Humanwell Pharmaceutical US, Inc.
421 Sovereign Court, Ballwin, MO 63011
Phone (636)-220-3636
www.humanwellus.com

Senior Analytical Scientist

Humanwell Pharmaceuticals US, St Louis, MO
Interested candidate, please submit resumes to email: Info@humanwellus.com

Summary:

This senior analytical scientist is responsible for developing/validating/transferring analytical methods, performing/optimizing/troubleshooting pharmaceutical analysis, preparing/reviewing validation protocols and reports, evaluating abuse-deterrent properties of formulations, designing/performing complex impurity identification/quantitation and physicochemical characterization, analyzing data using chromatography data system software and statistical software, and maintaining good laboratory records.

Key Responsibilities:

1. Develop analytical methods based on chromatography, particle size, dissolution, and mass spectroscopy following a scientific approach for complex oral and injectable drug products.
2. Complete method validation in a timely manner to support drug product development, New Drug Application (NDA) submissions, and Abbreviated New Drug Application (ANDA) submissions.
3. Collaborate with Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs) on method transfers supporting drug product development, manufacturing, and regulatory filing.
4. Responsible for performing, optimizing, and troubleshooting analysis of raw materials, in-process samples, and finished products.
5. Prepare and review analytical methods, validation protocols and reports supporting regulatory submissions and regulatory deficiency responses.
6. Independently design and perform complete studies as per current FDA/ICH guidance to evaluate abuse-deterrent (AD) properties of formulations.
7. Independently design experimental plans for complex impurity identification/quantitation, and physicochemical characterization.
8. Critically analyze data and information using chromatography data system (CDS) software and statistical software.
9. Maintain good laboratory records to meet Drug Enforcement Administration (DEA) and Quality Control (QC) requirements.

Required Qualifications:

- Ph.D. in Chemistry or Chemical Engineering.

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- Strong hands-on experience with HPLC/UPLC, GC, mass spectroscopy, and other general analytical instruments utilized in the pharmaceutical industry.
- Proficiency in Empower, ChemStation, Chromeleon, LabSolutions, or other similar chromatography data system (CDS) software.
- Proficiency in R, JMP, or other similar statistical software.