CHEMISTRY & BIOCHEMISTRY SEMINAR SERIES:

Leveraging SAXS for Biologics Formulation Development in the Pharmaceutical Industry

Abstract:

Formulation development of biologics is key for ensuring the safety and efficacy of biologics drug products such as monoclonal antibodies (mAbs) due to their complex degradation and aggregation pathways. Work has been completed by collaborators on linking cluster formation to viscosity and employing coarse grained modeling to understand protein-protein interactions in relevant formulations. While formulation screening approaches exist for the dilute concentration regime (1-10 mg/mL), a deeper understanding is needed with appropriate tools during biologics formulation development at the relevant formulation concentration. We merge small-angle X-ray scattering (SAXS) with other biophysical tools to provide insight on the role of pH and buffer system on the stability



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of pharmaceutically relevant biologics. In this talk, I will discuss how we can take advantage of advanced biophysical and particle characterization tools to drive innovation and accelerate development of complex biologics in the pharmaceutical industry and will also discuss my journey from academia to industry.

About the Speaker:

Rahul Upadhya is a Senior Scientist at Merck & Co, Inc. He has an undergraduate degree from the University of Rochester (BS, Biomedical Engineering) and a doctoral degree from Rutgers University (PhD, Biomedical Engineering). His graduate school research involved high throughput synthesis and characterization of polymers excipients for small-molecule drugs and proteins. In his current role at Merck within Analytical Research & Development, Rahul collaborates with various stakeholders to support analytical characterization of biologics by taking advantage of biophysical and particle characterization tools. He serves as a STEM mentor for the Society of Women Engineers (SWE) and is enthusiastic about implementing new capabilities.