

# Method Expert Analytical Sciences (m/f/d) (80-100%)

Job ID  
REQ-10009820  
Jun 28, 2024  
Austria

## Summary

LOCATION: Schafftenau, Austria, #LI Hybrid Role Purpose Are you skilled in Analytical Method Development? Have you developed analytical methods based on Quality by design (QbD) Principles for both, human and automated sample preparation? Have you used automated solutions for method development? Do you thrive on challenges and enjoy creating new physicochemical methods for biopharmaceutical molecules? Are you attracted to living in a vibrant region of Europe with abundant cultural and outdoor activities? If you answered "yes" to all of these questions, then we want you to join the Novartis Process Analytical Sciences team in Schafftenau / Austria. Our team develops Biologics Drug Substance (DS) and Drug Products (DP), from candidate selection to launch, emphasizing agility, innovation, and scalability to best serve our portfolio, partners, and patients.

## About the Role

### Your key responsibilities

As Method Expert you will be part of the Method Expert Team of Process Analytical Sciences at our Biologics site in Austria

Your responsibilities include, but are not limited to:

- **Method Development and Optimization using QbD Principles:** Applying QbD principles, drive and execute the physicochemical analytical (PCA) method development and optimization of assigned pipeline projects for all relevant sample matrices (DS, Drug, DP, Intermediates). Design experiments, perform risk assessments, and utilize statistical tools to develop robust and reliable analytical methods.
- **Method trending:** Ensure appropriate trending of method performance parameters by establishing trend/control charts for relevant methods.
- **Advanced Instrumentation and Technology:** Leverage advanced analytical instrumentation and emerging technologies to enhance existing analytical methods.
- **Miniaturization and Automation:** Explore opportunities for miniaturization and automation to increase throughput, reduce sample and reagent consumption, and enhance efficiency. Implement automated platforms to streamline method development.
- **Data-Driven Approaches:** Utilize data analytics, machine learning, and artificial intelligence to analyze large datasets and develop data-driven approaches for method development. Identify critical quality attributes, process parameters and correlations to optimize method performance.

- **Regulatory Compliance:** Ensure compliance with regulatory requirements and support filings applying principles described in recent guidelines for analytical method development (e.g. ICH Q2(R2) and Q14). Stay updated on evolving regulatory expectations e.g. related to validation strategies.
- **Collaboration:** Collaborate with cross-functional teams, including research, DS & DP process development, quality assurance, and regulatory affairs, to align method development activities with organizational goals and project timelines. Provide technical leadership, guidance, and mentorship to junior team members.

### What you'll bring to the role

- Hands-on experience with state-of-the-art analytical instrumentation (HPLC/UPLC, CE, cIEF)
- Expertise in physicochemical analytical method development
- Expertise in applying QbD principles
- Expertise in automation and data & digital
- Sound technical and scientific knowledge of pharmaceutical development, analytical sciences, or equivalent
- Experience in biotechnological Chemical Manufacturing Control (CMC) development
- Ability to work in a matrix environment
- Influencing without authority

### Desirable requirements

- University degree in life sciences with practical experience in PCA (e.g. Biotechnology, Chemistry, Pharmacy)
- Minimum of 2 years of proven experience in the pharmaceutical industry

### Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

### You'll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is €55,610.59/year (on a full-time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

We are open for part-time and job-sharing models and support flexible and remote working where possible.

**Commitment to Diversity & Inclusion:**

Novartis is committed to building an outstanding, inclusive working environment and diverse teams, representative of the patients and communities we serve.

**Adjustments for Applicants with Disabilities:**

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to [disabilities.austria@novartis.com](mailto:disabilities.austria@novartis.com) and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

**Join our Novartis Network:**

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

<https://talentnetwork.novartis.com/network>

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other.

Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

<https://www.novartis.com/about/strategy/people-and-culture>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

Division

Development

Business Unit

Innovative Medicines

Location

Austria

Site

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regulär

Shift Work

No

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Wenn Sie aufgrund einer Erkrankung, einer körperlichen Behinderung oder eines neurodiversen Zustandes eine Unterstützung bei verschiedenen Teilen des Rekrutierungsprozesses benötigen, wenden Sie sich bitte an [disabilities.austria@novartis.com](mailto:disabilities.austria@novartis.com) und teilen Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterstützung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das österreichische Gesetz sieht die Möglichkeit vor, die örtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies wünschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.

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