

BETH LYNCH

Validation Engineer / Project Leader

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PROFESSIONAL SUMMARY

An effective, people-friendly Chemical Engineer with 20+ years of project management and technical experience who is able to provide hands-on support to a validation team. Able to prepare and execute validation and qualification protocols for process and support equipment at pharmaceutical and medical device manufacturing facilities. Experienced in the preparation of quality systems documentation such as SOPs, OOS investigations, and project reports. Able to apply knowledge of manufacturing processes and equipment, process development, and strong writing and organizational skills. Available on a project basis to work at any location.

EXPERIENCE

10/2001 - Present

Engineering Consulting & Validation Services, Inc

Tucson, AZ.

Validation Engineer

Performed system and component impact assessments and wrote validation plan and protocols for equipment qualification and process validation of compounding and packaging processes for eight OTC product families.

Responsible for design and implementation of modifications to manufacturing facility for a new product launch. Lead team in risk assessment, equipment commissioning and IQ, OQ, PQ qualification, creation of SOPs and device production records, and cleaning and process validation. Wrote validation master plan and facility master plan and tracked and reported progress in MS Project.

Wrote validation master plan for an API manufacturing facility covering utility systems, reactors, and purification and drying equipment. Performed and reported gap analysis of executed VMP.

Wrote and executed IQs and OQs for formulation tanks and mixers, a thin film evaporator, and portable heat exchangers for a new parenteral pharmaceutical product and wrote and compiled the summary reports. Assisted with the development of a CIP process and helped execute the CIP PQ.

Wrote and executed IQ and OQs for formulation tanks, mixers, and packaging equipment for an OTC product. Wrote and compiled final IQ and OQ summary reports. Assisted with execution of PQs, Mixing Validation, and Process Validation. Programmed and operated Kaye Validator 2000 for temperature mapping studies.

Executed IQ, OQ, and PQs and wrote operating, cleaning, and maintenance SOPs for four autoclaves at a new vaccine facility (BL-2). Assisted with execution of filler PQ and capper PQ. Wrote SOP for plant-wide calibration program. Assisted Validation Manager with project schedule & data entry.

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10/1994 - 8/1995

Nestle Beverage Company

Jacksonville, Illinois

Production Supervisor

Supervised hourly workers in receiving and process department and filling and shipping department in the Coffee Mate manufacturing facility. Assigned work by skills and seniority. Identified and fixed quality and rate problems. Arranged equipment repairs and maintenance. Assured component availability. Reported material, manpower, production, and inventory data daily.

10/1991 - 8/1994

The Andrew Jergens Company

Cincinnati, Ohio

Section Head - Soap Products R&D

Responsible for Process and Product Development of bar and liquid soaps which included the following. Supervised chemists and their lab work. Surveyed and evaluated new chemicals/ingredients. Developed and scaled up new formulas and processes and modified formulas of existing brands for cost, manufacturability, or product improvement. Wrote purchasing specs for new materials. Oversaw consumer and clinical and microbiological testing for claims substantiation, stability, and performance. Coordinated R&D work with Marketing Research, Marketing, Purchasing, Sales, Manufacturing, and Engineering departments. Developed strategy and timelines together with new product team. Wrote department monthly reports and presented project progress and results to other departments.

1/1989 - 10/1991

Neutrogena Corporation

Los Angeles, California

Senior Research Project Manager

Responsible for all Process and Product Development on bar soaps for Neutrogena. Developed and implemented a scrap soap rework procedure that resulted in reduced waste and cost and produced a product that consistently met the quality specification. Developed a continuous, high-throughput process for casting soap to allow plant expansion at lower capital cost. Optimized the existing soap synthesis process then wrote and implemented an SOP that decreased out-of-spec product.

6/1979 - 1/1989

The Dial Corporation

Phoenix, Arizona

Research Associate, Senior Research Engineer, Research Engineer

Responsible for Process and Product Development of Dial brand bar soaps. Evaluated alternative soap synthesis / amalgamation / refining process for performance and economics. Developed and implemented a proprietary strategy for least cost formulation that increased profitability while giving strategic advantage in marketing byproduct chemicals. Designed and carried out pilot plant trials to assess manufacturability of new formulas and coordinated R&D's assistance to Manufacturing for production startups.

EDUCATION

5/1985	Arizona State University	Tempe	M.B.A.
6/1979	University of Illinois	Urbana	B.S. Chemical Engineering

RELEVANT SKILLS

Experienced with operation of Kaye Validator 2000
Proficient in the use of MS Word, Excel, Project, Visio, etc.