CareerCross

【光工場】 Head of Non-Sterile Quality Assurance (Director)

募集職種

採用企業名
武田薬品工業株式会社

支社・支店
武田薬品工業

求人ID
1476751

業種
医薬品

会社の種類
大手企業 (300名を超える従業員数) - 外資系企業

雇用形態
正社員

勤務地
山口県

給与
1500万円 ~ 2500万円

勤務時間
8:00～16:45

休日・休暇
土曜、日曜、祝日、メーデー、年末年始など（年間123日程度）

更新日
2024年07月23日 10:00

応募必要条件

職務経験
10年以上

キャリアレベル
中途経験者レベル

英語レベル
基礎会話レベル

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

OBJECTIVES/PURPOSE

- Provide leadership of the Quality Assurance functions for Active Pharmaceutical Ingredients (API) & Oral Solid Dosage (OSD) manufacturing, and Warehouse/Distribution. Develop and drive mid and long-term strategy and operational excellence, training/education, talent review and personnel development.
- Responsible for and manage all aspects of API/OSD/Warehouse Quality Assurance at the facility, ensuring that quality

systems, processes and related functions are in place and meet current Good Manufacturing Practices (cGMP), Takeda and other regulatory quality standards and requirements.
- Approve and manage site deviation investigations and assess product impact
- Drive API/OSD GMP adherence on the shopfloor in manufacturing areas
- Drive and manage the application of strategic goals
- Achievement of defined goals and targets in order for the Hikari plant to reach operational and compliance excellence
- Responsible for timely and effective communication and escalation processes to the Site Quality Head in order to raise quality and safety issues
- Responsible for the department expenses and department budget planning
- Ensures adherence to the EHS program

ACCOUNTABILITIES

- Establish strategic goals for the API/OSD/Warehouse Quality Assurance organization in alignment with the global and site strategy, and drive action as needed to ensure timely delivery of those goals.
- Lead and ensure consistency in Deviation Investigation processes.
- Drive and manage Shop Floor QA activities, change control and validation execution.
- Manage warehouse support and pest control.
- Drive and lead Data, Digital, & Technology (DD&T) and AGILE programs in the Quality organization to be future ready
- Drive and lead new ways to improve and streamline current business and system processes. Identify, manage, and where appropriate, lead multiple process/product improvement projects with the objective of achieving quality, efficiency and cost improvements.
- Responsible for the coaching, training, and development of the Quality Assurance team.

スキル・資格

DIMENSIONS AND ASPECTS

Technical/Functional (Line) Expertise

- Knowledge of the local and international regulatory regulations including GXP, International Council on Harmonization (ICH), other related guidelines.
- Knowledge in API, solid dosage forms, parenteral technology, biologics or combination products.
- Strong analytical and problem solving skills to make key decisions regarding potential risks associated with product quality or regulatory violations.
    - Excellent verbal and written communication skills in both Japanese and English.
- Adaptive communication and presentation skills to effectively reach different levels, including senior management.
- Skilled in Microsoft Office applications (Excel, Powerpoint, Word)
- Experience/expertise with TrackWise Deviation/CAPA, Change Control Management (CCM), SAP and Electronic Batch Management (EBM) systems preferred.

Leadership

- Strong leadership skills and demonstrated success in managing a team.
- Strong interpersonal skills including ability to build authentic relationships, constructively challenge conventional thinking, engender trust, influence key stakeholders, cooperate as a team leader or team member, share information and deliver results with a team.
- Adopt and exemplify the Takeda leadership behaviors throughout the GQ organization and Hikari Plant.
- Must have the ability to act as a change agent as well as effectively lead and motivate team members to achieve team goals.

Decision-making and Autonomy

- Must be able to deal with ambiguity, and make decisions under stressful conditions.
- Great sense of urgency.

Interaction

- Interacts with the Site Quality Head and all site functions (EHS, HR, Finance, IT, Manufacturing, Engineering, Supply Chain, etc.)
- Interacts with global Quality functions and Regulatory Affairs, as well as local and global regulators.
- Interacts frequently with subordinates, functional peers, and the Senior Leadership Team.

Innovation

- Strong knowledge of Quality Risk Management principles.
- Should be current in knowledge of state-of-the art processes and systems related to production as well as control of the products.

- Identify and implement strategic opportunities to drive cost reductions/process improvements in site-business.
- Lead and engage employees by initiatives of “Qualtiy Culture”, "AGILE 4.0" "Digital" to drive continuous improvements.

Complexity

- Key stakeholders include but not limited to: Quality Control, Manufacturing, Supply Chain, Distribution, IT, Manufacturing Sciences, Pharmacovigilance, Regulatory Affairs, and Health Authorities.

EDUCATION, BEHAVIOURAL COMPETENCIES AND SKILLS:

- Native Japanese Language Skill is mandatory
- Bachelor’s degree in Chemistry, Pharmacy, Engineering, Biology or related discipline.
- At least 10 years of management experience in the following areas in the pharmaceutical in-dustry: Quality assurance, Quality Control; understanding of the requirements for manufactur-ing, plant utilities, computer systems and project management.
- In depth knowledge of applicable regulations and laws for medicinal products, such as FDA CFR, ICH, GMPs and guidelines.
- Knowledge in areas related to Manufacturing, Finance, EHS and HR (incl. Labor law)
- Strong leadership skills (i.e. Communication, Coaching, Project Management, Decision Making, Problem Solving, Team building and etc.)
- Business level English skills are necessary (both verbal and written)

会社説明