Technical Manager

Job ID
REQ-10060755

8月 26, 2025

China

摘要

Represents the main technical interface between Novartis and external suppliers by providing technical expertise on manufacturing and packaging process design, process- and cleaning-validation and resolution of technical issues. Applies an appropriate level of product and process oversight to ensure product quality and process robustness.

Performs the technical due diligence in pre-evaluation phase to select the appropriate external suppliers together with BD&L.
Acts as responsible Technical Transfer Lead to facilitate Product Transfers for legacy products as well as new development products from Novartis to external suppliers or between external suppliers.
Aligns with the Development organization for manufacturing process design during early-stage development

Acts as the MS&T representative in assigned Supplier Relationship Team (SRT). Provides technical / scientific process support to respective Supply relationship teams (SRT) and works in close relation with other SRT members (QA Managers, Site Change Coordinators, Supply relationship Manager etc.) for evaluation of technical compliance activities (Deviations, Change controls, Customer Complaints, CAPAs). Ensures seamless flow of knowledge and

information transfer within the organization and across functions with focus on process and product know-how.

About the Role

Major Accountabilitie

Technical Interface to external supplier:

- Establish partnership with external suppliers with focus to ensure and improve product process capability, to keep the knowledge of process up to date and to maintain the product in constant state of validation.
- Support respective external suppliers with Science- and Risk-based approaches to ensure that product quality
- can be sustainably reproduced.

Product/Technical Stewardship for defined key molecules**:**

- Act as SPOC to maintain the oversight and knowledge for entire manufacturing process throughout the entire commercial lifecycle at given external suppliers.
- Ensure a proper understanding of manufacturing process and influencing factors (i.e. CQAs, CMAs and CPP) to ensure product quality and process robustness at the commercialization site.
- Analyze product-specific manufacturing data from APQRs and other relevant sources where needed and agree on state of control
- Assess impact of technical changes, assess technical feasibility and determine scope / design of technical batches, challenge technical risk and business benefit of proposed technical changes.
- Contribute to the registration strategy and ensure alignment of (regulatory) timelines for technical changes, transfers, launches and/or major deviations.
- Lead / support root cause investigation of product and process failures.
- Effectively liaise with external suppliers to initiate and lead/support product / process remediation / improvement activities, involving cross-functional teams and with clear interfaces to Quality, Operations, Engineering and Technical Development.
- Maintain Division and/or cross-division networks to share lessons learned and best practices related with process and technologies.

Validation - for product(s) in scope:

- Responsible for the validation oversight and for maintaining the product in constant state of validation.
- Challenge defined control strategy based on CQA and where necessary on CPP, CMA. prior to validation and for defined improvement projects
- Review respective Quality Risk Analysis (QRA) prior to validation for technical changes.
- Ensure that technical batches generate sufficient process knowledge by thoroughly testing critical variables and use the output to verify critical process parameters.

- Review validation protocol and report as appropriate.
- Provide all necessary information to generate the validation documentation.
- Support Validation Lead and Experts to assess need and plan validations, assess revalidation need.

Launch & Transfer- for product(s) assigned:

- Participate in external supplier / product evaluation and selection process. Responsible for gathering technical information on manufacturing process capability at external supplier.
- Provide the necessary data for the technical activities involved in transferring out a product through the appropriate documentation, focusing on existing knowledge. Support technical activities at the giving / receiving site as needed.
- Define product acceptance criteria for the transfer, agree on acceptable performance with receiving organization and monitor routine manufacturing performance following transfer
- Ensure successful and well-documented transfers and launches of products with external manufacturing involvement.
- Active support for Product Launch and Transfer governance processes

Interface to Development for the product(s) assigned:

- Ensure that new products and processes are well developed for the commercial scale and the entire product lifecycle at the commercialization site
- Provide input to formal stage gates during development and up to first APR/PQR as part of the development process to ensure early integration and to ultimately meet manufacturing requirements
- Support development of comprehensive control strategy early on in the development to ensure that validation requirements meet regulatory requirements and other critical metrics (e.g., quality, safety, environmental, cycle times, etc.).

Manufacturing Excellence - for defined product(s):

- Define and execute design and control optimization projects where needed.
- Provide SME expertise to perform process characterization of pharmaceutical processes to increase robustness and sustainability.

Training:

- Own the Training Curriculum for its Job Description and direct reports.

Novartis Manufacturing Manual:

- Support implementation of applicable Novartis Manufacturing Manual practices.

Key Performance Indicators

- Assigned products can be manufactured reliably and without recurring process-, material-, equipment-issues that would trigger Quality events, such as OOS results, Deviations or Customer Complaints.
- Manufacturing process is robust and maintained in constant state of validation.

- Technical reports executed on time and with the right expectations.

Education (minimum/desirable):

- BSc in pharmacy, pharmaceutical technology, chemistry or equivalent scientific degree.
- Desirable MSc. or PhD

Languages:

- Fluent in English speaking and writing.

Relevant Experiences:

- Minimum 5 years of experience in pharmaceutical (chemical) manufacturing.
- Experience in a global/matrix environment in the pharmaceutical industry
- Comprehensive know how in pharmaceutical (chemical) technology
- Project Management experience
- Drug Development experience
- Sound experience of data handling and applied statistics

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

部门
Operations

Business Unit
Innovative Medicines

地点
China

站点
Changshu (Jiangsu Province)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

Accessibility and accommodation

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

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

Job ID
REQ-10060755

Technical Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10060755-technical-manager

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://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10060755
5. mailto:diversityandincl.china@novartis.com
6. https://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10060755