Eurofins Amatsigroup NV

Scientist Method Validation

Eurofins CDMO is one of the leading CDMOs in Europe providing high-quality, customized drug development solutions for specialty and biopharma clients. Our focus is to support clients on the earliest phases of their development pathway (from API to the clinical packaging). Its Belgian subsidiary, Eurofins Amatsigroup NV, is based in Ghent, offering a complete drug development package for new drug entities (biological and chemical) up to early clinical phases to third parties to help them in speeding up the development and manufacturing of their drugs.

Job Description

We are looking for a person that reports to the QC Manager of Eurofins Amatsigroup NV.

His/her main responsibilities

- Key responsibility: you are responsible for the validation of analytical methods to support the quality control testing of Drug Products used in clinical trials.
- You interact with Analytical Development, Project management and the Sponsor in preparation of validating the different analytical methods needed for the Drug Product Release and stability testing.
- You write Validation Protocols in accordance with international recognized guidelines (ICH, FDA, Ph. Eur., USP).
- You execute and follow-up the execution of the Validation Protocol in compliance with the GMP principles and the procedures of the Eurofins Quality Management System.
- You calculate, review and summarize the analytical test results in Validation Reports.

Qualifications

Education and experience

- Master Degree with a scientific orientation (Analytical Chemistry or Pharmaceutical sciences) with a first profound professional experience, preferably in a pharmaceutical setting.
- Key scientific knowledge: in-depth knowledge of Liquid Chromatography is a must (Waters U(H)PLC systems; UV/ELSD detectors and Empower CDS).
- Proven record of accomplishment in analytical method validation.
- Experience within a GMP environment is a major asset.
- Experience with Karl Fischer, Dissolution, UV spectroscopy and Laser diffraction techniques provide added value.

Competences

- Able to work independently after training in matters entrusted to you.
- Team player with strong organizational and communication skills.
- Problem solving, flexible mindset whilst being punctual and quality driven.
- Professionally fluent in English and Dutch (written and spoken).
- MS office adapted.

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Additional Information

- Work in a fast growing organization.
- A position with responsibility within a dynamic company.
- Personal development through learning on the job and additional external trainings.
- A market oriented compensation.

Interested?

Please apply via our career page: https://jobs.smartrecruiters.com/Eurofins/743999718187725-scientist-method-validation