



【1100～1700万円】 Process Engineering Associate Director Japan New ...

武田薬品工業株式会社での募集です。 メディカルGQP・GMP・品質保証・品質管...

## Job Information

### Recruiter

JAC Recruitment Co., Ltd.

### Hiring Company

武田薬品工業株式会社

### Job ID

1470270

### Industry

Pharmaceutical

### Job Type

Permanent Full-time

### Location

Osaka Prefecture

### Salary

11 million yen ~ 17 million yen

### Work Hours

08:00 ~ 16:45

### Holidays

【有給休暇】初年度 12日 1か月目から 完全週休二日制（土・日）、祝日、メーデー、年末年始、他 特別有給休暇、リフレッシュ休...

### Refreshed

June 22nd, 2024 00:00

## General Requirements

### Career Level

Mid Career

### Minimum English Level

Fluent

### Minimum Japanese Level

Native

### Minimum Education Level

Bachelor's Degree

### Visa Status

Permission to work in Japan required

## Job Description

【求人No NJB2212078】

### ■OBJECTIVES/PURPOSE

・ Own Process Equipment is "fit for purpose" for the manufacture of drug substance and drug products meeting Regulatory Quality Capacity and EHS requirements

- ・ Main objectives (key services)
  - ・ Technology selection
  - ・ Capacity Modeling and Site Master Planning
  - ・ Engineering and Equipment Design

- Safety engineering design and management
- “Factory Floor” Continuous Improvement/ Troubleshooting / System ownership
- Own strategic preparation of sites for the future by introducing new process technologies such as robotics and delivering agile process engineering solutions
- Provides leadership to all engineering disciplines during the development of the project requirements scope design (concept basic and detail) timeline and budget#
- The incumbent is responsible for improving existing equipment to minimize production downtime and provide leadership to all process equipment related investigations
- Develop and implement strategies to ensure cost and time effective designs while ensuring innovation and adhering to user requirements while managing daily operational support

#### ■ACCOUNTABILITIES

- Technology selection
  - Drive Cross functional stakeholder management with our Partners in Manufacturing e.g. Sciences and/or Pharmaceutical Sciences. Sponsor the evaluation and selection of new state of the art technologies and process equipment and applicable process equipment vendors (e.g. Robotics Single Use Technology)
  - Identify future industry trends and decide on strategies for process equipment/technologies
  - Own business case development for CAPEX investments in process equipment incl. Total Cost of Ownership (TCO) calculations
  - Manage Process Equipment Vendors and Architectural/Engineering firms in the delivery of CAPEX and OPEX projects in areas of responsibility
- Capacity Modeling and Site Master Planning
  - Mentoring of Process Unit Operation Capacity models and identify capacity bottlenecks / constraints in GMP manufacturing processes / production process and in the utilities delivery systems
  - Apply knowledge of heat transfer mass transfer fluid dynamics reaction kinetics to solve common process engineering problems
- Engineering and Equipment Design
  - Own Front End Engineering and Design activities in feasibility study and conceptual design phases
  - Sponsor Project Turnover Packages for Process Equipment are delivered to site and that critical engineering knowledge such as as built drawings operating and maintenance manuals equipment and instrument data sheets spare parts lists are maintained remain accurate and up to date
  - Gather requirements from Stakeholders such as from Quality Manufacturing Reliability Maintainability Automation and EHS · to decide on Process Basis of Designs specifications and designs for Process Equipment Process Control Systems Process Instrumentation and Process Safety Systems and Devices
  - Lead Scope of Work and RFx Packages for Process Equipment Vendors Process Engineering Consultants Architectural / Engineering services Commissioning services and (Sub ) Contractors
  - Sponsor commissioning activities such as Factory Acceptance and/or Site Acceptance Testing of process equipment
  - With Partners in Engineering Validation mentor the Qualification and Validation activities for Process Equipment
  - SME Design Reviews of Process Equipment with Stakeholders including Quality Manufacturing Utilities Operations Maintenance Calibration Reliability Automation
- Safety engineering design and management
  - Conduct Process Hazard Analysis (e.g. PHA Hazop) of hazardous manufacturing / production processes and incorporate improvements into the design of process equipment process control and process safety systems
  - Perform Design Reviews of all process equipment with relation to EHS and lead for the relevant changes
  - Own Investigations for process equipment and implement Corrective and Preventive Actions (CAPA)
- “Factory Floor” Continuous Improvement/ Troubleshooting / System ownership
  - Provide leadership the Manufacturing and Maintenance departments with troubleshooting activities of Process Equipment on the factory floor
  - Owner continuous improvement activities for Process Equipment applying continuous improvement tools such as DMAIC FMEA RCA identify improvements design and implement improvements and sponsor 3rd level troubleshooting in collaboration with “Manufacturing” ” Manufacturing sciences”
  - Mentor Management of Change for Process Equipment in area of responsibility
  - Responsible for internal and regulatory Audits and Inspections
  - Engage in the Process Engineering Community of Practice (CoP) through sharing of best practices and lessons learned

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#### Required Skills

【応募要件】 ■Engineering degree or equivalent required; for example Chemical Biochemical Mechanical or Industrial engineering is preferred ■Minimum 5 years of relevant experience ■Expert of Process Unit Operations in Pharmaceutical Manufacturing ■Leader of CAPEX project delivery and equipment acquisition processes ■Mentor in applying process improvement methodologies such as DMAIC and Root Cause Analysis (RCA) and tools such as Failure Mode and Effects Analysis (FMEA) ■Understanding of Good Manufacturing Practices (GMP) ■Experience with leading expert for e.g statistical data analysts and data visualization tools ■Experience in managing of all machines/lines/systems and all its components ■SME of Process Unit Operations in Pharmaceutical Manufacturing ■Expert of CAPEX project delivery and equipment acquisition processes ■Fluency in English ■Fluency in Japanese is preferred

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#### Company Description

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