薬事・規制関連業務担当者（Regulatory Officer）【関西】

PSI CRO Japan株式会社での募集です。 薬事申請のご経験のある方は歓...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
PSI CRO Japan株式会社

Job ID
1570253

Industry
Contract Research Organization

Company Type
International Company

Job Type
Permanent Full-time

Location
Osaka Prefecture

Salary
6 million yen ~ 10 million yen

Work Hours
09:00 〜 18:00

Holidays
【有給休暇】初年度 最大10日（入社月によって異なる） 【休日】完全週休二日制 土 日 祝日 年末年始

Refreshed
December 25th, 2025 14:27

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 NJB2349124】
As a Regulatory Officer will work closely with our global team of experts to prepare clinical trial dossiers for regulatory and authorities deliver regulatory training to project teams and communicate with stakeholders on regulatory related matters. Join PSI and help drive innovation and excellence in advancing healthcare solutions.

Prepare clinical trial regulatory submission dossiers including applications for import and export licenses

Track regulatory project documentation flow and progress reporting
Review translations of essential documents subject to clinical trial submission
Liaise with project teams to procure documents necessary for regulatory submissions
Communicate with regulatory authorities sponsors and vendors on all regulatory related matters
Track changes/amendments to legislative acts pertaining to clinical trials in Japan
Review documents to greenlight IP release to sites
Manage safety reporting to authorities
Deliver training on regulatory environment in Japan
Participate in the regulatory aspects of feasibility research

Required Skills

・University degree in Life Sciences Medicine or Pharmacy or an equivalent combination of education training and experience
・Experience with clinical trial submissions to PMDA
・Knowledge of the regulatory environment for clinical research
・Full working proficiency in English and Japanese
・Detail oriented
・Communication collaboration and problem solving skills

Company Description

PSI is a leading Contract Research Organization （CRO） with over 25 years of experience in the pharmaceutical industry. Originating from Switzerland PSI is a privately owned full service CRO with a global reach supporting clinical trials across multiple countries and continents. Our reputation for being highly selective about the projects we undertake highlights our commitment to delivering high quality timely services across a broad spectrum of therapeutic indications.In an industry where cost cutting and layoffs are common PSI stands out as a stable and secure workplace. Our dedication to stability is evident in our exceptionally high repeat and referral business rate and minimal staff turnover. Many of our colleagues have been with us for over 15 years contributing to our long standing traditions and history. Our expansion into Japan continues this legacy and we seek team members who will grow with us for the long term.At PSI we foster an environment where a diverse range of colleagues feel welcomed and valued. Our inclusive culture is a cornerstone of our success enabling us to attract and retain top talent globally.We are not just about conducting clinical trials; we are about building a community where every team member has the opportunity to thrive and contribute to groundbreaking advancements in the pharmaceutical industry.