

## BACKGROUND SUMMARY

Managed raw material testing in the Quality Control Laboratory and a comprehensive raw material and finished product specification migration between two work sites.

Analytical Chemist with over six years experience in method development, identification, and analysis of compounds, in complex to simple matrices at the trace, micro, and macro levels by using a variety of modern and classical techniques. Designed and implemented requested sample analysis schemes, performed analysis, and directed other analysts to ensure the quality and completion of these projects.

Compliance Specialist for a global pharmaceutical contract manufacturer, focused on product development quality assurance. Experienced at conducting internal and external audits. Supported clinical supplies manufacture through all phases of development and production. Hosted several compliance audits from customers, as well as hosting a mock pre-approval inspection.

## PROFESSIONAL EXPERIENCE

BANNER PHARMACAPS, High Point, NC (6/1997 to 8/2008)

Quality Control Laboratory Supervisor (10/2006 to 8/2008)

- Responsible for the proper and timely testing of raw materials
- Conduct Out-of-Specification investigations and create CAPA items
- Train QC personnel in analytical techniques and cGMP compliance

Raw Materials Manager, Quality Control (6/2003 to 3/2004)

- Responsible for the proper and timely testing of all raw materials
- Conduct Out-of-Specification investigations
- Schedule workflow and personnel resources to accomplish rapidly changing production schedules
- Train QC personnel in analytical techniques and cGMP compliance
- Modify or create raw material specifications and written procedures

Compliance Specialist (12/1999 to 9/2002)

- Function as the Quality Control Unit for Product Development
- Review and release raw materials and finished products
- Audit external laboratory and packaging contractors for cGMP compliance
- Perform internal cGMP audits
- Review and approve clinical batch production records, perform quality clearances during clinical supply production and release clinical supply materials to the clinic
- Train Product Development personnel in cGMP compliance
- Develop written procedures for cGMP compliance

Quality Control Laboratory Supervisor (6/1997 to 12/1999)

- Supervise second-shift operations in the Quality Control Laboratory

- Perform extensive raw material testing according to USP/NF, FCC, AOAC, AOCS, and Banner-generated methodology
- Train QC personnel in analytical techniques and cGMP compliance
- Create internal auditing programs
- Review notebooks and train other personnel in proper notebook review
- Modify specifications and methods to meet changing requirements

NOVARTIS ANIMAL HEALTH, Greensboro, NC (5/2005 to 9/2006)

Quality Specialist I (5/2005 to 9/2006)

- Batch record review and evaluation
- Assign final disposition to finished drug products
- Review and approve analytical method protocols and reports
- Track and trend finished product analytical release data
- Laboratory Investigation report review
- Facilitate Annual Product Reviews and MCSR submissions to the FDA
- Evaluate product defect complaints and adverse drug experience reports

PROCTER & GAMBLE, Greensboro, NC (12/1993 to 3/1996)

Technician (Analyst), Quality Control Laboratory – Respiratory Care

- Perform routine instrumental analysis of pharmaceutical products for bulk and finished product release
- Investigate Out-of-Specification analytical results
- Conduct USP/NF testing of raw materials
- Train other analysts in chromatographic instruments, technique, and theory
- Perform routine and in-depth instrument maintenance
- Create audit logs and operational manuals for chromatographic instruments
- Perform upgrades and optimization of laboratory automation

## INSTRUMENTATION EXPERIENCE

- Gas chromatographs with FID, TEC, ECD, and MSD detectors. Capillary and packed columns. Both conventional inlet and headspace GC
- High Performance Liquid Chromatographs with UV, RI, and ELSD detectors on quaternary-solvent gradient systems
- Flame Atomic Absorption Spectroscopy
- Digital Scanning Calorimetry
- Fourier-Transform Infrared and UV-Visible Spectroscopy
- Automated titrators (Mettler and Brinkmann)

## COMPUTER SYSTEMS/SOFTWARE

System-level fluency in Windows and MacOS. Application fluency in Microsoft Office, FoxPro, FileMaker, VG Multichrom, Agilent's ChemStation, and Thermo Electron's Atlas.

## EDUCATION

B.S. Degree, Chemistry, May 1991  
Guilford College, Greensboro, NC