

# Regulatory Affairs Specialist

## 产品注册专员

Vamos Biotech (Shanghai) CO., LTD

威莫思生物科技公司

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[www.vamos-biotech.com](http://www.vamos-biotech.com)

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## Job Description 岗位描述

This role will cover the registration and approval of medical devices according to Malaysian guidelines.

You will be a key part of the introduction of new products into the local market.

This will be a 2-year contract role on a new product registration project.

产品注册专员将根据马来西亚法律法规进行医疗设备的注册审批工作。在新产品导入当地市场的过程中，您的作用将至关重要。针对新产品注册项目，本职位两年一签。

## Main Responsibilities 主要职责

- Key responsibilities will involve:  
主要职责包括:
- Managing the entire process for regulatory approval of spa products, supplements, medical devices, and drugs  
管理水疗产品、补品、医疗设备和药品的注册审批全流程;
- Analyse data for new product submissions  
为提交的新产品进行数据分析;
- Implement regulatory plans and ensure submissions are done in a timely manner  
制定实施注册计划, 并确保提交及时;
- Engaging with government bodies such as the CFDA and possibly other bodies to ensure compliance with local guidelines  
与 CFDA (国家食品药品监督管理总局) 等政府机构合作, 确保符合当地法律法规;
- Regular reporting on registration status to management  
定期就注册进展向管理层汇报;
- Keep up-to-date on market trends and devise new registration strategies

了解市场动态，设计新的注册策略：

- Review advertising materials to ensure guidelines compliance  
审查广告材料，确保符合注册指南。

## Requirements: 要求

- Bachelor's degree in biotechnology, biomedical science, pharmacy, or a related discipline  
生物科技、生物医学、药学或相关学科学士学位；
- Experience in regulatory affairs in a medical device or pharmaceutical company  
有医疗设备或制药公司注册经验；
- Familiarity with local regulatory bodies such as the MDA (Medical Devices Authority) and NPRA (National Pharmaceutical Regulatory Agency)  
熟悉当地监管机构，如MDA(医疗器械管理局)和NPRA(国家药品监管机构)；
- Strong initiative and ability to take the lead on projects  
较强的主动性和项目带头能力

## Additional Information 附加信息

|                     |   |
|---------------------|---|
| Career Level:       | Senior Executive  |
| 岗位等级:               | 高管  |
| Qualification:      | Bachelor's Degree, Post Graduate Diploma, Professional Degree |
| 资格证书:               | 本科学历、研究生学历、专业学位   |
| Years of Experience | 1 year  |
| 经验年限:               | 1 年   |
| Job Type            | Full-Time   |
| 职业类型:               | 全职  |
| Job Specializations | Sciences, Science & Technology                                |
| 职业类别:               | 科学、技术   |

## Company Overview 公司概况

Vamos Biotech (Shanghai) CO., LTD (91310000MA1H3AQB3D) is a high technology startup biotech company engaged in discovery, R&D, and commercialization of new generation of medical substances for treatments in cancers, viral infections, antibiotic-resistant bacterial infections, and other incurable diseases.

上海威莫思生物科技有限公司(91310000MA1H3AQB3D)是一家高科技生物科技创业公司。公司致力于探索、开发和商业化新一代药用物质，用于治疗实体癌症、病毒感染、抗生素耐药细菌感染等疑难杂症。

The company is already a global leader in the area of biosynthesis and first in the world to successfully complete clinical trials and obtain market authorization for medical products in the area of antibiotic resistance and is position strongly to achieve significant progress and growth in its operations.

该公司是生物合成领域的全球领导者。在抗生素耐药性领域，其医疗产品率先完成临床试验并成功获得市场授权，正以强有力的姿态拓展业务和实现增长。

The headquarters of Vamos Biotech is located at 1F, Building #5, Lin Gang Fengxian Industrial Park, 1800 Xin Yang Road, Feng Xian District, Shanghai 201413, P.R. China.

威莫思生物科技公司总部位于上海奉贤区新杨公路 1800 号临港奉贤工业园 5 号楼 2 层，邮编 201413。

## Welcome to Vamos Biotech

### 欢迎来到威莫思生物科技

From early Discovery, Research and Development, Product Development, to marketing, sales and customer support, Vamos Biotech aims to unlock the potential in every team. We are committed to providing a diverse, inclusive, and supportive environment, where all our staff can succeed and take pride in their work.



从早期的探索、研发、产品开发，到之后的营销、销售和客户服务，威莫思生物技术公司旨在释放每个团队的潜力。我们致力于提供一个多元化、包容性和支持性的环境，让所有的员工都能取得成功并为自己工作感到自豪。

## What we look for 我们的追求

- **Diversity and respect 多样性和尊重**

Diversity is essential to growth and success of any business. Vamos Biotech creates an environment of diversity of perspectives, experiences, cultures, genders, and age, where ideas can be shared without fear of discrimination or harassment.

多样性对于任何企业的成长和成功都是至关重要的。威莫思生物技术公司创造了一个观点、经验、文化、性别和年龄多样化的环境，在这里，你可以尽情分享想法而不必担心歧视或骚扰。

- **Creativity 创造性**

Success in any organization relies on creative innovation. We strive to create a culture of knowledge sharing, boundary pushing, norm challenging to try new things and learn from experience.

任何组织的成功都有赖于创造性的创新。我们努力创造一种知识共享、边界突破、规范挑战的文化，鼓励尝试新事物并从经验中学习。

- **Collaboration 协作**

The best ideas are a collective effort! We actively support collaboration across projects, teams, seniorities, and countries, encouraging our employees to think outside the box and achieve our goals.

好想法往往需要集思广益！我们竭力支持跨项目、跨团队、跨资历和跨国家的合作，鼓励我们的员工打破常规思维、实现我们的目标。

- **Initiative 主动性**

We value initiative, ownership and leading by example. We reward employees who go the extra mile and always strive to improve outcomes for themselves, their team, and the business.

我们重视主动性、主人翁意识和以身作则。我们奖励那些愿意付出额外努力以促进自身、团队及企业发展的员工。

## Global Perks 福利待遇

- **Career development and learning 职业发展和学习**

We encourage you to set high standards for yourself and take ownership for your personal development and future career through our development and education programs.

我们鼓励你为自己设定高标准，并通过我们的发展和教育计划，在个人发展和未来的职业生涯中掌握主动权。

- **Health and wellbeing 健康和幸福感**

Healthy people are happy people! So, we provide healthy breakfast, fruit and snack options, access to clubs and sporting teams, mental health support and health benefits, like flu shots.

健康的人是快乐的人！因此，我们提供健康的早餐、水果和零食，员工可以参加俱乐部和运动队，在这里你还能得到心理健康支持和其它健康福利（如流感疫苗）。

- **Awards and recognition 奖励和表彰**

We celebrate outstanding performance through our recognition and rewards schemes, including Employee of the Quarter, tenure awards and the annual Vamos Biotech Global Recognition Awards.

我们通过表彰和奖励计划来为出色的表现喝彩，包括季度员工奖、任期奖和年度范莫思生物技术全球表彰奖。

- **Social activities 社会活动**

At Vamos Biotech, we work hard and play hard! Get to know your work family with regular Friday get-togethers, team building activities, hack days and annual functions.

在范莫思生物技术公司，我们努力工作，努力玩耍！通过定期的周五聚会、团队建设活动、黑客日和年度活动来增进同事情谊。

- **Flexible working 灵活工作**

Everyone has different priorities and needs. That is why we have flexible working arrangements to allow you to find a work schedule that suits you and encourages a healthy work-life balance.

每个人都有不同的优先事项和需求。这就是为什么我们有灵活的工作安排，让每个人能找到适合自己的工作时间表。在范莫思，我们鼓励健康工作和平衡生活。

- **Global opportunity 全球机遇**

With global presence and operations, there are no shortage of opportunities to grow, change and take on new challenges in new environments.

随着全球业务的开展，员工将有充分机会在新环境中成长、改变和应对全新挑战。