



AOP Health is the European pioneer for integrated therapies for rare diseases and in critical care. To enhance our team in Vienna we are looking for a:

## (Senior) Analytical Lead, Process Science

1190 Wien | Vollzeit | Start: as of now |



***We are looking for a (Senior) Analytical Lead, Process Science to provide scientific and technical leadership for complex analytical programs across the product lifecycle. As a key expert within Process Science, you will shape robust analytical strategies, support product development and regulatory submissions, and help ensure reliable clinical and commercial manufacturing. The role combines deep analytical expertise with cross-functional leadership, continuous improvement, and close collaboration across Technical Development and the wider organization.***

### What Your Day To Day Will Look Like

- Develop, validate, and implement robust, phase-appropriate analytical methods for intermediates, drug substances, and drug products, including HPLC, GC, MS, and UV methods.
- Lead the strategy, planning, and execution of complex analytical development and testing programs, including photostability, development stability, in-use stability, E&L studies and compatibility studies.
- Review and approve analytical validation protocols and reports, SOPs, technical summaries, and other analytical documentation in line with cGMP and applicable ICH, FDA, and EMA requirements.
- Interpret development and stability data together with Drug Substance and Drug Product Leads and support the development of specifications.
- Lead impurity assessments, including nitrosamine and elemental impurity assessments, and provide technical guidance when analytical issues arise.
- Collaborate with Technical Project Management, MSAT, External Manufacturing, Technical Writing, and other key stakeholders to support seamless product development.
- Represent Process Science in Technical Development matrix teams, and lifecycle management subteams, proactively communicating risks, critical topics, and proposed solutions.
- Support regulatory submissions with analytical data and technical justifications and provide technical input for due diligence and portfolio expansion opportunities.
- Plan and monitor budgets for assigned activities and identify opportunities for cost and risk reduction.
- Drive continuous improvement in analytical technology, methodology, and AOP processes, while promoting knowledge sharing and scientific learning.

- Mentor Process Science Analytical Leads and support the onboarding, training, and development of team members.

## Your Qualifications And Experience

- Higher degree, ideally a PhD or Master's degree, in a technical or scientific discipline such as chemistry, biotechnology, or process engineering.
- At least 10 years of professional experience in analytical development and validation of small molecules and/or biologics.
- Deep expertise in at least one CMC area, combined with a strong working knowledge of the broader CMC environment.
- In-depth knowledge of analytical instruments and techniques especially chromatography and mass spectrometry, with experience in stability studies and impurity profiling.
- Familiarity with applicable EMA, FDA, ICH, WHO, and global regulatory requirements; experience with regulatory submissions or health authorities is an advantage.
- Experience with investigations, out-of-specification results, deviations, and CAPAs is beneficial.
- Proven ability to lead without hierarchical authority and to work effectively in international, cross-functional matrix teams.
- Strong strategic thinking, execution, project management, analytical, and problem-solving capabilities.
- Customer-oriented and collaborative mindset, with the ability to build strong relationships with internal and external stakeholders.
- Excellent verbal, presentation, and written communication skills in English; basic German is beneficial.

## Our offer

- Open corporate culture with the opportunity to bring in your own ideas
- Great opportunities for personal and professional development
- Attractive work environment with excellent career opportunities and flat hierarchies
- Competitive salary package plus bonus and various benefits
- Gross annual salary provided for this function is a minimum of EUR 49.840,- based on full-time employment (38,5h/week). Any potential overpayment depends on professional experience and qualifications.

*By submitting your application, you accept [AOP's Data & Privacy Policy](#).*

### Main Benefits



Bonus



Homeoffice



Employee mobile phone



Flexible working hours



Laptop



Initial and continuing education



Canteen



Good transport connection



Employee events



Meal allowance



Company doctor



Parking spot



Healthmeasures



Employee discount

## Your Contact



**Kenny Trappl**

Talent Acquisition Manager

*Further information on our website:*  
[aop-health.com](https://aop-health.com)