



## Associate Director Process Engineering Synthetic Molecule Pro...

武田薬品工業株式会社での募集です。化学（研究・開発・分析）のご経験のある方は...

## Job Information

**Recruiter**

JAC Recruitment Co., Ltd.

**Hiring Company**

武田薬品工業株式会社

**Job ID**

1488180

**Industry**

Pharmaceutical

**Job Type**

Permanent Full-time

**Location**

Kanagawa Prefecture

**Salary**

7 million yen ~ 16 million yen

**Work Hours**

09:00 ~ 17:45

**Holidays**

【有給休暇】有給休暇は入社時から付与されます・4月1日～9月30日入社の場合、入社時に12日付与・10月1日～翌年3月31...

**Refreshed**

December 19th, 2024 00:00

## General Requirements

**Career Level**

Mid Career

**Minimum English Level**

Business Level

**Minimum Japanese Level**

Native

**Minimum Education Level**

Bachelor's Degree

**Visa Status**

Permission to work in Japan required

## Job Description

【求人No NJB2244167】

※ご推薦には英文レジュメが必要となります※

※英語面接がございます※

**●仕事内容**

効果的にプロセス開発/最適化/スケールアップ/トラブルシューティングを行うためのプロセス向上のために、数理モデルとPATを組み合わせ、加速するための新しいワークフローを創出するチームです。

- ・ Process Engineeringをリードし、技術指導、チームマネジメントを行う
- ・ 部門内のリソース/エキスパートとしてプロセスエンジニアリングの技術を活用

- ・ Process Chemistry Analytical Development 製剤設計、製造、QA、薬事などと部門横断的に協力し効果的なプロセスエンジニアリング戦略の立案・実施する
- ・ ラボからパイロットプラント、商業規模生産へのプロセススケールアップを監督し、円滑な技術移管とプロセス検証を保証する
- ・ バイブラインプロジェクトにおいて、エンジニアリングの責任を負う
- ・ 社内外の製造拠点やベンダーへの技術移管の調整・主導
- ・ タケダを代表し、アカデミックおよび産業界のパートナーとの共同研究に積極的に参加する

#### ●部門

Synthetic Molecule Process Development (SMPD) は、新しい合成分子医薬品製造において、高水準の純度と品質の実現し、コントロールする手法に加え、高い信頼性、持続可能で費用効果の高いプロセス開発を担っています。

#### Job Description

"Better Health for People Brighter Future for the World" is the purpose of a company. We aim to create a diverse and inclusive organization where people can thrive grow and realize their own potential while enabling our purpose. We continue to innovate and drive changes that will transform the lives of patients. We're looking for like minded professionals to join us.

Takeda is a global values based R D driven biopharmaceutical leader. We are guided by our values of Takeda ism which has been passed down since the company's founding. Takeda ism incorporates Integrity Fairness Honesty and Perseverance with Integrity at the core. They are brought to life through actions based on Patient Trust Reputation Business in this order.

Synthetic Molecule Process Development (SMPD) is responsible for the development of robust sustainable and cost effective processes for the manufacture of new synthetic molecule pharmaceuticals along with methods for achieving and controlling high standards of purity and quality.

The successful candidate will be responsible for leading a group of Engineers responsible for all aspects of reaction particle engineering including the development of scale down models for the study of unit operations process safety evaluation as well as technical transfer to external contract manufacturing organizations. The ideal candidate will have deep experience in using process analytical technologies (PAT) in combination with mathematical models (both statistical first principle) to enhance process understanding to effectively develop/ optimize/ scale up and troubleshoot processes. The Associate Director will have experience with building scale down equipment and developing innovative advanced process control strategies for both batch and continuous processes. The ideal candidate will strive to continuously improve how pipeline projects are supported and will be developing new workflows to facilitate and accelerate process development optimization and understanding as well as technical transfer to manufacturing leveraging digital tools automation robotics and/ or cobotics.

The successful candidate will be recognized as a technical resource/expert within SMPD and across Pharmaceutical Sciences and utilize his/ her technical expertise to contribute across multiple projects and drive technical/scientific strategy. The Associate Director will be collaborating closely with the Chemistry and Technology groups to apply enabling emerging development and manufacturing technologies and will be responsible for helping shape the department's technology roadmap based on pipeline needs and current trends in research. The successful candidate will be responsible for maintaining and growing the department's strategic relationships with our outsourcing partners as well as directing and managing outsourcing across a product platform as appropriate.

#### Accountabilities :

Leads and manages a group of Engineers providing technical guidance mentoring and performance management to ensure the team's success and professional growth.

Develops project and/ or significant technical strategy and leverages technical skill (s) as a resource/expert within the department.

Collaborates closely with cross functional teams including process chemistry analytical development drug product development manufacturing quality assurance and regulatory affairs to develop and implement effective process engineering strategies.

Drives process optimization initiatives to improve sustainability process efficiency yield quality and cost effectiveness utilizing expertise in process chemistry and fundamental engineering principles.

Oversees process scale up activities from laboratory to pilot plant and commercial scale production ensuring smooth technology transfer and process validation.

Has full accountability for all engineering aspects for multiple pipeline projects.

Initiates complex projects with extraordinary technical challenges and applies strong technical risk assessment skills.

Owns a discipline/technical skill in its entirety and continues to develop expertise in other key technical skills.

Contributes significantly to develop drive and set the vision and direction of departmental activities management of resources time personnel and financial resources. Maintains ownership of overall vision of scientific platform.

Communicates and coordinates implementation of technology/scientific improvement to senior management across therapeutic and scientific areas.

Conducts analysis of technical and conceptual risk through robust process characterization failure mode analysis and risk assessment methodologies identifies trends and defines and champions process or scientific strategies.

Incorporates novel manufacturing technologies and industry trends as a key aspect of scientific strategy development.

Maintains complete technical responsibility for program (s) /initiative (s) within the department.

Leverages cross functional knowledge to guide pharmaceutical sciences teams on potential impact of actions across projects particularly in technical aspects.

Ensures effective project management of all plans and projects within area of responsibility linking all scientific efforts to company program and functional goals.

Leads small working groups as appropriate to address knowledge gaps in programs linking departmental strategy to strategies of other relevant functions.

Identifies topics for initiatives and leads local/global initiatives on behalf of senior staff.

Recognized as a technical leader/resource by the group and fosters development of technology skill sets within department and among junior staff.

Contributes to departmental strategy around scientific improvement and new capabilities.

Makes proposals regarding sourcing/consultancy strategy.

Coordinates and leads technology transfer to internal or external manufacturing sites or vendor

Communicates with senior management of other functions on implementation of infrastructure technology work processes or

business processes.

Responsible for authoring relevant sections of regulatory documents validation plans development reports process flow diagrams (PFDs) piping and instrumentation diagrams (PIDs) process descriptions and peer reviewed manuscripts.

Defines outsourcing strategy for department in conjunction with senior staff.

Proactively identifies vendors and builds relationships to gain access to technologies as needed to deliver against pipeline goals.

Manages key vendor relationships across multiple projects as appropriate and proactively affects resolution of issues arising at vendors.

Represents Takeda and is an active member on pre competitive collaborations with academic and industrial partners.

## Required Skills

- ・ 化学工学（プロセスエンジニアとしての知識・経験）
- ・ 大学院での修士卒以上
- ・ ラボおよびパイロットプラント設備の構築における豊富な経験
- ・ 技術的・戦略的リーダーシップの経験と実績
- ・ プロセス分析技術（FT IR NIR FBRM UV vis etc.）の使用経験
- ・ 連続プロセスの開発経験
- ・ 技術移管の管理経験
- ・ 数理モデルおよび高度プロセス制御システムの使用経験が豊富であることが望ましい
- ・ 粒子径制御のための粉碎技術の使用とスケールアップの経験があることが望ましい
- ・ 結晶化プロセスの開発及びスケールアップの経験
- ・ ケモメトリクスモデル構築の経験があれば望ましい
- ・ パイロットプラントでの実務経験があれば望ましい規制当局への申請に貢献した経験があり、後期段階での申請経験があることが望ましい
- ・ ビジネスレベルの英語力 海外のマネージャにレポート

Education and Experience:

Required:

A Ph.D. degree with 7+ years of academic or pharmaceutical industry experience; an MS degree with 13+ years of pharmaceutical industry experience; or a BS degree with 15+ years of pharmaceutical industry experience. Degrees in chemical engineering required

Extensive experience in the use of mathematical both statistical and first principle models as well as advanced process control systems preferred.

Extensive experience in building reaction kinetic models as well as process models preferred.

Extensive experience in building laboratory and pilot plant equipment preferred.

Experience in crystallization process development and scale up with an emphasis on polymorph purity and particle size control a plus.

Experience in the use and scale up of milling technologies (both dry and wet) for particle size control preferred.

Experience managing staff preferred.

Experience in the use of process analytical technologies (FT IR NIR FBRM UV vis etc.) required.

Experience in building chemometric models preferred.

Experience in developing continuous processes a plus.

Sound knowledge of current Good Manufacturing Practices (cGMP) .

Experience working in a pilot plant a plus.

Previous experience with the use of contract facilities and managing technical transfers.

Experience in working in a multi disciplinary team environment.

Significant technical and strategic leadership and accomplishments

Previous experience contributing to regulatory filings regulatory filings preferably experience will late stage filings.

Proven scientific track record through presentations at scientific conferences and publication of peer reviewed manuscripts.

Knowledge and Skills:

Analytical and Problem Solving Skills Able to troubleshoot critical issues or problems using appropriate information and determine causes and possible solutions

Teamwork Ability to work well on global cross functional teams.

Communication Skills Able to express oneself clearly and concisely within team; documents issues and/or concerns concisely with colleagues; adjusts communication style as appropriate for the audience; timely and effectively communicates with senior management; technical writing skills to support authorship and approval of internal technical documents

Organization ・ Exercises good time management and prioritization skills to balance multiple project and departmental objectives

Technical Subject matter expertise in a specific scientific area or areas. Demonstrated ability to successfully contribute across multiple scientific endeavors

Knowledge Sharing Ability to capture knowledge within the organization; improves solutions processes and deliverables through use of information; improves information capital by contributing experience theories deliverables and models for others to use

Resource Management Project management skills; ability to manage one's time within individual departmental and corporate goals and timelines; management of internal and external resources (vendors)

External Involvement ・ Demonstrated involvement in professional community evidenced by presentation of scientific posters or lectures at professional conferences or events. Interacts with external vendors for projects

Leadership Skills ・ Develops and uses knowledge and interpersonal skills to appropriately influence and guide others towards the accomplishment of department/function goals and objectives.

## Company Description

医薬品、医薬部外品等の製造・販売・輸出入