Director of Quality Assurance

AREAS OF EXPERTISE

- **ISO 17025 experience and training**
- **Part 11 Policy, procedures, & remediation**
- **cGMP Quality Management**
- **Pharmaceutical QC Management**
- **QMS Policy and Procedure Development**
- **Leading successful transfer of methods/specifications to new facilities**
- **Maintaining quality, while increasing the size of operations**
- **Product, Area, and System Auditing**
- **Problem solving in production processes and analytical methodology.**
- **Team participation and collaboration with corporate, R&D, IT, production, process technology, logistics, customers, regulatory, and quality.**
- **Commitment to continuing education and tear development**

INTRODUCTION

Consultant is experienced in Pharmaceutical cGMP Development and Management. Skilled in building high-performance teams, developing technical supervision and staff, implementing quality systems, and solving analytical and process problems. Excels in productive interactions across multiple disciplines, with effective communication and technical skills.

WORK EXPERIENCE

2016 – Present
Industry Consultant
Duties:
- Development and oversight of compliant quality management systems.
- Auditing services.
- Part 11 interpretation, guidance, and policy implementation.
- CMC development, writing, and review.
- Technical resource for manufacturing and testing planning and problem resolution.

2017 - 2018
Minnesota Department of Agriculture
Quality Assurance Officer
Duties:
- Provide internal auditing of government laboratory for compliance to ISO 17025.
- Represent department quality assurance in external audits.
- Provide QA support for cross-functional teams.
- Develop technically sound policy to support ISO 17025 accreditation.

2012 - 2016
QOL Medical, LLC, Vero Beach, FL
Director Quality Assurance
Duties:

- Maintained change control system for SOPs, master production records, specifications, and test methods.
- Working with vendors, reviewed and approved master production records, test methods, and stability programs.
- Oversaw process and analytical validation activities in support of master records and test methods.
- Wrote protocols, coordinated execution, and developed reports.
- Investigated and managed deviations and out of specification occurrences, and implemented CAPAs both internally and with contract vendors.
- Working with production planning, coordinated timely manufacture and release of drug substance and drug product by issuing purchase orders, authorizing manufacturing and testing, approving labeling and packaging, and developing and dispositioning quality issues.
- Working with regulatory affairs, developed and maintained stability and retain program, and support of statistics based shelf life expiry determinations.
- Wrote, reviewed, and approved certificates of analysis, stability protocols, and stability summaries.
- Trended manufacturing and analytical data by tracking and summarizing key performance indicators.
- Tracked and trended adverse drug experiences and complaints, and performed complaint investigations.
- Audited label vendors, drug substance and drug product manufacturers, contract testing laboratories, and distributors.
- Working with regulatory affairs, developed and reviewed CMC sections for INDs and NDAs.
- Prepared and supported vendors during regulatory inspections.
- Maintained training documentation internally and audited vendor training.
- Reviewed and approved clinical protocols, and assured randomized packaging.
- Reviewed and approved clinical SOPs.
- Maintained internal and external audit schedules.
- Working with legal, developed and maintained pharmacovigilance agreements and quality agreements with vendors.
- Wrote, reviewed, and approved SOPs, specifications, protocols, and reports as required.
- Supported process and analytical development and validation.
- Characterized sacrosidase isolated from baker's yeast extraction process to verify consistency with published glycosylated SUC2 gene, including N-linked-mannose oligomers in Asp-X-Thr/Ser codons. Methodology included denaturing reduced SDS-PAGE, non-reducing native-PAGE, EndoH and PNGase mediated deglycosylation, peptide mapping, N-terminal and C-terminal sequencing, differential scanning calorimetry, and polarimetry.
- Characterized sacrosidase extraction and purification process to help assess impact of digestion and purification parameters on extraction efficiency, glycosylation, papain levels, bioburden, formulation stability, and yield. Methodology included ELISA, SDS-PAGE, freezing point depression, specific gravity, polarimetry, USP, and BAM chapters.

2003 – 2012
Cimalabs, Inc./Teva Pharmaceuticals, Brooklyn Park, MN/North Wales, PA
Senior Quality Control Manager, (2005 – 2012)
Duties:

- Established analytical technology transfer system.
- Lead successful transfer of dozens of methods and specifications for several product lines to sister plant.

Quality Control Manager, (2003 – 2005)

Duties:

- Built 24/5 QC operation into fully functional shifts capable of analyzing all products using all instrumentation, and working with CDS, QMS, and SAP systems.
- Solved critical analytical problems to support testing in HPLC, GC, Dissolution, and Disintegration, including compendia interpretations and method improvements.
- Worked with R&D and regulatory affairs at specification setting.
- Developed strong interactions with R&D, QA, logistics, production, HR, and customers by developing communication spreadsheets, participation in internal and external audits, and representing QC in recurring meetings.
- Grew department by 50% while maintaining 6 day turn time and ensuring compliance.
- Chartered Empower CDS paperless team to streamline analysis and review processes.
- Business lead for global Cephalon LIMS system.

2001 – 2003

Pfizer/Pharmacia Corp., New York, NY

Quality Assurance Manager

Duties:

- Built system for identifying and reducing process impurities in low-dose compounds using HPLC, photodiode array detection (PAD), BOMS, and UV Spectral Libraries, and spiking studies.
- Developed extractable / leachable tools and policy in support of corporate team.
- Assisted sister plant in solving process contamination of API during manufacture.

1998 – 2001

Orphan Medical (Now Jazz Pharmaceuticals), Minnetonka, MN

Quality Analyst

Duties:

- Characterized impurity pathway, including impurity identification, in Xyrem (sodium oxybate) using mass spectrometry, pH profiling, and HPLC.
- Qualified reference standards.
- Determined critical impurity in Busulfex (busulfan) using ELS, HPLC, derivatization, NMR, and mass spectrometry.
- Improved robustness of final processing of Sucraid (sacrosidase) by developing polarimetry in-process control, with glycerin dilutions.

EDUCATION

University of Kansas, Lawrence, KS

Doctor of Philosophy: Pharmaceutical Chemistry

Minnesota Sate University, Saint Cloud, MN

Bachelor of Science: Chemistry

CERTIFICATIONS AND COMMISSIONS

- ASQ Certified Quality Engineer, Exam Developer, 2015.
- ASQ Certified Quality Auditor, 2010 – present.
- ASQ Certified cGMP Professional, Exam Developer, 2009
- ASQ Certified Quality Engineer, 2008 – present.
- ASQ Certified Manager of Quality / Organizational Excellence, 2006 – present.
- Cephalon DISC Personality Profiling, 2006.
- CIMA Leadership Forum, 2005.
- Dale Carnegie Training, 2004.

PUBLICATIONS

- Miller, B., Hageman, M., Thamann, T., Barròn, L., Schöneich, Ch.; Solid State Photodegradation of Bovine Somatotropin (Bovine Growth Hormone): Evidence for Tryptophan mediated Photooxidation of Disulfide Bonds. Journal of Pharmaceutical Science, 2003, 92, 1698-1709.
- Schöneich, Ch., Miller, B, Hug, G.L., Bobrowski, K., Marciniak, B.; Intermolecular Complexes between Sulfide Radical Cations from Beta-Hydroxy Sulfides and Phosphate. Research on Chemical Intermediates, 2001, 27, 165-175.
- Schöneich, Ch., Sharov, V., Miller, B.; Stereoselectivity of Radical Reactions of Superoxide and Oxygen in Peptides and Proteins. Radiation Research, 2000, 2, 38-41.
- Miller, B., Kuzcera, K., Schöneich, Ch.; One-electron Photooxidation of N-Methionyl Peptides. Mechanism of Sulfoxide and Azasulfonium Diastereomer Formation Through Reaction of Sulfide Radical Cation Complexes with Oxygen or Superoxide. Journal of the American Chemical Society, 1998, 120, 3345-3356.
- Bobrowski, K., Hug, G.L. Marciniak, B., Miller, B., Schöneich, Ch.; Mechanism of One-Electron Oxidation of Beta-, Gamma-, and Delta-Hydroxyalkyl Sulfides. Catalysis through Intramolecular Proton Transfer and Sulfur Oxygen Bond Formation. Journal of the American Chemical Society, 1997, 119, 8000-8011.
- Jensen, J.L., Miller, B., Zhang, X., Hug, G.L., Schöneich, Ch.; Oxidation of Threonylmethionine by Peroxynitrite. Quantification of the One-Electron Transfer Pathway by Comparison to One-Electron Photooxidation. Journal of the American Chemical Society, 1997, 119, 4749-4757.
- Miller, B., Williams, T.D., Schöneich, Ch.; Mechanism of Sulfoxide Formation through Reaction of Sulfur Radical Cation Complexes With Superoxide or Hydroxide Ion in Oxygenated Aqueous Solution. Journal of the American Chemical Society, 1996, 118, 11014-11025.