

PATRICK E LINK
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CAREER OBJECTIVE

A position in Manufacturing, Quality Assurance or Regulatory Affairs where auditing, problem solving, training, team motivation and organizational skills would enhance the quality of a company's products.

SUMMARY OF QUALIFICATIONS

- Four years experience as Compliance Specialist for manufacturing of yeast based tarmogens.
- Six years experience as manager and supervisor for medical manufacturing, tissue banking and multidisciplinary teams of QAL analysts for Biopharmaceutical Plant.
- Five years of experience in the supervision of a biopharmaceutical pilot plant at cGMP and GLP levels.
- Nine years of experience in mammalian cell culture research.

Qualified in:

- Management of projects directed towards product quality improvement and new process technology utilizing cross-functional teams.
- Development and supervision of teams to analyze samples for Quality Analytical Labs, to process human donated tissue into quality allografts, and to produce medical equipment in one facility and recombinant proteins and associated data for R&D in another facility.
- Auditing, documentation review, quality improvement and creation of training systems for safe and successful assembly of medical products, bacterial and yeast fermentation and protein recovery processes.

PROFESSIONAL EXPERIENCE

Compliance Specialist

Jan 2006 – present

GlobeImmune, Inc
Louisville, CO

GlobeImmune is a private biopharmaceutical company developing targeted molecular immunogens for the treatment of cancer and infectious diseases.

Management of documentation and process compliance for GMP production of yeast based immunogens.

- Ensuring timely review of batch records and associated documents for product release to clinical demands.
- Creation and management of GMP and 21 CFR compliant training system for manufacturing process.
- Write, revise and train on Batch Records, SOP's and departmental policies.
- Maintain internal database tracking of auditing, documentation errors, deviations and documentation flow.
- Manage postmortem reviews on projects and production runs to implement quality improvements.

Manager of QAL Teams

Sept 2004 – Jan 2006

Lancaster Labs, Inc @ Amgen
Longmont, CO.

Lancaster Labs was an analytical service providing professional scientific staffing onsite at Amgen, Colorado

Management of QAL analysts in Cell Biology, Immunochemistry, Analytical Chemistry and Microbiology:

- Ensuring timely completion of analytical assays for varied samples through appropriate use of human and technological resources, scheduling and effective problem solving.
- Thorough understanding of cGMP, Regulatory and FDA guidelines for analytical testing of samples, auditing and review of documentation, and investigations of nonconformances.
- Focus on service to make heroes of the clients.

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Processing Supervisor/Operations Manager June 2002- April 2004 **Allosource,
Centennial, CO.**

Allosource is a bone and tissue banking company that produces quality allografts for surgical implantation.

Supervision of technicians for the processing of donated human bone and tissue into quality allografts:

- Ensuring operations schedules were met within budget through appropriate use of human and technological resources, scheduling and effective problem solving.
- Thorough understanding of good cGMP to enhance cleanroom effectiveness, meet and exceed FDA/QSR requirements and to produce the highest quality material for human implantation.
- Personnel development, staff management, recruitment, training and safety systems, conflict resolution.

Production Supervisor June 1999-Nov 2001 **Gambro U.S. Products Inc.
Lakewood, CO.**

Global medical technology and healthcare company with leading positions in renal care and blood component technology (BCT).

Supervision of assemblers (35 to 80) in a flow line process for the manufacture of disposable medical products:

- Productivity: focused on keeping a high level of quality material to help meet business demands.
- Personnel development, staff management, recruitment, training systems, conflict resolution.

Research Supervisor/Manager Feb-Dec, 1998 **Heska Corporation,
Fort Collins, CO**

Biopharmaceutical Company develops, manufactures, and markets companion animal health products.

Supervision of technicians engaged in the dissection and preparation of tissues for companion animal research:

- Scheduling of personnel and time for dissections of flea tissues and animal challenges.
- Creation of GMP environment in Flea Lab for documentation, training and product flow.

Pilot Plant Supervisor 1992 - 1997 **Somatogen, Inc.,
Boulder, CO.**

Biopharmaceutical Company engaged in bringing Recombinant Hemoglobin to market as a blood substitute.

Supervision of pilot operation and three shifts of personnel for E. coli fermentation at 2 Liter to 1500 Liter scale in Process Development and Manufacturing from fermentation through purification:

- Scheduling and analysis of experimental fermentations and resolution of process problems.
- Writing monthly progress reports, audit reports, training guides and standard operating procedures.
- Personnel development, staff management, recruitment, training systems, conflict resolution and customer interaction.
- Process auditing and project management.

Staff Research Associate III 1977 - 1992 **Dept's of Nutritional Sciences,
Zoology & Molecular Biology and Virus Lab
University of CA., Berkeley, CA.**

Academic endocrine research laboratory under NIH grant.

Primary cell culture and hybridization of rat pancreatic and gut epithelial cells for endocrine research:

- Production and characterization of hybrids by the methods of tissue culture, immunocytochemistry, karyotyping, radioimmunoassay and electron microscopy preparation.
- Set up and maintenance of tissue culture and biochemistry facility.
- Supervision and training of lab personnel and students.

Academic cancer research laboratory under NIH grant

- Conducted mammalian cell culture research examining the role of cytoplasmic inheritance and gene mutation on the development of drug resistance.
- Isolated and radiochemically quantified enzymes and cell waste products.
- Isolated and purified mouse DNA obtained from cell cultures.
- Isolated and characterized mutant cell types through cell cloning and differential cell growth in specially prepared selective media.

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EDUCATION

B.S. Biology, Kent State University, Kent, Ohio.
Graduate work in Medical Microbiology, University of Missouri, Columbia, MO.

CONTINUED EDUCATION

Supervision I & II; Supervision in a Team Environment; Time Management; Train The Trainer; Coaching skills for Managers/Supervisors: *Mountain States Employer's Council, Denver, CO.*
Performance Management; Conflict Resolution; Leadership Skills: *PRAXIS Consulting, Inc., Denver, CO.*
Microsoft Windows NT computer systems certification training: *Knowledge Alliance, Boulder, CO.*
Practical Injection Molding (Paulson Training Programs): *Gambro BCT, Lakewood, CO.*
Customer Service Training: *Lancaster Labs, Longmont, CO*
7 Habits of Highly Effective Managers: *Lancaster Labs, Longmont, CO*

CERTIFICATIONS

Regulatory Affairs Certification (RAC), June 2010
Certified Tissue Banking Specialist (CTBS)

PUBLICATION

Aponte GW, Keddie A, Hallden G, Hess R, Link PE 1991 Polarized intestinal hybrid cell lines derived from primary culture: Establishment and characterization. *Proc. Natl. Acad. Sci.* 88:5282 - 5286