

Objective

Ambitious, motivated engineering professional seeking a new and exciting technical position that can utilize my creative ability to solve problems. Possesses a solid educational foundation, combined with background in pharmaceutical validations, research, production, and QC. Thrives in high-pressure, deadline-driven environments.

Related Experience

Validation Engineer

Wyeth

Pearl River, NY

11/2004 – 5/2005

Assisted authoring and execution of OQ and PQ templates, protocols, addendums, and reports, as well as preparation of turnover packages for the Syringe Filling Facility's Feed Water System including: US Filter UV and RO, WFI Tank and distribution System, WFI loop, Muller Still Steam Generator, and Techniserv Cooling Skid.

Completed OQ testing and wrote reports for the Crest Ultra Sonic Washer

Assisted the execution Component Preparation Area HEPA OQ.

Assisted the execution of the autoclave PQ testing

Skills: Use of Kaye Validator 2000 for SIP testing; TOC, conductivity, bioburden, and endotoxin for WFI test sampling.

Validation Engineer

Aventis Pasteur

Swiftwater, PA

05/2004 – 11/2004

Authored and executed IQ, OQ, and PQ protocols, and wrote the reports for the Diphtheria Transfer Station

Assisted authoring of Diphtheria Transfer station SOP.

Re-designed the Transfer Station to attain proper functionality.

Authored and executed the PQ protocols and reports for ultrasonic cleaning transfer station specific items.

Skills: Use of Documentum; TOC Swab, TOC, conductivity, bioburden, and endotoxin water sampling; Kaye Validator and BIs for SIP testing, clean room gowning.

Validation Engineer

Johnson & Johnson

Raritan, NJ

09/2003 – 5/2004

Assisted in the manufacturing and equipment qualification for the: Nikka Densok pinhole detector, 5 ml ampoule labeler, and vision systems.

Consulted in-house engineers of current industry techniques and practices.

Researched, ordered, and qualified new equipment for the processing facility.

Developed, authored and reviewed new and existing operating protocols.

Provided hands-on support as a backup for the production technicians.

Skills: Consistently worked OneSource (Documentum). Clean Room Gowning

Validation Engineer

AMGEN

W. Greenwich, RI

05/2003 – 9/2003

Developed, authored and reviewed IQ, OQ, PQ, PM protocols and reports.

Performed cleaning validation runs on glass washers, drum washers and 8,000L media tanks (CIP).

Reviewed site wide cleaning protocols to create a matrix of current protocols and validated hold times.

GMP Skills: Sampling of TOC, conductivity, bioburden, and endotoxin. Use of Trackwise (Documentation) for protocol and SOP drafting. clean room gowning.

Associate Research Scientist

ArQule Inc.

Woburn, MA

05/2002 - 12/2002

Performed chemical validation mappings of combinatorial arrays utilizing robotics.

Developed production protocols

Developed organic combinatorial reactions.

Maintained research equipment including Genevac's, Savants, HPLCs, and Sedex equipment.

Other Skills: Operation and theory of: HPLC, UV, MS, NMR, ELSD, centrifugal evaporators, heater/shakers.

Production and Validation Engineer Intern

Abbott Bioresearch Corporation (BASE)

Worcester, MA

05/2001 - 08/2001

Performed *Clean In Place (CIP)* validation of acid and base rinse on large (6000 L) fixed reactors, small (100L) portable tanks, and transfer lines using pH and conductivity wash data and riboflavin sprayball coverage tests.

Assisted *Sterilization In Place (SIP)* validations on large reactors, small tanks, and transfer lines using Kaye Digistrip temperature point data and a bacterial control strips

Setup and operated large-scale bioreactors in a research setting (pilot plant).

Created standard control procedures (SCPs)

GMP Production Skills: Cell transfer from initial bag to increasing sized bio reactors; buffer & media preparation; cell counts; pH measurements and adjustments; centrifugation; ultra-filtration; Ion-exchange and affinity chromatography.

Quality Control Technician

DuPont Pharmaceuticals (Dupont-Merck)

No. Billerica, MA

05/1998 - 08/2000

Operated and maintained and qualified laboratory instruments and equipment

Wrote and performed qualification protocols (IQ, OQ, PQ) under strict cGMP guidelines on dishwashers freezers, Atomic Absorption (AA's) Spectrophotometers, Auto- titratorS, Karl Fisher titrators, and pH Meters.

Wrote and maintained standard operating procedures.

Performed biological environmental monitoring of clean rooms in GMP pilot plant.

Other GMP Skills: Chromatography: HPLC, GC, TLC, paper and gel electrophoresis; *Spectroscopy:* UV, IR, AA, Polarimeter; *Titration techniques:* Polargraph, Carl-Fisher, Autotitrator, bench-top potentiometric Acid/Base titration, organic extractions; pH meter; scintillation counter; pharmaceutical water systems; radiation safety; clean room/pilot plant monitoring; level 1&2 bacteria handling/culturing; use of auto clamp; sterile technique; Pharmaceutical cGMPs; Writing, editing, using, and keeping current SOP/SCPs against current USP/ACS practices.

Education	<p>Bachelor of Science: Biotechnology with a concentration in Chemistry <u>Worcester Polytechnic Institute</u> Worcester, MA 1/2006 Acquired Skills: <i>Chromatography</i>: HPLC, GC, TLC, paper, affinity, gel, IX, HIC; <i>Spectroscopy</i>: UV-VIS, GC, IR, NMR, MS operation & theory <i>Computer genetics</i>: database quarrying (Pubmed, Entrez, Protein), computer cloning software, homology searching and other sequence comparisons; journal research; <i>Protein purification</i>: Northern, southern, and western blots; gel electrophoresis: 2-D, SDS-PAGE, capillary and agarose; <i>Molecular Synthesis</i>: plasmid and protein prep, enzyme digestions, use of plasmid insertion vectors, inert and atmospheric organic/inorganic chemical synthesis and purification; <i>Cell Culture</i>: animal tissue culture (suspension and adherent cell lines), phase contrast microscopy, pH buffer preparation/theory, basic fermentation techniques.</p>
Other Work Experience	<p>Payroll and Administration Clerk / Data Entry Clerk <u>U.S. Census Bureau</u> Worcester, MA 01/2000 - 03/2000 Organized confidential paper file system and Entered field data into the government computer system.</p> <p>Web designer / Webmaster <u>Michelle Lisowski</u> Pelham, NH 07/1999 - 05/2000 Designed small electronic commerce business site called "ancient desert remedies"</p> <p>Technical Support Specialist <u>DuPont-Merck</u> No. Billerica, MA 06/1997 - 08/1997 Troubleshoot and wiped viruses, installed software packages, and responded to AS 400 system alerts.</p>
Computer Skills	<p>Familiar with Windows (all: 3.11 - XP); Unix, GNU/Linux; and Macintosh. Proficient in web based research and html language with working knowledge of PHP, XML, and CSS. Used many software packages including LIMS, VAX Multichrome, Chemstation (GC/LC), Vision 32 (UV), Brinkman Titrimo Workstation (autotitrator), SAS, SPSS, PSPP, R-statistical package, Matlab, Maple, various Office productivity suites</p>
MQP	<p><u>DNA demethylation in Artemisia Annuu</u>: Media prep and culture of A. Annuu plant YUT16 roots; plant tissue DNA extraction; methylation sensitive acid hydrolysis of DNA; DNA base separation and quantification by TLC and UV; determination of total Artemisinin by HPLC analysis.</p>
IQP	<p><u>Case study of a phosphorylated pond</u>: Water testing: nitrates, phosphates, DO etc.; Recommend various biological remediation techniques.</p>