



## 薬事・規制関連業務担当者 (Regulatory Officer)

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迎です。

### Job Information

#### Recruiter

JAC Recruitment Co., Ltd.

#### Hiring Company

PSI CRO Japan株式会社

#### Job ID

1598507

#### Industry

Contract Research Organization

#### Company Type

International Company

#### Job Type

Permanent Full-time

#### Location

Tokyo - 23 Wards

#### 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

June 25th, 2026 17:00

### 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 NJB2327428】

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

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## 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
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## 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.