Manager, Analytical Validations
Req# 2025-000020

Company:	MedPharm Manufacturing Services, LLC
Location:	4018 Stirrup Creek Dr, Durham, NC, 27703
Position Title:	Manager, Analytical Validations
Hours:	Monday – Friday, 8:00 am to 5:00 pm
Summary of Duties:	Manage and oversee the Analytical Validations team regarding the following tasks: validating and transferring analytical test methods; developing and validating cleaning verification method; and troubleshooting analytical and instrument problems. Manage multiple projects simultaneously and communicate with study sponsors and business partners. Supervise a team of junior to mid-level scientists. Author, review, and approve protocols, reports, and Standard Operating Procedures (SOPs). Ensure current Good Manufacturing Practices (cGMP) including Good Documentation Practices (GDP) are followed throughout lab operations. Perform and provide oversight for data generation and analysis using Waters Empower 3 software, extensively utilizing built-in functions like custom fields, custom calculations, calibration curves, peak integrations, and generation of reports. Provide oversight for annual calibrations and performance qualifications for analytical lab equipment and High-Pressure Liquid Chromatography (HPLC) troubleshooting. Coordinate with the Quality Assurance Department to identify, initiate and implement corrective and preventive actions. Lead, review, and trend laboratory investigations from aberrant data, system suitability failures, method/protocol deviations, and OOS/OOT results, implementing Corrective Actions and Preventive Actions (CAPA) for such occurrences. Review and maintain laboratory notebooks, data packets, and project files. Maintain a GMP-compliant analytical laboratory and safe working environment.
Qualifications:	Position requires a Bachelor's degree in Pharmaceutical Sciences, Chemistry, Biology or related field of study plus six (6) years of experience in the job offered or six (6) years of experience as a Chemist or related occupation. Alternatively, the employer will accept a Master's degree in Pharmaceutical Sciences, Chemistry, Biology, or related field of study and four (4) years of experience in the job offered, or four (4) years of experience as a Chemist or related occupation. Requires three (3) years of experience in a Current Good Manufacturing Practices (GMP) laboratory setting. Requires experience developing and validating GMP-compliant High Pressure Liquid Chromatography (HPLC) methods to assess drug product stability. Requires experience with analytical method development and validation for semi-solid products. Requires experience in topical product development. Requires experience diagnosing and troubleshooting HPLC instrumentation and addressing Out of Specification (OOS) and Out of Trend (OOT) results. Requires experience with operation of High-Pressure Liquid Chromatography (HPLC) and Karl Fisher (KF).