

# Yi Li

## Senior Research Chemical Engineer - Merck & Co., Inc

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### WORK EXPERIENCE

#### Senior Research Chemical Engineer

Merck & Co., Inc - West Point, PA - 2000 to Present

Leading downstream team in PhI process development for CMV/RSV live virus targets: aqueous two- phase, clarification, TFF, membrane chromatography, in-process viability and biophysical characterization

Led team in late stage development and manufacture process demonstration for Mening and Pneumo polysaccharide and conjugates: centrifugation, organic extraction, enzymatic delipidation, and TFF. process definition, tech transfer to manufacture, process consistency, and regulatory documentation

Led biophysical characterization and high-throughput formulation screening for pre-clinical antibody and outer membrane vesicle (OMV) targets

Led capture chromatography (ion-exchange) development, protease inhibition, VLP in-process stability (from PhIIa to process demonstration/validation) for HPV viral like particle; participated in FDP/FMP definition, process validation, safety assessment, pilot plant tech transfer, process manual documentation

Led multiple chromatography (IEX, HIC, affinity) development for antibodies and therapeutic protein

Contribute to Recombivax new process development in antigen refolding, adjuvant adsorption; GMP Phase I campaign and GMP documentation

#### Assistant Research Manager

Sunrise Pharma - 1996 to 1998

Process development, manufacture supervision and GMP documentation for therapeutic proteins.

### EDUCATION

#### Regulatory affairs certificate

Lehigh University

2012 to 2013

#### Ph.D. in Chemical Engineering

University of Delaware

#### M.S. in Chemical Engineering

University of Arkansas

#### B.S. in Chemical Engineering

Zhejiang University