

Regulatory Affairs Assoc. Dir

外資系動物薬メーカーでの募集です。 薬事申請のご経験のある方は歓迎です。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
外資系動物薬メーカー

Job ID
1587583

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
7.5 million yen ~ 16 million yen

Work Hours
09:00 ~ 17:30

Holidays
詳細は求人ご紹介時にご案内いたします。

Refreshed
October 30th, 2026 07:00

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native Level

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2327311】
【POSITION OVERVIEW】
The Associate Director of the Regulatory Affairs（RA）is responsible for the overall management of regulatory affairs activities including pharmacovigilance work at RA department at PDRA division Animal Health in Japan. The position requires a combination of scientific knowledge understanding of regulatory requirements strategic thinking and team leadership to ensure timely development of new products and regulatory affairs activities.
The individual will ensure that the RA team develops and successfully executes project plans for timely product registrations.

The individual will motivate and encourage the RA Team to perform successfully and will mentor and coach team members to oversee their personal development in the organization.
The individual will closely communicate with members at the Product Development department to optimize the regulatory submission and get products approved.

【Reporting lines】
The RA Associate Director reports directly to the PDRA director
The RA Associate Director manages a team of 5 7 colleagues of RA department.

【PRIMARY ACTIVITIES】
Support PDRA director to optimize/maximize PDRA's activities by following ways:
Build PDRA as one team to have a seamless communication/collaboration
Review/advice Gap analysis done at PD department and create PDRA's one
Set up agreed product profiles among PD and RA.
Harmonize local requirements into the global development plan based on the well prepared development plan.
Liaise with Sales BU in the identification of market potential/requirements for new vaccines vaccine improvements and pharmaceutical products
Oversee the scientific quality of work within the unit to maintain and enhance reputation for excellence
Lead the RA team to ensure timely development of biological and pharmaceutical veterinary products in Japan in compliance with the general pharmaceutical guidelines and with local laws.
Ensure that the RA team develops optimized development plan by leveraging global data.
Oversee the collaborations with Contract Research Organizations （CROs）. Ensure contract management and quality oversight of CROs.
Ensure compliance of organizational structures internal processes operational activities reporting including national and overseas pharmacovigilance requirements in line with the respective pharmaceutical law guidelines
Provide advice on research issues problems and trends having significant impact on RA activities of short and long term goals
Optimize the performance of RA colleagues by coaching motivating training and evaluating them properly in line with global and local development program including setting and reviewing individual yearly objectives and development plans

Required Skills

【BACKGROUND REQUIREMENTS】
Following leadership behaviors are expected

・Be Purposeful ・ Capturing the meaning of our work following our mission to improve people's lives and adhere to ethical behaviors.
・Be empowering ・ Unfolding potential in self and others by providing guidance driving personal development and sharing enthusiasm.
・Be collaborative ・ Working together across departments encouraging teamwork that respects diverse backgrounds and culture differences.
・Be Results driven ・ Setting ourselves stretch performance target as well as establishing as establishing a feedback culture and taking responsibility.
・Be innovative ・ Constantly experimenting and driving change initiatives. This includes being open to new ideas. Making quick decisions and taking risks.
・Be future oriented ・ Continuously seeking best practice solutions and embracing opportunities of new technologies to shape the future of our business.

◯Education
Veterinarian or PhD in Biological or Animal Sciences preferable.

◯Experience
・Minimum 7 years of relevant experience in a regulated industry preferably healthcare most preferably in the field of veterinary vaccines or pharmaceuticals.
・Knowledge of Japanese Regulatory System preferable
・Experience leading teams and developing/coaching people to maximize people/team capability.
・Working in a matrix environment with multiple stakeholders at local and global levels.
・Experience in planning and drafting budgets.

◯Skills Knowledge and Competencies
・Language ・ Japanese（fluent） English（professional level ・ verbal and writing）
・Highly developed skills in negotiating influencing leadership and staff motivation.
・Excellent communication and organizational skills.
・Ability to work well with other departments in a multicultural team setting and matrix organization
・Familiarity with animal diseases and animal husbandry techniques and ability to understand our product users including farmers and veterinarians.
・Knowledge of Microsoft Office

Company Description

ご紹介時にご案内いたします