NOVARTIS

Analytical Project Leader (TRD) (m/f/d)

Job ID
REQ-10031499
déc 09, 2024
Suisse

Résumé

Location: Basel, Switzerland

Role Purpose:
Defines, leads and manages the analytical project strategy including the overall analytical control strategy for Drug Substance(s) and Drug Product(s) in line with the overall CMC project development plan; ensures project specific high quality analytical submission documents and ready for inspection status at all time; support/coach analytical team members and thereby contribute to the overall Technical Research & Development strategy and objectives.

About the Role

As part of the Analytical Research and Development group, this is a new role waiting for you to put your own stamp on it. The position is located at the Novartis Headquarter site in Basel within the Technical R&D (TRD) department of Global Drug Development.

Your responsibilities

Your responsibilities include but are not limited to :

- Formulating, developing and driving an overall science, quality and regulatory driven analytical project strategy including contingency plans and risk evaluations in the course of clinical development (API and formulated drug product, essentially small molecules intended for oral administration).
- Leading and overseeing analytical activities throughout drug development within a global project team such as specification setting, method development and validation, stability and release testing. Activities may cover pre-clinical support, early/late phase clinical development as well as transfer to commercial operations and registration.
- Being a core member of the technical development sub-team, representing Analytical Research & Development; co-owning the technical development in partnership with Chemical and Pharmaceutical Development; contributing actively to the elaboration of the overall CMC technical development plan and driving state of the art control strategy.
- Accountability to meet quality, timelines and budget for assigned projects, defining clear analytical project plans
- Managing interactions with internal and external stakeholders, including potential outsourced activities
- Proactively identifying potential scientific, technological and GMP gaps, proposing creative solutions and ensuring appropriate communication within and across units
- Providing input into CMC documents to support regulatory submissions
- Acting as the analytical project representative in peer reviews as well as internal and external audits

- Supporting the analytical project teams with quality awareness, strategic input, scientific and technical expertise in a phase dependent manner
- Strong contribution to advance science, technology and innovation within Analytical R&D

What you'll bring to the role:

- Minimum BS / MS in analytical chemistry with relevant experience in industry, PhD in analytical chemistry or equivalent desirable
- Minimum 3-5 years' experience in the pharmaceutical industry, preferably in analytical development and/or quality control
- Experience in managing projects ideally in a global matrix environment
- Strong quality focus, experience in a GMP environment
- Understanding of regulatory expectations and profound scientific knowledge in analytical development (e.g. Chromatography, dissolution rate, titration, physical state etc...)
- Fluent in English (oral and in writing)
- Ability to perform in a highly dynamic environment

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

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Emplacement
Suisse

Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

Job ID
REQ-10031499

Analytical Project Leader (TRD) (m/f/d)

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10031499-analytical-project-leader-trd-mfd*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Analytical-Project-Leader--TRD---m-f-d-_REQ-10031499
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Analytical-Project-Leader--TRD---m-f-d-_REQ-10031499