

Process Expert

Job ID REQ-10064755

10月 23, 2025

China

摘要

Over 30 years outstanding operations in Novartis Changping site, Beijing. We are equipped with most state of the art technology across solid and liquid manufacturing and packaging process, including up to 500 million cartons per minute high speed packaging line. More than 3 billion units of medicines are packed by our team in one year. We deliver high quality, affordable medicines on time, every time, safely and efficiently to our patients.

About the Role

Your key responsibilities:

Your responsibilities include, but are not limited to:

 Act as Subject Matter Expert (SME) for product and process, provide technical support to production front line for process-specific issues to ensure smooth production plan execution

- Ensure that all batch manufacturing documents and SOPs are up to date per version control
 or change execution in relevant DMS (Document Management System) and/or MES
 (Manufacturing Execution System), and are available for validation/revalidation of processes
 per required timelines
- Ensure timely handling of deviations, complaints and relevant non-conforming issues where applicable, in an effective and timely manner, by using proper investigation tools /methodology as well as proper CAPA defined and/or implemented
- Ensure proper management of various technical projects assigned: coordinate with relevant functions and teams throughout the project stages to ensure timely completion and handover to operation team, and in compliance with cGMPs and HSE
- Participate or take lead in OpEx continuous improvement projects, such as on OAE\Yield\
 productivity or simplification of complexity etc.
- Prepare, support and follow-up of Health authority and internal inspections and collaborate with Regulatory Compliance for dossier submissions, revisions where necessary.
- Provide inputs and contribute to quality system implementation, quality and HSE relevant gap and risk assessment etc.
- Support shop-floor people 's technical development and by providing proper inputs or delivery of trainings or materials

What you'll bring to the role:

- University degree or above in Pharma science or technology, Bio- or chemical engineering etc. with solid experience in pharma or biopharma industry
- Minimum 3 years experience in a GMP manufacturing environment, i.e. a production technical role or relevant roles for equipment qualification or process validation etc.
- Good technical learning, mastery and understanding about manufacturing process and equipment, preferably with experience in aseptic manufacturing and/or bio-pharma manufacturing or process validation etc.,
- Fluency and proficiency in both English and Chinese as working languages
- Good understanding of cGMP and regulatory requirements across multiple health authorities
- Hands on experience in a digitalized working environment, i.e. work with MES (Manufacturing Execution System) and relevant ERP (Enterprize Resource Management, e.g. SAP), eDMS (Document Management System) etc.
- Team player with strong sense of collaboration, effective communication and influencing skills

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

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** Production / Manufacturing 地点 China 站点 Changping County (Beijing) 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

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 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.

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