Project Engineer (Design Phase)RLT Sasayama

Job ID
REQ-10001509

12月 03, 2024

Japan

摘要

On the occasion of launching a new manufacturing department, Prepare SOPs and Establish the manufacturing process. Also contributes to the smooth running of the new organization by establishing a system for recruitment and employee training.
製造部門の立ち上げに際し、SOPを作成し、製造プロセスを確立させる。また採用および社員教育の仕組みを構築することで、新組織が円滑に運営できるよう貢献する。

About the Role

MAJOR ACCOUNTABILITIES

- Understand overseas manufacturing processes and reflect them in domestic manufacturing processes. Ensure that manufacturing equipment and procedures are at a level that ensures product quality and compliance in commercial production.
- Hire associates and offer proper training.

- Supervise the day-to-day operations to ensure that quality products are manufactured and delivered to customers in a compliant, efficient and cost-effective manner, in a manner consistent with a culture of self-management (delegation and accountability).
- Ensure that resource planning on the manufacturing floor is adequate in correlation with production workload vs planning.
- Management of production schedules within Operation Horizon.
- Fix priorities in the event of unforeseen events and readjust the production schedule if necessary.
- Ensures that human and technical resources are used effectively to achieve the objectives set.
- Continuously improve productivity, quality and safety management through the use of operational excellence techniques

Essential Requirements:

- 5+ years' experience in a GMP environment in the pharmaceutical or life sciences industry with commercial production experience
- At least 2 years' experience in a managerial position in a GMP environment.
- Must have experience in handling aseptic products.
- University degree in science. pharmacy, pharmaceutical technology or chemical engineering is preferred.
- Qualifications in Lean Management, Operational Excellence certificate
- Fluent both in English and Japanese

主な役割責任 :

- 海外製造プロセスを理解したうえで、国内製造プロセスに反映させる。製造機器および製造手順がコマーシャル生産において製品品質ならびにコンプライアンスを確保できるレベルに達していることを確実にする。
- 従業員を採用し適切なトレーニングを実施する。
- 製造ユニット内の日常業務を監督し、自己管理権限委譲と説明責任の文化に合致した方法で、コンプライアンスを遵守し、効率的かつコスト効率の高い方法で高品質の製品を製造し、顧客に提供する。
- 製造現場のリソースプランニングが、生産ワークロードvsプランニングとの相関関係において適切であることを確認する。
- オペレーションホライズン内での生産スケジュールの管理
- 不測の事態が発生した場合の優先順位を確定し、必要に応じて生産スケジュールを再調整する。
- 設定された目標を達成するため、人的・技術的リソースが効果的に使用されていることを確認する。
- オペレーショナルエクセレンスの手法を活用し、継続的に生産性、品質、安全管理を改善する。

必須要件:

- 製薬またはライフサイエンス業界におけるGMP環境下での5年以上の経験（商業生産の経験があること）

- 無菌製剤の取り扱い経験があること
- GMP環境での管理職経験が2年以上あることが望ましい
- 理系の大卒が望ましい、薬学または化学工学であれば尚良い
- リーンマネジメント、オペレーショナルエクセレンス資格、または同等の資格をお持ちの方
- 日本語と英語に堪能であること

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部门
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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Accessibility and accommodation

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