

## Technical System Lead (Qualification)

Job ID  
REQ-10010896

7月 31, 2024

Japan

### 摘要

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.

新ビジネスの立ち上げに際し、建屋の設計から建設までを管理、監督する。外部のサプライヤーの選定および管理に責任を持つ。全体のスケジュールおよび予算の管理を担う。

### 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

#### 主な役割責任

- ノバルティス社内外のステークホルダーと強い関係を築き、維持し、特にオペレーションセンターやサイトディベロップメントと効果的かつシームレスに連携するための強力な協力関係を構築する。
- 部門の期待と効率を満たすために必要な時間枠内で、あらゆるフォーマットのパッケージングフロア全体のセットアップ、トラブルシューティング、メンテナンスを行う。
- プロセス方法を研究し、改善のための提案を行い、そのような改善の実行を支援することにより、業務の有効性を向上させる。
- FDAに準拠したオペレーションを維持するため、適切な文書化を行う。
- エンジニアリングスタディ、バリデーション、FAT、資格認定を支援し、装置関連のSOPにインプットを提供する。
- SOP、Good Documentation Practice (GDP)、トレーニング要件、会社および安全方針のロックアウト/タグアウトなど、および現行の適正製造基準(cGMP)の遵守を維持する。
- 品質や安全性を犠牲にすることなく、業務効率や生産量を維持するために、必要に応じて他のラインや役割をサポートする。
- 適用されるすべての手順、cGMP、会社方針、その他すべての品質または規制要件(OSHA、DEA、FDA、EMEA、ANVISA、HS&Eなどを遵守する。
- すべての作業が、安全かつ効果的な方法で、適切な業界および規制(FDA、DEA、OSHA)基準ならびに部門、工場の品質および安全に関する行動を遵守して行われていることを確認する。

- 機械および包装担当者のトレーニング

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>

部門  
Operations

Business Unit  
Innovative Medicines

地点  
Japan

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



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