임상 관련 직무 신입 및 경력 사원 모집

프랑스에 본사를 둔 사노피 그룹은 전세계 100 여 개국에 진출해 있으며, 끊임없는 혁신을 추구하는 세계 선두의 헬스케어 기업입니다. 국내에서는 사노피-아벤티스 코리아/사노피파스퇴르/사노피 젠자임을 통해 ***예방에서 치료까지 환자들의 다양한 니즈에 부응하는 글로벌 헬스케어 기업****으로 자리매김하고 있습니다.*

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patient's needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, and consumer healthcare.

[모집 내용]

1) **모집 부서:** Clinical Study Unit
2) **모집 포지션:** CSO Support 및 SSU Associate (각각)
3) **근무 형태:** 파견 계약직(1년)

[Part I. CSO Support]

1) Purpose of this job

- The Clinical Safety Officer (CSO) Support is responsible for conducting defined pharmacovigilance tasks and safety documentation and reporting of safety events (especially Serious Adverse Events and Adverse Events of Pre-specified Monitoring) related to clinical studies within her/ his organization.

2) 주요 업무내용

1. General

- Management of safety CSU generic mailbox and fax.
- Communication with CSL, as applicable.

2. Interface with Global Pharmacovigilance & Epidemiology (GPE)

- Ensure that all Individual Case Safety Reports (ICSRs) (initial and follow-up) are adequately completed, supporting documents translated into English (if applicable), and forwarded to GPE, in a timely manner, according to Corporate and Local Quality Documents (QDs).
- Ensure that GPE is informed of all questions/clarifications/requests for supporting documents already requested to the investigators or monitoring team members (according to local procedures), and make sure of answer in due time.
- Ensure that all questions coming from GPE are received and distributed to the corresponding monitoring team members and ensure that answers are forwarded to GPE in due time, as per QDs timelines for ICSRs reporting.
- Attend applicable GPE training sessions and applicable CSO/GPE meetings.

3. Interface with CSU / Monitoring Team (MT)

- In collaboration with the MT, make sure investigators are trained on safety reporting and safety information filing requirements in clinical studies (investigator's meeting, initiation visit, specific safety meeting).
- Together with the MT, ensures a proper filing of safety documentation in local study files during the clinical trial.

4. Distribution and handling of safety information:

- Coordinates the handling and distribution of safety information (ICSRs, DILs and Periodic Safety Reports), and ensures shipment, per global & local QDs, and, as applicable according to local regulation, to the following recipients: Investigators/ECs/ Has/ ISS sponsors

5. Tracking and Metrics

- Ensures a tool is set up to track all safety inbound and outbound activities (ICSRs, DILs and Periodic Safety Reports).
- Maintain metrics to verify adherence to local/global QDs and timelines.

3) 지원 자격

- Medical 또는 자연 계열 Prefer
- Demonstrated Knowledge and understanding of ICH-GCP, the regulations pertaining to safety in relevant country
- Prior work experience demonstrating knowledge and understanding of clinical trials
- Be able to communicate efficiently on different levels, be assertive and can work on several projects at once with high flexibility, be detail oriented and have excellent time management and organizational skills

[Part Ⅱ. SSU Associate]

1) Purpose of this job

-The Study Start-up (SSU) Associate functions as a subject matter expert on all SSU-related activities in the country, conducts SSU activities in collaboration with other clinical research stakeholders.
-Provision of appropriate input and support for all the regulatory activities.
-Provision of updated information regarding the regulatory environment and trends that could impact positively or negatively the approval processes, mainly those related to timelines for approval to the study team(s), CSU and investigators if appropriate.

2) 주요 업무내용

Study Start-up Coordination and Execution: Coordinates, guides and assists with all start up activities prior to site activation, including but not limited to:
- Ethics Committee information, meeting dates & costs
- Ethics applications & associated online systems
- Ethics & Governance submission processes
- Clinical Trial Health Authority application and regulatory submission process: Prepare the regulatory package in collaboration with Regulatory Affairs department according to the local requirements.
- Submit the Regulatory package to the IRB / IEC when it is appropriate and/or to the Health authorities either in parallel or in sequential way according to the local regulations.
- Concentrate communications and answer questions, inquiries from the Regulatory / Health authorities after discussion with the appropriate functions (i.e. Clinical Project Leader, Medical Advisor, Regulatory Affairs..)
- Be the liaison between the CSU and the Affiliate Regulatory Department

- Contracts & Indemnity request process
- Work together with sites and appropriate legal departments for successful contract execution
- Maintain up to date knowledge, ensure adherence and compliance with local regulatory requirements and associated documentation.
- Review, analyze and collate metrics to ensure processes are in place that drive efficiency and reduction of timelines across start up and contracts negotiation.
- Ensure all start up information & requirements are kept up to date in a central repository for project teams.

3) 지원 자격

- Prior work experience demonstrating knowledge and understanding of clinical trials, such as that obtained in a clinical trial monitor capacity, and experience managing projects
- Demonstrated Knowledge and understanding of ICH-GCP, the regulatory, ethics and contractual requirements for starting clinical trials in relevant country
- Be able to communicate efficiently on different levels, be assertive and can work on several projects at once with high flexibility, be detail oriented and have excellent time management and organizational skills
- Strong networking abilities and an ability/willingness to work with internal and external stakeholders across the globe

[지원 및 문의]

이메일 **recruitment.kr@sanofi.com**

[제출 서류]

자유 양식의 이력서 및 자기소개서 (국영문 무관)

[접수 기간]

2017.08.15까지 (채용 시 마감)

[전형 절차]

서류 및 면접

장애인 및 국가 보훈 취업 지원 대상자는 관계 법령에 의거하여 우대
People with disabilities as well as descendants will be given preference according to the related law.