Product Steward, Manufacturing Sciences & Technology (f/m/d), DS Schaftenau, Tyrol, Austria

Job ID
REQ-10054779

6月 13, 2025

Austria

摘要

Technischer Transfer-Lead
Verantwortlich f ü r Technologietransferaktivit ä ten auf Standortebene (Within, Inbound und Outbound), einschlie ß lich etwaiger Scale-up- oder anderer Prozessanpassungen.
Leitet das technische Transfer-Projektteam vor Ort und arbeitet effizient mit den beteiligten Funktionen zusammen (z. B. Technische Entwicklung, Supply Chain, Produktionseinheit, Qualit ä tskontrolle, HSE, andere Standorte).

Produkt-Steward
Besitzt das Prozesswissen ü ber das/die Produkt(e), das w ä hrend des gesamten kommerziellen Lebenszyklus zugewiesen wurde, beh ä lt den Ü berblick ü ber die Prozessf ä higkeit durch Datentrends und statistische Analysen kritischer Variablen, um sicherzustellen, dass die Prozesse robust sind, sich in einem kontinuierlichen Validierungszustand befinden und sich kontinuierlich verbessern.
Gew ä hrleistet einen nahtlosen Wissens- und Informationsfluss zwischen den Funktionen und gegebenenfalls mit anderen Websites, wobei der Schwerpunkt auf dem/den zugewiesenen(n) Produkt(en) liegt. Bietet technische/wissenschaftliche Prozessunterst ü tzung in der zweiten Linie.

Technischer Steward
Stellt dem Standort als Fachexperte (SME) das Fachwissen und die Expertise bestimmter pharmazeutischer Prozesse oder Prozesstechnologien zur Verfügung (z. B. Technical Steward für Galenik, für Filmbeschichtung, Biologika - vor- oder nachgelagert usw.).
Überwacht Prozesse und Standards zur Aufrechterhaltung und Verbesserung bestehender und zur Implementierung neuer innovativer Fertigungstechnologien.

Validierungs-Lead (Validierungs-Lead)
Verantwortlich für die Entwicklung, Implementierung und Verwaltung der Standortprozessvalidierung, der Primärverpackungsvalidierung, der Reinigungsvalidierung und der Revalidierungsstrategien, um die cGMP- und Qualitätsanforderungen pünktlich und im Rahmen des Budgets zu erfüllen, um sicherzustellen, dass die Programme den Erwartungen der Regulierungsbehörden und den damit verbundenen SOPs entsprechen.

Wissenschaftliche Mitarbeiterin MSAndT
Entwerfen, Planen, Durchführen, Interpretieren und Berichten von wissenschaftlichen Experimenten unter der Leitung des Abteilungsleiters, um zu den allgemeinen MSAndT-Strategien und -Zielen beizutragen.

About the Role

Major Accountabilities:

- Maintain the oversight and knowledge for entire drug substance manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as single point of contact (SPOC).
- Support an appropriate process control strategy based on critical quality attributes (CQA) and on critical process parameter (CPP), critical material attributes (CMA) and support improving the control strategy where applicable.
- Monitor and evaluate all critical and key variables as appropriate using statistical analysis and conduction regular product specific data trending (e.g. ongoing process verification OPV, APQR) and communicate at site level.
- Provide the necessary data for the technical activities involved in transferring a product, including definition of needed studies.
- Supports Process Experts in trouble shooting / root cause investigations / implementation of CAPAs.
- Supports Validation Lead and Process Experts to assess and plan process validations and assess re-validation needs.
- Contribute to registration strategy and support registration activities during life cycle of the product as well as site inspections.

Role Requirements:

- MSc. in Biotechnology, Chemistry, Pharmacy, Chemical Engineering.

- Minimum 5 years of experience in GMP manufacturing relevant and/or late stage development to the specialist area of expertise and/or QA/QC.
- Shown process understanding of up- and downstream technologies (cell culture cultivation, chromatographic separation, filtration, etc.)
- Detailed experience in computerized systems and fundamental understanding of applied statistics (MS-office, SAP, Minitab, JMP, etc.)
- Understanding and oversight of relevant regulatory requirements, e.g. GMPs, ICH Q-guidelines.
- Proactivity and a can-do attitude towards problem solving.
- Fluent in English, German beneficial.

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 € 65.605,54 year (on a full-time basis). In most cases, the actual salary will be 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:

We are committed to building an outstanding, inclusive work 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 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

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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

部门
Operations

Business Unit
Innovative Medicines

地点
Austria

站点
Schaftenau

Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regul ä r

Shift Work
No

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Unterst ü tzungen f ü r BewerberInnen mit Behinderungen

Wenn Sie aufgrund einer Erkrankung, einer k ö rperlichen Behinderung oder eines neurodiversen Zustandes eine Unterst ü tzung bei terschiedlichen Teilen des Rekrutierungsprozesses ben ö tigen, wenden Sie sich bitte an disabilities.austria@novartis.com und teile n Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterst ü tzung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das ö sterreichische Gesetz sieht die M ö glichkeit vor, die ö rtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies w ü nschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.

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