



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

Associate Director Analytical Development

Humanwell Pharmaceuticals US, St. Louis, MO

Interested candidate, please email your resume to: hr@humanwellus.com

Summary:

Humanwell Pharmaceutical US, Inc. is a Ballwin, MO-based pharmaceutical research and development company which focuses on research and development of novel therapeutics for unmet medical needs.

The laboratory is currently seeking a highly motivated Associate director, analytical development scientist with proven track record in pharmaceutical development. This role will be leading analytical development activities on multiple projects. The major responsibilities include analytical method development, transfer, and validation for complex formulation. The selected candidate should have strong problem-solving skills with deep understanding of pharmaceutical development process. The candidate will work in multidisciplinary teams and with CRO/CMOs in support of drug product development, manufacturing, and regulatory filing.

Primary Duties and Responsibilities

1. Represent analytical function in cross-functional teams. Define scope that are aligned with project objectives and team needs.
2. Design studies, generate and analyze data, interpret experimental results, prepare study reports, and present summaries to project teams and management.
3. Possess strong problem-solving skills with attention to details and the ability to troubleshoot.
4. Develop, validate, and transfer analytical methods for raw materials, in-process materials, finished products, and stability samples.
5. Independently perform hands on bench work and apply expertise to a wide range of assignments, such as performing complex HPLC/UPLC method development, identifying impurities with MS, developing invitro release testing and other analytical methods as needed.

6. Prepare and review regulatory submission documents, support regulatory deficiency responses.
7. Follow pharmaceutical cGMP and GDP practices.
8. Guide and mentor junior scientists.
9. Assist in maintaining laboratory instruments and facilities.
10. Adhere to all health, safety, and environmental requirements.
11. Extended work hours may be occasionally required based on project needs.
12. Ability to travel domestically and internationally up to 15% of time.
13. Additional duties and assignments as needed.

Required Qualifications and Skills:

1. Ph.D. in analytical chemistry or related disciplines, with at least 8-10 years of relevant experience in a pharmaceutical analytical R&D environment. M.S. in chemistry with at least 15 years of relevant experience. Demonstrated track record in leading analytical development activities. Strong candidates with combinations of education and experience with complex formulation will be considered.
2. Strong problem-solving skills with deep understanding of pharmaceutical development process.
3. Ability to define problems, collect data, establish facts, and draw valid conclusions.
4. Strong hands-on experience with HPLC/UPLC, GC, mass spectroscopy, dissolution and other advanced techniques for analysis of complex products.
5. Good knowledge of common physicochemical characterization techniques used in pharmaceutical development, such as particle size, viscosity, TGA/DSC for evaluating of complex formulation.
6. Familiar with USP/NF, EP and JP compendial methods and verification requirements.
7. Updated knowledge of FDA, ICH Guidelines and other related regulatory requirements.
8. Experience and knowledge of cGMP required, experience with DEA requirements preferred.
9. Ability to take initiative and work independently while effectively managing timelines.
10. Demonstrate ability to work as part of a cross-functional team.
11. Ability to communicate in an open, clear, timely and consistent manner.
12. Qualified candidate must be eligible to work in USA.



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Job Type: Full-time, in Person

Job Location: Ballwin, MO

At Humanwell, all of our employees are part of a team that cares about them. We all share the purpose of making the world a healthier place. We hope that you seek to join us on our journey as we develop medicine and improve global human well-being.