

Harshit Agarwal
Staff Engineer, PMPD

EDUCATION

12/2021

Ph.D., Chemical Engineering**Graduate Certificate in Entrepreneurship**

University of Wisconsin-Madison, Madison, Wisconsin, US

Thesis – Design, synthesis, and characterization of liquid-infused antifouling materials

10/2016

B.Tech., Chemical Engineering**Minor, Biochemical Engineering and Biotechnology**

Indian Institute of Technology-Delhi, Delhi, India

EXPERIENCE

04/2023 – Present

Regeneron Pharmaceuticals, Inc., Tarrytown, NY**Staff Engineer, PMPD**

- Applied expert knowledge and engineering principles to develop and implement new methods and approaches related to membrane-based separation, purification, and formulation of biologics to enable intensified and continuous bioprocessing and reduce manufacturing time/costs
- Managed a team responsible for the design, development, and characterization of biopharmaceutical manufacturing processes
- Prepared and delivered effective oral presentations in various internal and external professional meetings and authored various internal and external publications
- Facilitated onsite support and troubleshooting for clinical GMP manufacturing

08/2021 - 03/2023

Catalent Pharma Solutions, Madison, WI**Scientist, Downstream Process Development**

- Developed and characterized downstream purification processes for various biotherapeutics, including monoclonal antibodies and Fc-Fusion proteins
- Provided downstream process development-related client-facing support for multiple drug development programs, including presenting development updates, defining and spearheading project-related activities, and solving process development and technology-transfer-related problems under accelerated timelines and budget constraints
- Led various technology development and onboarding initiatives, in collaboration with both external and internal teams, related to continuous bioprocessing, process analytical technology, digital twins, and process intensification
- Managed, mentored, and trained junior staff to perform various bioprocessing-related activities; defined career-development plans and generated personal development opportunities

09/2016 - 08/2021

University of Wisconsin-Madison, Madison, WI**Research Assistant, Department of Chemical and Biological Engineering**

- Developed approaches for the fabrication of porous coatings and

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membranes that are scalable and can be integrated into commercial or industrial processes, tunable and can be used to fabricate materials with a broad range of physicochemical properties, and sustainable

- Mentored 3 undergraduates with emphasis on lab safety, experimental design, and crafting effective presentations; created and delivered lectures to ~80 students and provided personalized one-on-one learning assistance
- Served as the lab safety officer and provided safety training, coordinated lab clean-up and safety inspections, and implemented lab inventory organization system

PUBLICATIONS

- Agarwal, H., Wang, X., Kulkarni, N. R., Tao, S., & Demers, C. (2023). Application of machine learning in ensuring viral safety of biotherapeutics: Case study demonstrating prediction and optimization of viral clearance performance of anion exchange chromatography. *Current Research in Biotechnology*, 6, 100140.
- Agarwal, H., Thwin, C., and Thangaraj, B. (2023). Single-use centrifugal separator enables intensification of the clarification process in the biomanufacturing of recombinant proteins. *Journal of Chemical & Biotechnology*. 95(5).
- Agarwal, H., Quinn, L. D. J., Walter, S. C., Polaske, T. J., Chang, D. H., Palecek, S. P., ... & Lynn, D. M. (2022). Slippery antifouling polymer coatings fabricated entirely from biodegradable and biocompatible components. *ACS applied materials & interfaces*, 14(15), 17940-17949.
- Agarwal, H., Breining, W. M., Sánchez-Velázquez, G., & Lynn, D. M. (2022). Reactive Multilayers and Coatings Fabricated by Spray Assembly: Influence of Polymer Structure and Process Parameters on Multiscale Structure and Interfacial Properties. *Chemistry of Materials*, 34(3), 1245-1258.
- Agarwal, H., Breining, W. M., and Lynn, D. M. (2021). Continuous fabrication of slippery liquid-infused coatings on rolls of flexible materials. *ACS Applied Polymer Materials*. 4(2).
- Agarwal, H., Nyffeler, K. E., Blackwell, H. E., Hacker, T. A., & Lynn, D. M. (2021). Slippery nanoemulsion-infused porous surfaces (SNIPS): antifouling coatings that can host and sustain the release of water-soluble agents. *Chemical Communications*, 57.
- Agarwal, H., Nyffeler, K. E., Blackwell, H. E., Hacker, T. A., & Lynn, D. M. (2021). Fabrication of slippery liquid-infused coatings in flexible narrow-bore tubing. *ACS Applied Materials & Interfaces*, 13(46).
- Agarwal, H., Nyffeler, K. E., Blackwell, H. E., & Lynn, D. M. (2021). Liquid crystal-infused porous polymer surfaces: a “slippery” soft material platform for the naked-eye detection and discrimination of amphiphilic species. *ACS Applied Materials & Interfaces*, 13(28).
- Kateja, N., Agarwal, H., Hebhi, V., & Rathore, A. S. (2017). Integrated continuous processing of proteins expressed as inclusion bodies: GCSF as a case study. *Biotechnology Progress*, 33(4).
- Rathore, A. S., Kateja, N., & Agarwal, H. (2017). Continuous downstream processing for production of biotech therapeutics. *Continuous Biomanufacturing: Innovative Technologies and Methods*, 259-288.
- Sharma, A. K., Agarwal, H., Pathak, M., Nigam, K. D. P., & Rathore, A. S. (2016). Continuous refolding of a biotech therapeutic in a novel coiled flow inverter reactor. *Chemical Engineering Science*, 140.
- Agarwal, H., Sharma, A. K., Kateja, N., & Rathore, A. (2016). Continuous processing for the production of biopharmaceuticals. *BioPharm International*, 29(4), 14-19.
- Agarwal, H., Rathore, A. S., Hadpe, S. R. and Alva, S. J. (2016), Artificial neural network (ANN)-

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based prediction of depth filter loading capacity for filter sizing. *Biotechnology Progress*, 32(6).

- Kateja, N., Agarwal, H., Saraswat, A., Bhat, M., & Rathore, A. S. (2016). Continuous precipitation of process related impurities from clarified cell culture supernatant using a novel coiled flow inversion reactor (CFIR). *Biotechnology Journal*, 11(10).
- Rathore, A. S., Agarwal, H., Sharma, A. K., Pathak, M., & Muthukumar, S. (2015). Continuous processing for production of biopharmaceuticals. *Preparative Biochemistry and Biotechnology*, 45(8).

PATENTS

- Rathore, A. S., Nigam, K.D.P., Pathak, M., Agarwal, H., & Sharma, A. K. (2015). A coiled flow inverter reactor for continuous refolding of denatured recombinant proteins and other mixing operations. (WO2016116947A1)
- Lynn, D.M., & Agarwal, H. (2021). Slippery liquid-infused porous surfaces that release hydrophilic and hydrophobic agents. (US11825845B2)
- Lynn, D.M., & Agarwal, H. (2022). Slippery and Anti-Fouling Liquid-Infused Coatings Fabricated from Biodegradable and Biocompatible Components. (US20230303861A1)
- Lynn, D.M., & Agarwal, H. (2022). Liquid Crystal-Infused Slippery Anti-Fouling Surfaces. (US20220332954A1)

TECHNICAL SKILLS

- Process engineering, continuous processing, colloid and surface science, separation and purification science, experiment design, statistical analysis, empirical and mechanistic modeling, and current good manufacturing practice
- Design, characterization, and technology transfer of various bioprocessing methods, including clarification, chromatography, tangential flow filtration, and viral filtration
- Biophysical and chemical characterization techniques, including fluorescence, confocal and cross-polarized microscopy, UV-Vis, FT-IR (ATR, IRRAS), SEM, GPC/SEC, DLS, NMR, TGA, Langmuir–Blodgett trough
- Mechanistic, empirical, and hybrid modeling using MATLAB, JMP, and Python

CONFERENCE PRESENTATIONS

- Kateja, N., Agarwal, H., & Rathore, A. (2017, April). Continuous processing of biotherapeutics through application of a novel Coiled Flow Inversion Reactor (CFIR). In *THE AMERICAN CHEMICAL SOCIETY SPRING MEETING*, San Francisco, CA, USA
- Kateja, N., Rathore, A., & Agarwal, H. (2019, March). Continuous refolding of a biotech therapeutic in a novel coiled flow inverter reactor. In *THE AMERICAN CHEMICAL SOCIETY SPRING MEETING*, Orlando, FL, USA
- Agarwal, H., Nyffeler, K. E., Hacker, T. A., Palecek, S. P., Blackwell, H. E., & Lynn, D. (2020, November). Fabrication of Oil-Infused Anti-Biofouling Coatings on the Surfaces of Flexible Polymer Tubing. In *2020 VIRTUAL AIChE ANNUAL MEETING*