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

Job ID
REQ-10001855

4月 26, 2024

LOCCH

摘要

Are you skilled in Analytical Method Development? Have you developed analytical methods based on 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? Would you be willing to mentor and support your colleagues in their professional growth? 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 Basel, Switzerland. Our team develops Biologics drug substance and drug products, 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 Senior Method Expert you will be part of the Method Expert Team of Process Analytical Sciences at our TRD Biologics site in Basel.
Your responsibilities include, but are not limited to:

1) Method Development and Optimization using Quality-by-Design (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 (Drug Substance, Drug Product, Intermediates). Design experiments, perform risk assessments, and utilize statistical tools to develop robust and reliable analytical methods.

2) Method trending: Ensure appropriate trending of method performance parameters by establishing trend/control charts for relevant methods.

3) Advanced Instrumentation and Technology: Leverage advanced analytical instrumentation and emerging technologies to enhance existing analytical methods.

4) 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.

5) 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.

6) 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.

7) Collaboration and Leadership: 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)
- Senior expertise in physicochemical analytical method development
- Senior expertise in applying QbD principles
- Expertise in automation and data & digital
- Sound technical and scientific knowledge of pharmaceutical development, analytical sciences, or equivalent
- Significant experience in biotechnological CMC development

- Ability to work in a matrix environment
- Influencing without authority

Desirable requirements

- University degree (PhD or equivalent is desirable) in life sciences
- Minimum of 10 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

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部门
DIVGD

Business Unit
Innovative Medicines

地点
LOCCH

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
FCTRD

Job Type
Full time

Employment Type
Regular

Shift Work
No

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