

# Translating Fundamental Research in Particle Technology to Industry and Patient Needs for Improved Pharmaceutical Products

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## Overview

Our research focuses on developing fundamental understanding of particle properties and their interactions at the nano and micro scales and translating that knowhow to innovate pharmaceutical products to satisfy unmet industry and patient needs. This talk will provide an overview of this work enabled by significant support from the US National Science Foundation (NSF), numerous industry partners, as well as the US Food and Drug Agency (FDA), involving dozens of students and postdocs, and guidance from many industry partners. We have leveraged recent fundamental advances made in our group to develop innovative processes and products spanning three important areas: (1) Overcoming the difficulties in processing pharmaceutical powders due to their high cohesion via solventless mechanical coating of nanoparticles on their surfaces; (2) Improved bioavailability of poorly water-soluble drugs; and (3) Use of modeling tools including discrete element method (DEM) and population balance modeling (PBM) for enhanced process and product understanding. Recent advances will be highlighted uncovering the role of fine particle agglomeration on powder behavior and power-law relationship between agglomeration, flowability, and packing where the granular Bond number could be used as a dimensionless scaling parameter. As a key novelty, by examining the relative role of particle agglomeration and surface hydrophobicity based on the amount and nature of nano-coating we have demonstrated that even hydrophobic surface coatings could lead to enhanced drug dissolution rate.

These activities and expertise have led to recent establishing of an NSF funded Industry University Cooperative Research Center (IUCRC), called the Center for Integrated Materials Science and Engineering of Pharmaceutical Products (CIMSEPP) in partnership with the University of Minnesota. Unique contributions of the NJIT group include predictive property enhancements for powders, blends, and their compressed tablets through particle engineering, enabling digital product design and manufacturing of high-quality, low-cost, and smaller tablet products, as well as process understanding via multi-scale modeling, all for the benefit of the patients and industry partners.



**Bio:** Prof. Rajesh Davé Fellow of the American Institute of Chemical Engineers (AIChE), American Association of Pharmaceutical Scientists (AAPS), and National Academy of Inventors (NAI) is a Distinguished Professor of Chemical and Materials Engineering at New Jersey Institute of Technology (NJIT). He has made significant impact to particle technology and pharmaceutical sciences through grant funded research for improved understanding of particle behavior influenced by their particle-scale properties, their formation, processing, and cost-efficient manufacturing while developing patient compliant technologies including taste-masking. His trend-setting high-impact contributions include fundamentally based understanding of the effect of surface modification of drug or excipient particles, surface energetics of drug particle milling, functionalization and stabilization of nano and low micron sized particle suspensions and their composites, as well as development of platform technologies for taste-masking and thin polymeric films embedded with poorly water-soluble drug as a patient compliant platform for

precision medicine along with regulatory science. His research contributions include 195 journal papers (14,200+ Google citations, H-Index 63), numerous invited and keynote presentations as well as 22 issued patents, including licensing of a few. He has granted 35 PhDs to his students, seven of those are currently in US academia. He has received numerous awards, including 2022 American Institute of Chemical Engineering (AIChE) PD2M Award for Outstanding Contribution to QbD for Drug Product, 2016 Thomas Alva Edison Patent Award, and 2015 AIChE Particle Technology Forum Fluidization Lectureship. He is currently the U.S. Executive Editor of *Advanced Powder Technology*, has guest edited for *Powder Technology*, *Pharmaceutical Research*, and *Pharmaceutics*.