

Life Scientist as Method Development and Validation Specialist (m/f/d) in a global central laboratory

MLM Medical Labs is a global central laboratory dedicated to clinical trials with locations in Germany and the US. The team of over 150 highly skilled and experienced persons supports between 190 and 210 clinical trials, phase I–IV, at any given time.

Our broad range of analytical capabilities includes standard safety profiles, such as blood counts, coagulation, platelets, urinalysis, and clinical chemistry, as well as analyses of biomarkers, drugs and metabolites, and molecular diagnostic parameters.

We are looking for a biologist or chemist as a full-time **Method Validation Specialist (m/f/d)** to accompany analytical method validation studies in our over 95-person-team in Mönchengladbach, Germany.

Your responsibilities

- Design of validation plans compliant with the EMA and FDA Guidelines for Bioanalytical Method Validation, GLP and MLM's Standard Operating Procedures (SOPs)
- Set-up and supervision of the laboratory work on validation studies on various analytical platforms (Sunrise™, TECAN; MESO QuickPlex, MSD; cobas® 6000, Roche; KRYPTOR, BRAHMS; ACL TOP, Instrumentation Laboratory; ALLIANCE HPLC System, Waters etc.)
- Evaluation of experimental results and assessment of validation parameters like precision, accuracy, LLOQ, stability and robustness
- Summary of data in QA-reviewed validation reports
- Maintenance and regular updates of MLM's parameter data base

Your qualifications

- Master/doctoral degree or equivalent in life sciences (e.g. biology, biochemistry, biotechnology, chemistry, analytical/food chemistry, pharmacology, medical sciences)
- Hands-on experience with method validation experiments is required
- Knowledge of bioanalytical method validation guidelines and regulatory requirements of FDA and EMA is of advantage
- Hands-on experience with immunoassay techniques like ELISA, RIA or ECLIA is of advantage
- Experience in pharmaceutical or biotech research and development in an industrial setting or foreign experience is a plus, but not required
- Excellent communication and organizational skills
- Great interest in laboratory medicine is required
- Pro-active and self-motivated personality and very meticulous, able to work independently, strong team player
- Fluent in German and English

For those who speak German as their first language please send your application in German. If you are interested in joining a dedicated team, please send your application, including salary expectations via e-mail to recruitment@mlm-labs.com