on medicines that have the potential to transform the practice of medicine and improve the lives of people with serious diseases. Under Pad's leadership, the R&D organization has built a robust pipeline by sharpening Arcturus' research focus, employing cutting-edge therapeutic platforms, simplifying processes, and creating a culture that responds to the urgent needs of patients.

Prior to founding Arcturus in 2013 with Joseph Payne, President and CEO, Dr. Chivukula was employed by Nitto from 2008 until February 2013, during which he was Group Leader and Chief Scientist. Dr. Chivukula has more than 15 years of experience in drug delivery and therapeutic drug development, including leading the polymeric RNAi research department at Nitto. Dr. Chivukula earned his Ph.D. in Pharmaceutical Chemistry at the University of Utah where he specialized in nanoparticle technology.

Focusing on advancing Arcturus' scientific breakthrough leadership in RNA therapies and vaccines, Dr. Chivukula leads the R&D organization which is responsible for the development of all compounds through proof of concept, and provides pharmaceutical sciences, safety, and medical support to the entire R&D pipeline and all marketed medicines and vaccines. The Vaccines R&D team leads scientific efforts from discovery through registration of novel vaccines.

Madhu Pudipeddi, Ph.D.

Title: Senior Vice President of Technical Operations

Insitution: Prelude Therapeutics

LinkedIn: https://www.linkedin.com/in/madhu-pudipeddi-35ba709

Biosketch:

Madhu Pudipeddi, Ph.D. is Senior Vice President of Technical Operations at Prelude Therapeutics where he oversees drug product development, manufacturing, and clinical supply operations. Prior to joining Prelude, he was Executive Director at Novartis Pharmaceuticals, where he had roles of increasing responsibility for over 16 years in the areas of drug development and technical operations. Dr. Pudipeddi contributed to the development and commercialization of several new molecular entities, build-up of an R&D organization in India, and oversaw Manufacturing Science & Technology operations in Europe and Americas. Prior to joining Novartis, Dr. Pudipeddi was at Bristol-Myers Squibb where he was engaged in drug discovery-development collaboration and development of new molecular entities. Dr. Pudipeddi received his B.S. in Pharmaceutical Sciences from Andhra University, India and his Ph.D. in Pharmaceutical Sciences from the University of Wisconsin, Madison.

Michael K Schultz, Ph.D.

Title: Founder and Chief Science Officer, Associate Professor

Insitutions: Viewpoint Molecular Targeting, Inc. and University of Iowa

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Biosketch:

Michael K Schultz Ph.D. is a funded NIH investigator, Founder and Chief Science Officer of Viewpoint Molecular Targeting, Inc., and a tenured Associate Professor of Radiology, Pediatrics, Free Radical and Radiation Biology, and Chemistry at the University of Iowa. Dr. Schultz has been involved in NETs research and the development of new imaging and therapy agents for NETs for over 15 years and has been a Project Leader in the NETs Specialized Program of Research Excellence (SPORE) team at the University of Iowa since 2015. His expertise is cancer radiopharmaceutical sciences, radiochemistry, radiation biology, cancer oxidative metabolism and drug resistance, and bioconjugate chemistry with a focus on receptor targeted imaging-guided alpha-particle therapy for cancer. His recent publications demonstrate the potential for alpha-particle targeted radionuclide therapy; dosimetry of ^{212}Pb based peptides; production of ^{203}Pb/^{212}Pb radiopharmaceuticals; ligand design; and generator produced radionuclides. Professor Schultz serves as Co-Investigator on a current NCI R01 project to conduct a Phase I clinical trial of image-guided ^{203}Pb/^{212}Pb therapy for NET (R01CA243014). Dr. Schultz is also an academic entrepreneur and his company, and together with Viewpoint Co-founder Frances Johnson MD, Dr. Schultz has secured approximately $14M in peer-reviewed NCI Small Business Innovation Research grants and contracts and approximately $20M in private capital investment to advance ^{203}Pb/^{212}Pb image-guided radionuclide therapy for NETs to global availability. The company has secured safe to proceed designations for two imaging trials and two therapeutic trials for its ^{203}Pb imaged-guided ^{212}Pb alpha particle therapy for metastatic melanoma and NETs and has recently received Fastrack designation by the US FDA for its alpha particle therapy for NETs.

Jyoti Roy, Ph.D.

Title: Senior Scientist

Insitution: AstraZeneca

LinkedIn: https://www.linkedin.com/in/jyoti-roy-91140014

Biosketch:

After acquiring Ph.D. in Chemistry from Purdue University in 2016, Dr. Jyoti Roy joined National Cancer Institute/NIH in 2017, where she worked as a postdoc and research fellow on PET imaging and radionuclide therapy. In 2021 she transitioned into the industry. She is currently working as a senior scientist in AstraZeneca, continuing her expert research in imaging.

Michael Hageman, Ph.D.

Title: Distinguished Professor and Director of the Biopharmaceutical Innovation and Optimization Center

Insitution: University of Kansas

LinkedIn: https://www.linkedin.com/in/michael-hageman-2734031/

Biosketch:

Mike Hageman is a Distinguished Professor of Pharmaceutical Chemistry and Director of the Biopharmaceutical Innovation and Optimization Center, at the University of Kansas. Prior to joining the University of Kansas in 2017, Mike spent 30+ years in the Pharmaceutical Industry, 10 years as Director and Executive Director at Bristol Myers Squibb leading Discovery Pharmaceutics for both small molecules and biologics, and 20+ years at Pfizer and Legacy companies (Pharmacia, Upjohn) as a Research Fellow in preclinical development and technology oversight for soluble drugs. His current research program focusses on oral and subcutaneous delivery of small molecule and peptide drugs. Mike is an AAPS Fellow and current editor of JPharmSci.

Deepak Bahl, Ph.D.

Title: Associate Scientific Director

Insitution: Bristol Myers Squibb

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Deepak Bahl currently serves as an Associate Director at the Bristol-Myers Squibb (BMS). He has over 18 years of experience in developing conventional and enabled dosage forms of small molecules, liquids, parenterals, and peptides. Prior to BMS, he held positions of increased responsibilities at Celgene, Merck and Co., Catalent Pharma Solution, and Ranbaxy Research Laboratories.

Deepak has a Ph.D. in Pharmaceutical Sciences from the University of Connecticut, CT and Masters in Pharmacy (M. Pharm) from the College of Pharmacy, New Delhi. His work has led to the approval of four NDAs & MAAs, five ANDAs, three 505(B)(2)s and several patents/publications. Deepak has held several leadership positions at the American Association of Pharmaceutical Scientists (AAPS) and currently serves as the chair of the AAPS Preformulation & Formulaton Design/Development Community.

Dakshina Chilukuri, Ph.D.

Title: Team Leader in the Office of Clinical Pharmacology

Insitution: Food and Drugs Administration

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Biosketch:

Dakshina Chilukuri is a Team Leader in the Office of Clinical Pharmacology (OCP) supporting the Division of Infectious Disease Pharmacology (DIDP) at the Food and Drugs Administration (FDA). Over the past 20 years, he has made several notable contributions to support the approval of drugs in the infectious disease therapeutic area. He is recognized as the SME in the areas of BA/BE, biopharmaceutics, food-effect and clinical pharmacology of anti-infective agents. He has served as the lead of the BA Guidance revision committee responsible for the revision of the recently published BA guidance.

Surya Ayalasomayajula, M.D.

Title: Senior Principle Scientist

Insitution: Merck Pharmaceuticals

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Biosketch:

I have obtained bachelors in pharmaceutical sciences and masters in pharmacology. I graduated from UNMC in 2004 with PhD. My first job was at MDS Pharma services, Lincoln Nebraska (now called Celerion) as clinical PK scientist. I moved to Novartis in 2005 and worked there until 2016 in clinical PK group with increasing role responsibilities. Here I supported cardiovascular programs from first in human studies until NDA submission including life cycle management. Most notable contribution is approval of Entresto for heart failure for which I was the lead clinical Pharmacology scientist. I moved to Allergan as director clinical pharmacology in 2016 and worked there until 2020 in liver franchise. I joined Alkermes to support their CND portfolio in 2020. Following brief stint including intiating 3 FIH studies, I joined Merck pharmaceuticals (MSD) in 2022 as Sr Principle Scientist in QP2 group supporting their CV portfolio.