



Mark Robinson

Chemist

Analytical chemist with seven years developing and validating chromatography and mass spectrometry methods for pharmaceutical and specialty chemical products. Comfortable owning method transfer from research into quality control and writing the standard procedures and validation protocols that get audited. Known for closing out-of-specification investigations without dragging the release schedule.

CONTACT INFORMATION

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 Raleigh, NC

KEY SKILLS

- Liquid chromatography, ultra-high performance chromatography, gas chromatography with mass spectrometry and flame ionization
- Elemental analysis, moisture titration, ultraviolet-visible spectroscopy, infrared spectroscopy
- Method development and validation
- Stability program design
- Out-of-specification and out-of-trend investigations, corrective action authoring
- Current good manufacturing practices, quality management systems, electronic records compliance
- Lab information systems, statistical analysis software, Minitab
- SOP and technical report writing

PROFESSIONAL EXPERIENCE

2021 - Present

Senior Chemist, Analytical Development | Bellhaven Pharmaceuticals, Raleigh, NC

- Developed and validated 14 stability-indicating chromatography methods across three oral solid dose products, all cleared by quality assurance on first review.
- Reduced average out-of-specification investigation cycle time from roughly three weeks to under nine days by rewriting the triage checklist and pulling quality control and analytical development onto a shared Teams channel.
- Ran method transfer to the Puerto Rico contract site, including two rounds of co-validation and the comparability report that supported the post-approval change filing.
- Trained four junior chemists on Empower 3, forced degradation study design, and impurity peak tracking.
- Serve as subject matter expert for chromatography and dissolution during regulatory and internal audits; no observations against my methods in the last two inspections.

2018 - 2021

Chemist II, Analytical | Orion Specialty Chemicals, Durham, NC

- Ran release and stability testing on polymer additives using mass spectrometry, elemental analysis, and moisture titration, averaging 40 to 55 samples per week.
- Rebuilt the elemental analysis calibration workflow after a recurring drift issue and cut re-run rate from about 12% to under 4%.
- Wrote or revised 22 standard operating procedures during the site's quality system recertification and led the analytical portion of the audit walkthrough.
- Investigated a customer complaint on a coating additive, traced it to a raw material supplier change, and drafted the corrective action plan that closed the loop.

2017 - 2018

Associate Chemist | Midwood Contract Labs, Cary, NC

- Performed routine wet chemistry and titration on environmental water samples under regulated methods for metals and anions.
- Maintained chain-of-custody documentation for over 900 samples in the lab information system across a full year with no discrepancies flagged during external review.
- Cross-trained on gas chromatography for volatile organics and covered second-shift analyst PTO on short notice.

EDUCATION

M.S., Analytical Chemistry, North Carolina State University, 2017

B.S., Chemistry, University of Delaware, 2015