



Marissa Vidal-Ludewig
Chemical Engineering (B.S. '93)

I enjoyed solving practical physics and chemistry problems: the sound of bomb calorimetry and the smell of synthetic banana in the labs caught my attention. Then my brother, who studied Mechanical Engineering, encouraged me to pursue my studies in Chemical Engineering. I started in manufacturing as a Purification Operator at a booming Biotechnology industry after graduation. Within a year armed with a Chemical Engineering degree, I learned quickly and I was asked to join the Engineering Department as a Process Engineer: Assessed facilities, utilities, processes fit-for-use; Designed/Built bioreactors, centrifuges, ultrafiltration/diafiltration/dilution and chromatography systems. I wore multiple hats and filled many shoes (e.g. Process Engineer, Process Development & Manufacturing Liaison, Project Manager, Qualification/Validation/Audit/Inspection Lead) in numerous parallel technology transfers and scale-up projects. I was promoted to Principal Process Engineer within the first 7 years of my career.

With these hands-on experiences under my belt, I joined larger pharmaceutical/biotechnology companies as a strategic and collaborative leader: Qualification/Validation/Engineering Standards & Conformance Manager, Principal Technical Advisor, and Head of Annual Product Review (APR) Governance and Business Processes. Accountable for Engineering, Manufacturing, Quality, and Regulatory compliance. Technical expert in Technology Transfers, Validation, and global Health Authority requirements. Governance of Quality systems and lean business processes. I traveled across the globe and learned from my direct reports, colleagues and consultants with diverse disciplines. My over 26 years of experiences in pharmaceutical and biotechnology industries influenced the standardization of Engineering, Validation, Quality and Regulatory (e.g. FDA, EMA, MHA) practices and requirements, and contributed to the production of consistent quality medicines for patients with unmet medical needs.