Analytical Compliance Record Specialist (m/f/d)

Temporär Jobregion: Basel Stellenprozente: 100%

Beschreibung

As a first-tier supplier to our renowned business partner F. Hoffmann-La Roche Ltd. in Basel, we are currently looking for a motivated and dedicated **Analytical Compliance Record Specialist** for a temporary assignment of 12 months.

Analytical Development is responsible for the development of resource and cost efficient analytical methods for all materials used during drug manufacturing using state of the art methodologies such as e.g. High-performance liquid chromatography (HPLC), Gas Chromatography (GC), Ion Chromatography (IC), Mass Spectrometry (MS), and others. The ultimate goal of our work is a robust control strategy to release pharmaceutical products for clinical trials, and finally for commercial supply. The QC-Section within the Analytical Development Department is responsible for the Release of Materials based on the GMP compliant execution of Analyses of Inprocess controls, raw materials, intermediates, APIs and Drug products.

Tasks & Responsibilities

- Work in a modern quality control organization in compliance with cGMP regulations.
- Management of Compliance Records for the department, mainly Deviations, Changes and CAPAs
- Stakeholder management for the compliance record (including QA, Scientists, Senior Management)
- Facilitation and Documentation of Root Cause Analyses
- Active Participation in Quality Review Boards and other strategic and quality relevant governing bodies as needed
- Inspection Support, including preparation and presentation of records to internal and external auditors / health authority inspectors
- Critical evaluation of own work results
- Key role in ensuring an appropriate GMP standard in the department
- Scientific and regulatory documentation of the work don

Must Haves

- Advanced Degree: A university degree (Bachelor’s, Master’s, or higher) in a relevant Natural Science field (e.g., Chemistry, Pharmacy, Biology)
- Alternative Qualification: Candidates with a Laboratory Technician background will be considered if they possess over 10 years of high-level GMP experience

BERATER

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Seniority Level
Mitarbeiter

Berufskategorie
Pharma & Chemie & Life Science

Stellenprozent
100%

Jobtyp
Temporär

Referenz-Nr.
AFE-PC-T-52720

Jobregion
Basel

- Between 3 to 5 years of professional experience within a regulated pharmaceutical or biotech environment
- Proven, hands-on experience working under cGMP (current Good Manufacturing Practice) regulations is mandatory
- QMS Software: Proficiency in Veeva Vault or a comparable Quality Management System (e.g., TrackWise)
- Core Competencies: Demonstrated ability in managing compliance records, specifically Deviations, Change Control, and CAPAs
- Business fluency is mandatory (written and spoken) for documentation and stakeholder management
- Proficiency in German is considered a strong asset and highly beneficial for internal communication

Nice to haves

- Roche Experience
- Prior experience as a Deviation/CAPA Owner or previous experience in a Quality Assurance (QA) role

Benefits

- Become part of one of the most prestigious pharmaceutical companies and actively shape the future of healthcare
- Experience a work culture that promotes diversity and inclusion and where all employees feel valued.
- Work on a state-of-the-art campus featuring green spaces, meeting areas, and an inspiring atmosphere
- Work with modern and up-to-date tools in an innovative work environment
- Start with a professional onboarding process and a thorough introduction to your new role during the Welcome Days
- Benefit from financial support for your professional development plans
- Enjoy a selection of high-quality meals in modern staff restaurants
- As part of a sustainable mobility concept, on-site parking spaces are available to you (subject to eligibility criteria)
- Take advantage of unbeatable, year-round discounts at renowned retailers and over 200 top brands
- Benefit from fleet discounts when purchasing new cars or receive constant fuel discounts with our fuel card

Are you interested? Do not hesitate and submit your complete application documents online today. We look forward to hearing from you!

Wir wertschätzen Vielfalt und begrüssen daher alle Bewerbungen – unabhängig von Geschlecht, sozialer Herkunft, Religion, Alter und Identität. Zur leichteren Lesbarkeit und besseren Verständlichkeit verwenden wir nur eine Gender-Form. Selbstverständlich sind im jeweiligen Kontext alle Genderformen gleichermassen gemeint.

Unser Bewerbungsprozess