CareerCross

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

IT x ライフサイエンス

募集職種

採用企業名
メディデータ・ソリューションズ株式会社

求人ID
1462835

部署名
Global Compliance and Strategy

業種
ソフトウエア

会社の種類
外資系企業

外国人の割合
外国人 半数

雇用形態
正社員

勤務地
東京都 23区, 千代田区

最寄駅
山手線駅

給与
1100万円 ~ 1500万円

勤務時間
Super Flex

休日・休暇
Weekends, Japanese Public Holidays, Company Holidays

更新日
2024年06月27日 08:00

応募必要条件

職務経験
10年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル (英語使用比率: 50%程度)

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

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).

スキル・資格

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.

会社説明