

Technical System Lead (Qualification)

Job ID
REQ-10010896
Jun 17, 2024
Japan

Summary

Manages and supervises the building design and construction of new businesses as they are set up. Responsible for the selection and management of external suppliers. Responsible for managing the overall schedule and budget.

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
- 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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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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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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1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Sasayama/Technical-System-lead-
-Qualification-_REQ-10010896-3](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Sasayama/Technical-System-lead-
-Qualification-_REQ-10010896-3)
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Sasayama/Technical-System-lead-
-Qualification-_REQ-10010896-3](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Sasayama/Technical-System-lead-
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