

PROFILE

Ambitious, seasoned and accomplished leader highly skilled with quality & compliance, program development, program strategy, technical system implementation, and project management within Fortune 500 regulated environments spanning pharmaceuticals, biotech, and medical devices. Extensive experience in developing programs, processes and service excellence, strategic planning, problem solving, and navigating the challenges in leading cross-functional teams

CONTACT

PHONE: 201-482-9576

WEBSITE: rm.minaris.com

EMAIL:

evelyn.chang.xmslq@rm.minaris.com

EVELYN CHANG

Associate Director, Compliance

EDUCATION

Rutgers University

Executive Master of Business Administration, May 2018 Concentrations (3) in Finance, Strategy, and Leadership

New Jersey Institute of Technology

MS Pharmaceutical Engineering, August 2011 Concentrations (2) in Drug Substance Manufacturing and Drug Product Manufacturing

New Jersey Institute of Technology

BS Computer Engineering, May 2005 Concentrations (2) in Telecommunication and Project Management

WORK EXPERIENCE

Minaris Regenerative Medicine, **LLC.**, **Assoc. Director**, **Compliance** May 2020 - Present

Championed the development of programs: Internal Audit, Client Audit and Regulatory Inspection (Inspection Readiness Program), and Data Integrity. Responsible for the oversight and management of internal and external (client and regulatory inspections) audit and compliance at the Clinical and Commercial sites in Allendale, NJ and management review.

Legend Biotech, LLC., Sr. Manager, IT Quality and Compliance May 2019 – May 2020

Fulfilled organizational goals by continuously developing and improving systems, processes, & services to help cell therapy biopharmaceutical companies achieve commercial business outcomes. Advocated for conducting retrospective meetings to identify quantitative and qualitative ways to improve and increase regulatory compliance & business productivity and outcomes.

Additional Experience:

Corporate Manager, G&W Laboratories, Inc. Quality Assurance Manager, G&W Laboratories, Inc. Senior Quality Assurance Validation Engineer, G&W Laboratories, Inc. Validation Engineer IV, Technical Services – Drug Product Manufacturing, Pfizer, Inc. Validation Engineer IV, Technical Services – Process Monitoring & Informatics, Pfizer, Inc. Validation Engineer IV, Technical Services – Drug Substance Manufacturing, Wyeth, Inc. (acquired by Pfizer, Inc.) Quality Assurance Specialist, Kelly Scientific (for Wyeth, Inc.) Quality Engineer, Adecco Group (for Stryker Orthopaedics) IT Quality, Stryker Orthopaedics Project Engineer, The P.F. Laboratories, Inc.