

Technical System Lead (Qualification)

Job ID
REQ-10010896
Jul 31, 2024
Japan

About the Role

Key Responsibilities:

- Build and maintain strong relationships with internal and external Novartis stakeholders, particularly strong working relationships to ensure effective and seamless collaboration with the Operations Centre and Site Development.
- Set up, troubleshoot, and maintain the entire packaging floor in all formats within the timeframe required to meet departmental expectations and efficiencies.
- Improve the effectiveness of operations by researching process methods, making recommendations for improvements, and assisting in the implementation of such improvements.
- Maintain FDA-compliant operations with appropriate documentation.
- Support engineering studies, validation, FAT and qualification and provide input to equipment-related SOPs.
- Maintain compliance with SOPs, Good Documentation Practice (GDP), training requirements, company and safety policies (e.g. lockout/tagout) and current good manufacturing practice (cGMP).
- Support other lines and roles as required to maintain operational efficiency and production output without compromising quality or safety.
- Comply with all applicable procedures, cGMPs, company policies and all other quality or regulatory requirements (e.g. OSHA, DEA, FDA, EMEA, ANVISA, HS&E).
- Ensure that all work is performed in a safe and effective manner and in compliance with appropriate industry and regulatory (FDA, DEA, OSHA) standards, as well as departmental, plant and corporate quality and safety behaviors
- Training of machinery and packaging personnel

Requirements:

- No academic qualifications required.
- English language skills at business level and the ability to communicate fluently in Japanese.
- Experience in engineering project management.
- Experience in production and manufacturing engineering and the ability to design to EHS standards

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- FDA
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FAT

SOP

- SOP Good Documentation Practice (GDP) / cGMP
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- cGMP OSHA DEA FDA EMEA ANVISA HS&E
- FDA DEA OSHA
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Role Requirements

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>

Division

Operations

Business Unit

Innovative Medicines

Location

Japan

Site

Sasayama

Company / Legal Entity

JP99 (FCRS = JP005) Ciba-Geigy Ltd.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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