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RSVPGROUP

VISIONS FOR CHANGE

“Senior Biostatistician”

The Company

UCB (Union chimique belge; Euronext: UCB), is a biopharmaceutical manufacturer headquartered in Brussels, Belgium.

UCB was founded in 1928 by Emmanuel Janssen, a Belgian businessman. Initially focused on industrial chemicals, the company also included a small pharmaceutical division based around Meurice Laboratories.

In the early 1950s, UCB set up a research centre where new medicines such as Atarax (hydroxyzine) were developed. Successful sales enabled the pharmaceutical division to expand, and led to the discovery of another important compound, called piracetam. This was marketed in the 1970s as Nootropil and used to treat memory and balance problems. It remains one of UCB's key products. At this time, UCB was a company focusing on three core areas: pharmaceuticals, chemicals and films.

The success of Nootropil made it possible for UCB to build a modern pharmaceutical site in Braine-l'Alleud, south of Brussels. There, UCB developed Zyrtec (cetirizine), a blockbuster antihistamine. Other important products have followed including Keppra (levetiracetam), Xyzal (levocetirizine), and Cimzia (certolizumab pegol).

At the end of 2002, the chemicals and films divisions were merged and UCB added the resins, additives and adhesives activities of Solutia, to form the surface specialties division. The films part has since been sold to Innovia Films in September 2004. The chemicals division, Methylamines and Derivatives was spun off and later sold to form the company Taminco.

In May 2004, UCB acquired the British biotechnology company Celltech, followed in March 2005 by the sale of the surface specialties business to Cytec Industries. By divesting all of its non-pharmaceutical activities, and acquiring Celltech, UCB transformed itself into a global biopharmaceutical company.

In 2006, UCB started the purchase of the German pharmaceutical company Schwarz for €4.4 billion. As of July 2007, UCB holds approximately 87% of Schwarz's outstanding shares. The purchase of Schwarz enabled UCB to introduce two new drugs against CNS disorders: Neupro (rotigotine), a transdermal patch for treatment of Parkinson's disease and Vimpat (lacosamide), a new anticonvulsant. Another new drug of the Schwarz portfolio, Toviaz (fesoterodine), a compound to treat overactive bladder, was out-licensed to Pfizer in 2006.

The Company's efforts are focussed on treatments for severe diseases treated by specialists, particularly in the fields of central nervous system (CNS) disorders (including epilepsy), inflammatory disorders (including allergy), and oncology.

UCB has operations in more than 40 countries, supported by approximately 8,500 people globally with two Research Centres of Excellence based in Braine-l'Alleud (Belgium) covering CNS disorders and Slough (U.K.) covering immunology, where UCB's R&D headquarters are located as well. The main development sites are in Atlanta (U.S.), Braine-l'Alleud (Belgium), Monheim (Germany), Research Triangle Park (U.S.), Slough (U.K.) and Tokyo (Japan)

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The Company (continued)

UCB has close relationships with patients and the people who care for them and cutting-edge research that combines biology and chemistry (UCB’s expertise across large and small molecules enables them to approach severe diseases from different angles. They are combining their leadership in antibody research and long-established expertise in chemistry to better understand and address the complex biological pathways and interconnections of these types of diseases. This is underpinned by unique technologies, such as UCB SLAM and A2Hit™).

Additionally they are empowered, have multidisciplinary and multinational teams; more than 70 nationalities and numerous educational and professional backgrounds, the diversity of their staff is one of their greatest assets.

UCB has world-class partners across the value chain and they are a global player with a strong future pipeline.

“Senior Biostatistician”

The Position

For their Biostatisticians Department based in Monheim, Germany (close between Cologne and Dusseldorf), UCB is looking for an experienced Senior Biostatistician. This position is very critical and important within the team.

The position is fully responsible as a Clinical Trial Biostatistician for several clinical trials within a clinical project or across multiple clinical projects, from statistical input into the trial design through statistical analysis and reporting. He/she can also be involved in the statistical deliverables for a submission and he/she Will work under the supervision of the Clinical Program Biostatistician, especially for all aspects related to the clinical development plan and regulatory submission strategy.

The incumbent works within a global team and has close interaction with the statistical programmers, data managers, Clinical Project Managers (CPM), Study Physicians, Medical Writers, Health Outcome Research specialists and Regulatory Affairs managers and is recognised as a competent and experienced biostatistician by the staff in Global Biostatistics and other departments.

The postholder will have the unique opportunity as follows;

- acts as a Clinical Trial Biostatistician for several clinical trials within a clinical project or across multiple clinical projects.
- works very closely with the other biostatisticians and the Clinical Program Biostatistician assigned to the project.
- participates in the protocol development.
- gives input into the trial design, efficacy and safety parameters and the planned statistical analyses.
- performs the sample size calculations
- responds to the request for the randomization schedule and serves as randomization specialist when randomization schedule is generated internally. Has appropriate interactions with the IVRS vendor.
- reviews the CRF and other data management related documents. Evaluates the quality of the database.
- writes the Statistical Analysis Plan.
- coordinates with other biostatisticians and statistical programmers to prepare the statistical analyses.
- conducts the Data Review Meeting prior to breaking the blind in order to ensure accuracy.
- presents Top-line clinical trial results. Gives input into the executive summary report.
- reviews TFLs prior to release to the other project team members.
- reviews the clinical trial report and provides input on the interpretation of results.
- adheres to the company SOPs and working procedures.
- ensures implementation of the project and Biostatistics department standards.
- attends trial team meetings and collaborates with the clinical trial team to meet the timelines.

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The Position (continued)

- guides and supports the biostatistician(s) assigned to support the clinical trials. Acts as a resource for junior biostatisticians on the team.
- understands the regulatory requirements with respect to design and analysis of trials.
- assists the Clinical Program Biostatistician with the statistical deliverables for regulatory submissions.
- contribute and review publication document related to the responsible trials.
- Assists the Clinical Trial Biostatistician or Clinical Program Biostatistician on the coordination of the statistical activities with CRO statisticians. Communicates accordingly with the CRO. Validates selected statistical output delivered by the CRO.

The Senior Biostatistician will report to the Director, Head Global Biostatistics EU Group who is also based in Monheim.

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The ideal Candidate

The ideal candidate holds a Master’s degree, ideally a PhD with a background within Statistics, Mathematics or Natural Sciences.

Following specific skills are mandatory for this key position;

- Experience in clinical trials, preferably Phase II – III.
- Sound knowledge of the ICH guidelines. Understanding of the regulatory requirements from EU and US health authorities and of the submission process.
- Good knowledge of statistical methodology.
- Experience with sample size software.
- Good knowledge in clinical trial related SAS programming.
- Able to explain statistics in a non-technical manner to non-statisticians.
- Able to travel both, domestically and internationally, as business necessitates.

He/she strives on exchanging ideas with internal as well as external partners around the world and, at the same time, is a team player who can work effectively in a large organisation.

He / she is curious and passionate about what UCB does, with high expectations for the quality of work.

The successful candidate possesses solid analytical skills, well-practiced strategic knowledge as well as excellent written and verbal communication in English and ideally a good command of German.

The candidate is well structured and perseverant, possesses high integrity and is a good problem solver.

Candidates are required to be effective communicators as displayed through attitude and accomplishments. He/she must thrive in a fast-paced environment and exhibit the highest personal and professional standards of integrity and ethics.