James V. Scicolone, Ph.D.

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I am a PI, Co-PI, project manager, and researcher in the Chemical and Biochemical Engineering Department at Rutgers University, where I mentor, teach, and lead research in pharmaceutical and food manufacturing. My research expertise spans a broad range of particle processing technologies, including 18 years of experience in powder characterization and over 8 years in continuous manufacturing focusing on the process development of new formulations as well as batch-to-continuous conversion.

I have a strong interest in leading research that can have direct impact on the food and drug industry. Much of my work has focused on the operation of continuously manufactured direct compression tablets on a continuous line similar to what is currently used to manufacture Prezista® by the Janssen Supply Chain. Over ten years of managerial experience of leading post doctorates, PhD students, masters students, and undergraduate students, creating budgets, leading communications, and reporting of projects with domestic and international companies, including 18 funded grants as PI. Mentor to over 40 students and researchers alike in promoting proper execution of research tasks while promoting understanding and purpose of the work.

EDUCATION

2009-2011	***Ph. D in Materials Science and Engineering;*** *New Jersey Institute of Technology, Newark, NJ* Dissertation: Mixing of nanosize particles by magnetically assisted impaction techniques
2005-2009	***Masters of Science in Chemical Engineering;*** *New Jersey Institute of Technology, Newark, NJ* Thesis: Magnetically Assisted Impaction Mixing of Nanosize Particles
2000-2004	***Bachelor of Science in Chemical Engineering with a Minor in Environmental Engineering****, Pennsylvania State University, University Park, PA*

EXPERIENCE

2015 - Present	**Assistant Research Professor**, Rutgers University, Piscataway, NJ ERC C-SOPS, Department of Chemical and Biochemical Engineering Principal investigator, co-principal investigator, and project leader on a number of projects
2013 - Present	**Independent Consultant**, Integra CMS and Acumen Biopharma Principal Investigator on multiple research projects totaling over $400k.
2012 - 2015	**Project Manager, Post-Doctoral Associate**, Rutgers University, Piscataway, NJ ERC C-SOPS, Department of Chemical and Biochemical Engineering Project leader on many different project
2011 - 2012	**Post Doctorate Research Associate**, New Jersey Institute of Technology, Newark, NJ

	Department of Chemical Engineering
2009	**Visiting Graduate Researcher**, University of Wollongong, Wollongong, NSW, AU Department of Chemical Engineering
2009	**Visiting Graduate Researcher**, ETH Zurich, Zurich, Switzerland Functional Materials Laboratory, Department of Chemical Engineering
2005	**Intern**, National Starch and Chemical Company, Bridgewater, NJ Personal Care Department

GRANTS

I have been **Principal Investigator (PI)** on seventeen (17) projects and **Co-PI** on one project spanning over eight years of research. The total funding associated as **PI** is currently $667.6k.

Funder	Period	Title	Role	Value
Bayer OTC through Integra CMS	2023	Evaluation of an API for use in Continuous Direct Compaction	PI	$2.8k
Food & Drug Administration (FDA)	2020-2023	Development and Round-robin Verification of Dynamic RTD Models for the On-line Product Quality Analysis	Co-PI Technical Coordinator Lead Investigator	$2.19m
Bayer OTC through Integra CMS	2019-2022	Formulation, Process Development, Feasibility, and Evaluation of Transferring Two Drug Products from Batch Manufacturing to Continuous Direct Compaction Manufacturing	PI	$323.7k Total value of nine (8) projects
Topsoe (Haldor-Topsoe) through Integra CMS	2019	Evaluation of Pharmaceutical Continuous Manufacturing Models for use with Topsoe Constituents	PI	$26.9k
Infinitus (China) through Integra CMS	2018-2020	Formulation, Process Development, Feasibility, and Evaluation of Transferring Two OTC supplements from Batch Wet Granulation to both Continuous Wet Granulation and Continuous Direct Compaction Manufacturing	PI	$319k Total value of two (3) projects
Acumen BioPharma	2015-2019	Patent Reviews, Experimental Demonstration, and Knowledge Databasing for Various Patent Litigations	PI	$22k Total value of four (4) projects

I have been the **Project Manager** on seven (7) additional projects and **Co-Investigator** on four (4) projects spanning over eleven (11) years of research.

Funder	Period	Title	Role
Janssen Pharmaceuticals	2023-2024	The Evaluation of Impregnation of Janssen Preferred API- Amd1 12/2/19	Co-Investigator
Merck KGaA	2020-2024	Evaluation of Merck KGaA Powders for Continuous Manufacturing and Impregnation	Project Manager - Lead Investigator
Janssen Pharmaceuticals	2023	The Evaluation of Melt Coating and Granulation of Janssen Preferred API	Project Manager - Lead Investigator
Vertex Pharmaceuticals	2022-2023	Evaluating Methods to Improve Flowability of Highly Cohesive - Adhesive API	Project Manager - Lead Investigator
Janssen Pharmaceuticals	2022-2023	Evaluation of Melt Coated Granulation on Fenofibrate, a Poorly Soluble API	Project Manager - Lead Investigator
Bayer Pharmaceuticals	2021-2023	The Feasibility Evaluation of Three Bayer Preferred API for Direct Compaction Continuous Manufacturing	Project Manager - Lead Investigator
Thermo Fischer Scientific	2022	Configuring the Continua Digital Twin to include a continuous wet granulation module	Integration Lead
Janssen Pharmaceuticals	2019-2022	Evaluation of Shear Effects on Pharmaceutical Formulations	Project Manager - Lead Investigator
Food & Drug Administration (FDA) and NIPTE	2019-2022	Comprehensive Training Program in Continuous Solid Dose Manufacturing	Co-Investigator
United States Pharmacopeia (USP)	2019	Introduction to Continuous Manufacturing (CM): Pharmaceutical Industry	Co-Investigator
Janssen Pharmaceuticals	2015-2019	J&J Process Development for continuous pharmaceutical manufacturing. Project #3	Project Manager - Lead Investigator
Janssen Pharmaceuticals	2015-2017	J&J Unit Operation Characterization, Project #1	Project Manager - Lead Investigator
US Army Armament Research Development and Research Center	2012-2014	DOD-Army-ACC-W15QKN-11-C-0118-433248; 2012-2014 Project: Low Observable Tracer Project: Characterization and Dosating Energetic Material	Project Manager - Lead Investigator

PUBLICATIONS

Publications: 25 Accepted Manuscripts and 2 book chapter. 655 Citations, h-index of 15, and i10-index of 17.

Published

- Razavi, Sonia M., et al. "Selection of an appropriate tracer to measure the residence time distribution (RTD) of continuous powder blending operations." Powder Technology 429 (2023): 118864.
- Bhalode, Pooja, et al. "Optimal quantification of residence time distribution profiles from a quality assurance perspective." International Journal of Pharmaceutics 634 (2023): 122653.
- Bhalode, Pooja, et al. "Statistical Data Pre-Treatment for Residence Time Distribution Studies in Pharmaceutical Manufacturing." Available at SSRN 4249747 (2022).
- Razavi, Sonia M., et al. "Starch Products as Candidate Excipients in a Continuous Direct Compression Line." Journal of Pharmaceutical Innovation 17.2 (2022): 460-471.
- Sánchez-Paternina, Adriluz, et al. "Residence time distribution as a traceability method for lot changes in a pharmaceutical continuous manufacturing system." *International Journal of Pharmaceutics* 611 (2022): 121313.
- Li, Tianyi, et al. "Loss-in-weight feeding." *How to Design and Implement Powder-To-tablet Continuous Manufacturing Systems*. Academic Press, 2022. 29-57.
- Bhalode, Pooja, et al. "Using residence time distribution in pharmaceutical solid dose manufacturing–A critical review." *International Journal of Pharmaceutics* 610 (2021): 121248.
- Escotet-Espinoza M.S., et al. (2020). Silication of Adhesive Active Pharmaceutical Ingredients: A Method for Improving Feedability. *Journal of Pharmaceutical Innovation.* 16(2), 279-292.
- Scicolone, James, et al. (2020). "Optimizing loss-in-weight feeding of poorly flowing materials." *Pharmaceutical Technology* 2000.4: s24-s28.
- Alvarado-Hernández, B. B. (2020). Method transfer of a near-infrared spectroscopic method for blend uniformity in a poorly flowing and hygroscopic blend. *Journal of Pharmaceutical and Biomedical Analysis*, 180, 113054.
- Razavi S.M., Scicolone, J.V., Snee, R., Kumar, A., Muzzio, F.J. (2020). Prediction of tablet weight variability in continuous manufacturing. *International Journal of Pharmaceutics*, 575, 118727
- Li, T. Scicolone, J.V., Sanchez, E., Muzzio, F. (2019). Identifying a Loss-in-Weight Feeder Design Space Based on Performance and Material Properties. Journal of Pharmaceutical Innovation. https://doi.org/10.1007/s12247-019-09394-4
- Sierra-Vega, N. O., Román-Ospino, A., Scicolone, J., Muzzio, F. J., Romañach, R. J., & Méndez, R. (2019). Assessment of blend uniformity in a continuous tablet manufacturing process. *International journal of pharmaceutics*, *560*, 322-333.
- Escotet-Espinoza, M. S., Moghtadernejad, S., Scicolone, J., Wang, Y. F., Pereira, G., Schafer, E., ... & Muzzio, F. J. (2018). Using a material property library to find surrogate materials for pharmaceutical process development. *Powder Technology*, *339*, 659-676.
- Moghtadernejad, S., et al. "A Training on: Continuous Manufacturing (Direct Compaction) of Solid Dose Pharmaceutical Products." Journal of Pharmaceutical Innovation.
- Oka, S., Escotet-Espinoza, M. S., Singh, R., Scicolone, J. V., Hausner, D. B., Ierapetritou, M., & Muzzio, F. J. (2017). Design of an Integrated Continuous Manufacturing System. Continuous Manufacturing of Pharmaceuticals, 405-446.
- Scicolone, J. V., Metzger, M., Koynov, S., Anderson, K., Takhistov, P., Glasser, B. J., & Muzzio, F. J. (2016). Effect of liquid addition on the bulk and flow properties of fine and coarse glass beads. AIChE Journal, 62(3), 648-658.
- Deng, X., Scicolone, J., Han, X., & Davé, R. N. (2015). Discrete element method simulation of a conical screen mill: A continuous dry coating device. Chemical Engineering Science, 125, 58-74.
- Huang, Z., Scicolone, J. V., Han, X., & Davé, R. N. (2015). Improved blend and tablet properties of fine pharmaceutical powders via dry particle coating. International journal of pharmaceutics, 478(2), 447-455.

- Huang, Z. H., Scicolone, J. V., Gurumuthy, L., & Dave, R. N. (2015). Flow and bulk density enhancements of pharmaceutical powders using a conical screen mill: A continuous dry coating device. Chemical Engineering Science, 125, 209-224.
- Deng, X., Scicolone, J. V., & Davé, R. N. (2013). Discrete element method simulation of cohesive particles mixing under magnetically assisted impaction. Powder technology, 243, 96-109.
- Patel, R. B., Liu, J., Scicolone, J. V., Roy, S., Mitra, S., Dave, R. N., & Iqbal, Z. (2013). Formation of stainless steel–carbon nanotube composites using a scalable chemical vapor infiltration process. Journal of Materials Science, 48(3), 1387-1395.
- Scicolone, J. V., Lepek, D., Louie, L., & Davé, R. N. (2013). Fluidization and mixing of nanoparticle agglomerates assisted via magnetic impaction. Journal of nanoparticle research, 15(2), 1434.
- Scicolone, J., Mujumdar, A., Sundaresan, S., & Davé, R. N. (2011). Environmentally benign dry mechanical mixing of nano-particles using magnetically assisted impaction mixing process. Powder technology, 209(1), 138-146.
- Sanganwar, G. P., Gupta, R. B., Ermoline, A., Scicolone, J. V., & Dave, R. N. (2009). Environmentally benign nanomixing by sonication in high-pressure carbon dioxide. Journal of Nanoparticle Research, 11(2), 405.
- Scicolone, J. V., Davis, P. K., Danner, R. P., & Duda, J. L. (2006). Solubility and diffusivity of solvents by packed column inverse gas chromatography. Polymer, 47(15), 5364-5370.

HONORS

1. Fellow, NSF Navy Civilian Service, 2006-2007
2. NSF Civil Mechanical Manufacturing Innovation Conference, Honolulu, HI, 2009
3. Regional winner of the ISPE NJ Student Poster Competition, NJIT, Newark, NJ, 2009
4. Provost's Research Showcase, NJIT, Newark, NJ, 2009
5. Fellow, Integrative Graduate Education and Research Traineeship (IGERT), 2005-2010
6. NSF Research Experience for Undergrads Program, Mentor, NJIT, 2006-2012
7. NSF Research Experience for Teachers Program, Mentor, NJIT, 2010-2011

PERSONNEL SUPERVISED AT RUTGERS UNIVERSITY

Postdoctoral Research Associates

2015 - Zhonghui Huang – Unit operations for continuous manufacturing
2015 - Savitha Panakar – Unit operations for continuous manufacturing
2015 - Sejal Shah – Materials characterization and student management
2016 - Sara Moghtadernejad - Materials Characterization and unit operations
2018 – Wei Meng – Continuous Manufacturing
2019 - Sonia M. Razavi – Materials Characterization and unit operations
2020 - Andres Roman – Continuous Manufacturing operations
2021 - Thamer Omar – Project Management
2021 - Carlos Ortega – Continuous Manufacturing operations

Visiting Scientist

2018 – Hongzhang Chen -Infinitus (China)
2018 – Adriluz Sanchez – UPRM

2018 – Barbara Hernandez – UPRM
2018 – Pedro Martinez – UPRM
2018 – Kerimar Reyes – UPRM

PhD Students

2023-2024 Maryam Rezaeizadeh – Co-research Supervisor
2023-2024 Divyesh Dobaria – Co-Research Supervisor
2023-2024 Zankrut Vyas – Co-Research Supervisor
2022-2024 Riya Shinde – Research Supervisor
2022-2024 Yi Tao – Research Supervisor
2020-2022 Jingzhe Li – Research Supervisor
2021 Shashwat Gupta – Committee member
2015-2020 Tianyi Li – Research Supervisor

Masters Students

2022 Riya Shinde
2018 Suraj Katepally
2018 Deval Sharma
2017 Anuj Mehta
2017-2018 Anand Valia
2016-2017 Nikhita Shetty
2016-2017 Nikita Soni
2016-2017 Glinka Pereira
2016-2017 Ravish Kumar

Undergraduate Students

2022-2023 Ulises Roldan, Kenny Kuang
2022 Jonathan Esposito
2020-2022 Isaac Mercado, Ethan Sewell
2020 Emily Gillespie, Krishna Amin
2018-2019 Isabelle Prokopenko
2018-2020 Joshua Grou, Christopher Laliwala
2016-2017 Lan Le
2015-2018 Kien Chau
2015-2016 Alan Aldana, Joseph Duncan, Jo Huang