

GREG LYNCH

Senior Validation Engineer / Project Leader

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PROFESSIONAL SUMMARY

Energetic, self-starting Chemical Engineer and consulting business owner with over 21 years of industry experience and training. Looking for projects with technical challenge within the Pharmaceutical & Biotech Industry. Knowledgeable in both engineering, quality assurance, and validation activities from R&D through commercial operation of cGMP BL-3/BL-2, aseptic fill, parenterals, API, OTC, medical device, inhaled drug delivery products, vaccine, and laboratory facilities.

AREAS OF EXPERTISE

Process Validation	Technology Transfer	Technical Writing
Troubleshooting	Sterile Manufacturing	Drying & Agglomeration
Start-up & Process Optimization	Liquid & Powder Filling	Critical Utility Systems
BL-2 / BL-3 Facility Design & Validation	Bioreactor/Fermentation & Purification System Validation	
Technical Liaison (R&D – Manufacturing - QA)	Compliance Audits (internal / external)	
Autoclave/SIP Cycle Development & Qualification	Lyophilizer Qualification	Project Management

SUMMARY OF QUALIFICATIONS

- Over 8 years as Pharmaceutical Validation & Process Engineering consultant
- 21+ years experience in Project Management and Process Development/Optimization
- Knowledgeable in R&D, Manufacturing & Validation of sterile parenterals, lyophilized products, otics, ophthalmics, Powder products & processing, oil-based products
- Highly Skilled in Product Validation, Process Optimization & Validation, Facility re-design and start-up, Project Management, Design of Experiment, Statistical Analysis, and FMEA
- Experienced in all aspects of parenteral component preparation, compounding, filling, Sterile Filtration, support services, equipment preparation and cleaning
- Experienced with Protein Separation & Purification and Sterile Isolator technology validation

PROFESSIONAL EXPERIENCE

ECVS, Inc.
Tucson, AZ.

1999 - Present

President and senior consultant at engineering and validation consulting firm to the pharmaceutical, biotechnology, and medical device industry. Provide exceptional service to clients including: Validation document preparation & review (PV, PQ, IOQ, DQ), Process Development & Optimization, Process Evaluation and Validation, Process troubleshooting, SIP/CIP process design and validation, Equipment Commissioning/DQ/IQ/OQ/PQ, Line Set-up, SOP writing, Process and Document Audits, Project Management, QA systems development, and training. Satisfied clients include: Pfizer (Exubera®), Amgen, Allergan, Baxter, Zila Biopharm, Cord Blood Registry, Slim-fast/Unilever, Cardinal-Health, Acambis, O'Neil Engineering, Novartis, Gensia Sicor, Chesapeake Biological Laboratories, Emergent Biosolutions (formerly BioPort).

G R E G L Y N C H

Senior Validation Engineer / Project Leader

Schein Pharmaceutical Inc. / Steris Laboratories Division **1996 - 1999**

Phoenix, Arizona

Process Development Scientist IV (Technical Services)

Validation Project Leader

Nestle USA/Westreco R&D **1990 - 1996**

Jacksonville, IL., Marysville, OH., Fulton, NY., Van Nuys, CA.

Manager of Process Technology – Technical Services

Senior Development Engineer – R&D Technical Transfer

Senior Engineer – R&D

H.J. Heinz Company **1988 - 1990**

Long Beach, CA.

Process Engineer -R&D

General Mills, Inc. – JFB Technical Center **1984 - 1988**

Minneapolis, MN.

Research Chemical Engineer

Chemical Engineer

EDUCATION

BACHELOR OF SCIENCE, Chemical Engineering, Colorado State University, Fort Collins, Colorado
(Graduated May 1984) in 5-year program concurrent with CoOp at Eastman Kodak Company

Continuing Education (PDA, ISPE, AIChE, ISA, Center for Professional Development, etc. – over 135 CEUs obtained from 1984 to present, ASQ - CQE)

MEMBERSHIPS & CERTIFICATIONS

Member, ISPE (International Society of Pharmaceutical Engineers)

Member, PDA (An International Association for Pharmaceutical Science And Technology)

Member, ISA (Instrument Society of America)

Member, AIChE (American Institute for Chemical Engineers)

Member, ASQ (American Society for Quality)

Select Agent Security Clearance by FBI/CDC (42 CFR 73) – December 2003

Certified for handling of & vaccinated for various biohazardous materials (anthrax, smallpox, botulinum) in BSL-2 and BSL-3 manufacturing and laboratory facilities

ISO Class 5 (EU Grade A) Gown Qualified