CareerCross by JAC Recruitment

Senior Lead, Global Compliance and Strategy, APAC (治験業務経験者)

IT x ライフサイエンス

Job Information

Hiring Company
Medidata Solutions K.K.

Job ID
1462835

Division
Global Compliance and Strategy

Industry
Software

Company Type
International Company

Non-Japanese Ratio
About half Japanese

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards, Chiyoda-ku

Train Description
Yamanote Line Station

Salary
11 million yen ~ 15 million yen

Work Hours
Super Flex

Holidays
Weekends, Japanese Public Holidays, Company Holidays

Refreshed
November 28th, 2024 09:00

General Requirements

Minimum Experience Level
Over 10 years

Career Level
Mid Career

Minimum English Level
Business Level (Amount Used: English usage about 50%)

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

Your Mission:

With Medidata's continued growth in the Asia regions (including Japan, China, Korea, Singapore, and Australia), the ideal candidate will serve as a geographically local resource focusing on matters related to Medidata's Quality Management System and regulatory strategy with a specific focus on the Japan market and region. Enable both internal and external stakeholders to progressively enhance Medidata's value proposition through the adoption of emerging clinical trial technologies while successfully meeting and navigating global regulatory expectations. Reporting directly to the Director, Global Compliance and Strategy ("GCS") APAC, the ideal candidate will:

- Engage with key local regulatory agencies in the Japan region (e.g. PMDA, JPMA) and government authorities if applicable to ensure that Medidata's interest as a Software as a Service (SaaS) technology company serving regulated companies is considered in regulatory guidance documents and agency perceptions.
- Interact directly with customers to address quality and regulatory related matters relevant to the use of technology in performing clinical trials.
- Collaborate cross-functionally with other Medidata business units (e.g. Legal, Information Technology, Product Development, Sales, RFX) to contribute to achieving Medidata's goals, business plan, and long-term strategy.
- Grow Medidata's Unified Protection Strategy in collaboration with Information Security, Data Privacy and Cloud Operations and work closely with the Quality/Customer Management and Regulatory functions within GCS.
- Collaborate with GCS peers in the performance and delivery of day-to-day activities of the GCS organization.
- Balance multiple priorities, workload, and complete assignments to ensure the team achieves overall customer focused mission and objectives.
- Fulfill the responsibilities for providing operational support to GCS-managed programs (e.g. quality incident management, internal quality system audits, customer audit/inspection needs).

Required Skills

Your Competencies:

- Strong understanding of regulations governing clinical trials, including:
- Framework guidelines including ICH Good Clinical Practices (GCP) and regional distinctions.
- Clinical Regulations (e.g. JGCP, specific requirements in Japan on Clinical trials, and PMDA inspections).
- Regulations on data management in clinical trials.
- Computer Systems Validation.
- Extensive experience in clinical trial processes and technologies, including, but not limited to a strong working knowledge of trial master file and site master files (TMF/SMF) and eTMF.
- Understands quality systems processes and enablement including auditing, root cause analysis and CAPA development.
- PMDA inspection experience is preferred.
- Proven track record of working independently to evaluate requirements and propose solutions.
- Strong teamwork spirit and good communication skills.
- Fluent (read, write, speak) in English and Japanese.
- Based in Medidata's Tokyo office.

Your Education & Experience:

- Bachelor's degree required with 8 years of experience, 5 years of experience with a Master's; or equivalent years of experience in the life sciences industry and/or medical/clinical operations.
- Requires a minimum of 2 to 3 years of experience in clinical trial processes and technologies, including a strong working knowledge of Quality Management Systems enablement.
- Strong understanding of regulations governing clinical trials including Clinical Regulations and Framework guidelines including ICH Good Clinical Practices (GCP).
- Demonstrated experience as a compliance functional expert (especially with regards to clinical processes and technologies) with proven ability to present to corporate executives.
- Inspection management experience is a strong plus.
- Ability to travel expected at approximately 10%.
- Able to work independently.
- Prior experience with a large central IRB or Ethics Committee is preferred.

Company Description