JOB POSITION: Statistician

The company: Chiesi an international company based in Parma, with more 80 years of experience and a strong focus on research, development, production and the commercialisation of innovative medicines in the Respiratory, Neonatology, Rare Disease and Special Care Therapeutic Areas. Chiesi is a company which has grown - and continues to grow - rapidly, therefore we are looking for candidates who wish to grow with us.

Department: Data Management and Statistics Unit, Global Clinical Development (R&D)

Job Responsibilities:

- To contribute to the definition of Clinical Development Plans, regulatory strategy and submissions
- Statistical input to clinical studies (study design, sample size calculations and statistical methodology), ensuring methods are applied consistently within a program and in line with regulatory guidelines.
- To support clinical study setup (input on CRF design, database design, specifications for randomization, IRT, ePRO and other external data).
- To interact with CROs and other external vendors to oversee statistical activities, ensuring high level of quality and timely delivery
- To write/review/develop/approve all study related statistical documents: Data Review Plan, Statistical Analysis Plan, Data Quality Report
- To lead data review activities before database lock
- To review Clinical Study Reports
- To drive data interpretation, to plan and conduct statistical analysis (ISS, ISE), post-hoc analyses, exploratory analyses and other analyses requested by regulatory agencies
- To provide specifications to SAS programmers
- To collaborate in writing regulatory documents, eCTD submission modules; to represent Chiesi as statistician attending meeting with Regulatory Authorities.
- To write/review abstracts, posters and presentations.

Education: Master degree or PhD in Statistics.

Professional Experience: the ideal candidate would have a PhD in Statistics or similar, and 5 years of experience in a similar job, preferably in a pharmaceutical company.

Technical capabilities:

- Strong experience of clinical development and regulatory requirements
- In depth knowledge of statistical methods that apply to clinical trials: from first in human and PK studies, to phase II dose-finding and pivotal studies.
- Experience of regulatory interactions and submissions
- Knowledge of international standards (CDISC SDTM and ADaM) and FDA requirements
- Good SAS programming

Skills:

- Excellent communication skills and ability to establish good collaboration both internally and externally
- Strong commitment to quality
- Problem solving attitude
- Languages: Proficiency in both written and spoken English is a must.

Contract: Permanent

Job Location: partially home-based, Parma (Italy).

If interested, please contact Lucia Santambrogio: l.santambrogio@chiesi.com.