

## **BIOMETRICS DIRECTOR to be based in Switzerland or in the US**

*Our client is an international biopharmaceutical company currently looking for a Biometrics Director to set up the biometrics team with a possibility to be based in Switzerland or in the US.*

*They are offering an excellent opportunity to set up and develop the biometrics team for a highly skilled and experienced Biostatistician.*

*As a Biometrics Director you will be responsible for the management of biostatistics and clinical programming functions worldwide. In addition to the capability to be strategic and hands-on, a strong background in dealing with regulatory agencies is vital as is the ability to communicate clearly.*

*Your main responsibilities will involve:*

- *Develop study protocols, prepare statistical analyses and study reports that anticipate regulatory requirements and contribute to successful outcomes.*
- *Consultation to clinical project team on statistical issues related to the trial conduct; review protocols and case report forms for soundness of trial design.*
- *Work with the regulatory staff to plan and conduct successful interactions with the FDA to ensure efficient progression of the drug development programs.*
- *Participate in team and investigator meetings.*
- *Responsible for performance management including objective setting, appraisals, staff development, etc.*
- *Manage staff and oversee vendors as required.*
- *Evaluate and implement new technologies and processes.*

*You will have the following profile and personal skills:*

- *MSc in statistics with possibly PhD.; other related degrees will be evaluated together with experience.*
- *Minimum of 10 years experience in statistics is required (Pharma, biotech, or CRO acceptable) with experience in clinical programming and database management.*
- *Strong track record in international assignments*
- *Minimum of 5 years of people management experience is required with possibly experience of management team based in various locations/countries.*
- *In-depth knowledge of clinical trial methodology and FDA and ICH guidelines.*
- *Proven ability to apply appropriate statistical methodology to clinical development.*
- *Knowledge of a wide variety of statistical and programming techniques, SAS and other statistical and graphic software, and standard word processing and spreadsheet programs.*
- *A track record of dealing effectively with regulatory agencies.*
- *A working knowledge of other areas of R&D and commercialization such as project management, regulatory affairs, medical writing, marketing, etc.*
- *A solid, self-directed individual who can excel both independently and as a team player in a fast-paced, entrepreneurial environment.*
- *Ability to communicate clearly, both orally and in writing, with all levels of the organization and with outside vendors and regulatory agencies.*
- *Demonstrate a high level of influencing ability and be able to negotiate and strategically influence other team members.*
- *Fluent in English, any other European languages are well appreciated*
- *Results oriented, proactive, dynamic, entrepreneurial mindset*
- *Flexibility and ability to adapt to changing conditions; may work at very operational level as well as more strategic and process level*
- *Prepared to work in a challenging and busy environment; showing strong time management and project management track records*

*The company will offer:*

- *An excellent salary package*
- *A full relocation package (Shipping of the goods ...)*
- *Accommodation for the first months*
- *Visa/Work permits*

*If you are interested in this position, please send your CV with a covering note highlighting your experience in statistics to Louise Beka (louise.beka@secpharma.com ) or give me a call on +44 207 255 6600.*

**Louise Beka**

**Consultant - Pharmaceutical Division**

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