



【1150～1800万円】Senior Statistical Scientist

CSLベーリング株式会社での募集です。統計解析のご経験のある方は歓迎です。

募集職種

人材紹介会社

株式会社ジェイ エイ シー リクルートメント

採用企業名

CSLベーリング株式会社

求人ID

1591770

業種

医薬品

会社の種類

外資系企業

雇用形態

正社員

勤務地

東京都 23区

給与

1100万円～1800万円

勤務時間

08:45～17:30

休日・休暇

【有給休暇】入社月により異なる。入社日に最低3日間付与、入社7ヶ月目には最低10日以上 翌年1月1日に16日間付与 以後年に...

更新日

2026年05月28日 18:00

応募必要条件

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

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

【求人No NJB2376243】

■Position Purpose:

Provide an overview of the responsibilities of the position by providing a summary of the most important aspects and duties of the position.

The Statistical Scientist provides components of statistical contribution to a clinical development program. The Statistician

implements statistical strategies for the clinical trials and regulatory submissions and is accountable for the statistical deliverables. The position will support the Japan clinical/PMS team with statistical expertise ad hoc analyses and interpretation of requests from PMDA. The Statistical Scientist will collaborate with the global CSL team on the design of global studies including Japan and on stand alone studies conducted in Japan only. It is expected that the candidate will be experienced with PMDAs requirements regarding CDISC and to communicate these effectively to the global Biostatistics.

■Main Responsibilities and Accountabilities:

List the roles and responsibilities of the position (please limit the number of responsibilities to the primary ten.)

Support Biostatistics to conduct study data collection data analysis reporting and submission preparation.

Be accountable for timely completion and quality of the statistical analysis plan.

Manage outsourcing operations for assigned projects.

Ensure timeliness and quality of deliverables by CRO and conduct reviews of CRO deliverables to ensure quality.

Support Biostatistics and data management related interactions with authorities (especially PMDA) including submissions to PMDA.

Be responsible for compilation of the CDISC deliverables for the PMDA submissions and ensure its quality per the PMDA requirement.

Be responsible for result accuracy in study report and regulatory submission documents.

Manage preparation for the GCP inspections and lead the discussion at the on site sponsor inspections related to data science areas (biostatistics data collection and data management)

Conduct ad hoc statistical analyses.

Support improvement initiatives and related standards for infrastructure / process / scientific consulting.

スキル・資格

■Position Qualifications and Experience Requirements:

Provide hiring requirements for the specified position including educational experiential and competency requirements necessary for the position.

・ Education

PhD or MS in Biostatistics Statistics or related fields.

・ Experience

At least 5 years of experience in Clinical Development in a Pharmaceutical or Biotechnology setting

Japan native preferred; Strong interpersonal and communication skills (verbal and written in English and Japanese)

Ability to collaboratively work and provide leadership in a matrix environment

Statistical support in facilitating and optimizing clinical development programs especially for global studies including Japan (sample size in rare diseases)

Knowledge of CTD and CDISC submission requirements (SDTM and ADaM) for PMDA is highly preferred

Experience managing CRO preferred

Basic knowledge of clinical development and processes

Experience with statistical programming using the SAS software

Ability for overseas travel (mainly USA) once/twice a year

Desired: Advanced knowledge and training in applications of statistical methodologies

会社説明

血漿分画製剤、バイオ医薬品の輸入・製造・販売