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ucb

Assignment Brief

for the position of

Pathologist / Toxicologist Director

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The Organisation

Headquartered in Brussels (Belgium), UCB is a global biopharmaceutical company that combines the infrastructure and expertise of a traditional pharma company with the speed, innovation and entrepreneurship of a biotechnology company.

UCB is passionate about enabling families with severe diseases to enjoy normal, everyday lives.

- A global pharmaceutical company focused in severe diseases with operations in more than 40 countries and global revenues in excess of €3.2 billion in 2011.
- Two main research Centers of Excellence - Braine-l'Alleud & Slough
- A leader in CNS and Immunology Diseases with approximately 20 large and small molecules in their clinical pipeline spanning 16 diseases, from Crohn's and Parkinson's to multiple sclerosis.
- A leader in antibody research supported by propriety chemistry and over 30 major R&D partners.

Vision

UCB aspire to be the Patient-Centric global pharmaceutical leader transforming the lives of people with severe diseases.

UCB's vision is to be **"the next generation biopharma leader"** – through the development of scientific and technological advances to create new opportunities to address the complex interconnections of severe diseases with greater efficiency.

This can only be achieved by:

- Connecting science in new ways
- Connecting people
- Connecting patients

Values

- Passion Performance
- Care
- Accountability
- Entrepreneurship
- Integrity
- Innovation
- Embracing difference

With the acquisition of Celltech in 2004 and Schwarz Pharma in 2007 and the divestment of the Chemicals division in 2005, UCB has successfully transformed itself from a hybrid pharma and chemical company into a global next generation biopharma leader. UCB is one of the world's top biopharma players investing more than 25% of its sales in R&D.

UCB will continue with its model of organic growth, acquisition and partnership to continue to build upon and further develop its product pipeline and R&D success.

Its unique approach in integrating biology and chemistry allows UCB's discovery, research and development scientists to gain much deeper insights into disease pathways and produce more potent and cost-effective therapeutic solutions. The fruits of this approach can be seen in UCB's very rich R&D pipeline with more than 10 molecules in development.

The results are a powerful drug-discovery platform and the ability to target specialists in selected severe-disease areas with a relatively small sales force.

UVB's focus centres around two key therapeutic areas:

- Central Nervous System
- Immunology

UCB's strategy for continued success includes:

- Combining the very best biology and chemistry to achieve major breakthroughs
- Integrating expertise in large, antibody based molecules with small, chemically derived molecules
- Partnering with leaders in the pharmaceutical industry and academia
- Leveraging its global scale and intellectual capital

UCB's ambition is to offer patients innovative new medicines and ground breaking solutions that go beyond the drug. Through UCB's commitment to enabling cutting edge scientific research, driven by patients' needs, people suffering from CNS and immunological disorders are able to lead normal, everyday lives.

Having managed the company through **Transformation** into a Biopharmaceutical company (2005), **Scaling** through the acquisition of Schwarz Pharma (2006) and **Execution** preparing for future growth and implementing the new vision and strategy (2009), UCB is now prepared for **Growth**. With new products laying the foundation for future growth, there will additionally be increased investment in the research and development of new products.

Commercial growth and success

UCB is a highly successful biopharmaceutical company, with net sales of €3.2 billion euro in 2011.

Keppra (levetiracetam) reinforced its position as the leading treatment for epilepsy in the US and Europe with a 35% rise in global sales to €1,026 million – Keppra is currently manufactured in Braine l'Alleud. Keppra remains the market leader in the United States and Europe.

Zyrtec (cetirizine) still performed extremely well in the USA with an impressive growth and remains the market leader.

Xyzal (levocetirizine) also increased net sales for the year, further consolidating UCB's position as a global leader in allergy therapeutics. It is approaching market leadership in Europe and has recently been launched, under a co-marketing agreement in the United States.

The three major recent launches were:

- **Cimzia** (certolizumab pegol), a PEGylated tumour necrosis factor alpha blocker actively used in the treatment of Crohn's Disease and Rheumatoid Arthritis
- **Vimpat** (lacosamide), approved for use for the adjunctive treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy, aged 16 or over
- **Neupro**, successfully used for the treatment of both Parkinson's Disease (early stage idiopathic disease signs or symptoms) and Restless Leg Syndrome (moderate to severe disease in adults)

Key Facts and Figures

- UCB currently employs over 9,000 people
- Company operations exist in more than 40 countries worldwide
- 2011 net sales were distributed over the USA (35%), Europe (51%), Rest of the World (14%).
- 2011 net sales were distributed by therapeutic area: Immunology & Allergy (18%), CNS (41%) and Other (41%).
- Core products include Cimzia, Vimpat, Neupro, Keppra, Xyzal, Zyrtec which continue in development within new indications and many others NCEs / NBEs at various stages of development still in the pipeline.
- Healthy pipeline with > 14 molecules in clinical development
- Global R&D, marketing and sales platform
- Over 30 R&D and commercial partners

UCB recently reorganised its R&D organisation in two divisions: UCB New Medicines which covers all aspects from Discovery Research and up to and including clinical Proof of Concept, and Global Product Development, covering late stage, confirmatory trials.

UCB New Medicines is centred around two centres of excellence in Europe: Braine-l'Alleud (Belgium) is focused on the central nervous system, and Slough (UK) covering immunology.

UCB's global commercial operations are structured in three business units: Central Nervous System, Inflammation and Primary Care. These are responsible for marketing, medical information and distribution of pharmaceuticals originating from UCB's research and development in the fields of neurology, allergic/respiratory diseases as well as other primary care diseases. A strong international network of Medical Affairs teams supports these activities.

A significant advance in quality and efficiency to world class standards has also been achieved through several initiatives. This has included technical innovations within manufacturing processes, thereby reducing costs whilst at the same time ensuring the highest quality and the ability to meet increased demands without any interruption in supply.

UCB's main manufacturing sites are located in Braine-l'Alleud (Belgium), Bulle (Switzerland), Pianezza (Italy) Rochester (USA), Tokyo (Japan), Vapi (India) and Schwarz Pharma have additional sites in USA, Ireland, China and Germany.

Further information relating to UCB's successful product portfolio, pipeline and growth strategy is available from their web site at www.ucb-group.com

Context of the Role

- UCB is a leading research-driven biopharmaceutical company. Using innovative approaches to drug discovery, research and development, it has an unmatched combination of expertise in both chemically derived medicines and biologics. The key features of the R&D organisation are:
- A dual pipeline approach to Research and Development encompassing both New Chemical Entities (NCEs) and New Biological Entities (NBEs), allowing UCB to address disease treatment through a range of targets and disease pathways.
- A highly innovative Research and Early Development organisation, UCB New Medicines with approximately 1,000 staff and a Global Product Development (post POC) organisation of 700 staff.
- A strategy designed to focus on severe diseases treated by specialists, covering two main therapeutic areas: central nervous system and inflammation
- World-class scientists harnessing leading and in many cases unique technology platforms.
- A track record of success through working in partnership with academia such as Harvard, Oxford etc and other leading drug discovery organisations. UCB New Medicines actively seek further partnerships through which it can apply its expertise (particularly in antibody-based drug discovery and development) in order to optimise the delivery of innovative new medicines to the market.

Primary Purpose of the Role

As a Director Toxicology within the non-clinical safety department you will have enjoyed a succesful career either as a Senior Pathologist or as a Senior Toxicologist. You will have significant drug development experience and the ability to provide excellent leadership and management.

You will be responsible as Director within the non-clinical safety department for the non clinical development of small molecules and monoclonal antibody (mAB) drug candidates and for the strategic leadership of late stage / post marketing phases.

You will provide non clinical support to global project teams at all stages of development from early research through to First in Man (FIM), Proof of Concept (POC), launch and beyond.

You will work in a collaborative environment as a member of interdisciplinary and mulitcultural project teams and respresent the Non Clinical Development Department (NCD).

You will demonstrate outstanding skills regarding the partnership and management of CRO relationships, guide toxicology interpretation and issue resolution and participate in many toxicology and R&D initiatives and other cross-functional collaborations.

You will be responsible for the review of regulatory documentation and represent UCB in meetings with regulatory authorities.

In addition to project teams work, you will provide the strategic leadership and take managerial responsibiltity within the Toxicology Depeartment.

You will be based in Braine, Belgium.

The position will report directly to the Senior Director, Non-Clinical Safety Evaluation.

- Non clinical development of UCB drug candidates, small molecules and mABs
- Provide strategic leadership for late stage / post marketing phases of development
- Support development of all immunology and CNS products within the R&D pipeline
- Support global project teams
- Provide non clinical support from early research through to marketing authorisation
- Provide expert pathology/toxicology advice and interpretation
- Ability to champion projects with a multi-disciplinary approach
- Prepare and review regulatory documentation
- Represent UCB in meetings with regulatory authorities

Person Specification

- Senior Pathologist or Toxicologist with in depth non clinical Toxicology knowledge in a development and commercial environment - Pharma / Biotech
- Experience within mAB and small molecule research and/or development
- Good knowledge of immunology and/or CNS product development will be an asset
- Broad experience and expertise within all aspects of non clinical Toxicology ideally including Biologics development
- Excellent knowledge of early drug development processes with proven track record of successful contribution to discovery and development projects
- Desire and ability to drive the strategy and vision within the Late Stage and Post-marketing NCD
- Responsible for NCD of all molecules post POC
- Track record of success leading development projects, from a non-clinical Toxicology perspective with last stage / post marketing projects
- Ability to communicate effectively with internal and external opinion leaders including pharmaceutical regulatory agencies, e.g. FDA, EMEA
- Ability to work in a matrix type environment
- Experience and comfort independently managing external service providers, CROs
- High performer, strong team-commitment. Innovative with the flexibility and maturity to manage uncertainty and manage complex situations and problems
- Ability to work independently and to solve complex problems and contribute to multiple projects with strong decision making skills
- Ability to anticipate program needs and to act accordingly, and prioritise as necessary
- Interpersonal skills
  - Team orientated
  - Self – motivated
  - Ability to motivate others
  - Willing to travel
- Quality of experience will be more important than quantity. However, it is unlikely that candidates with less than ten years' regulatory toxicology and GLP compliance within pharmaceutical research in the industry would have sufficient experience for the role
- Confidence and professional competence to gain credibility and win respect at all levels both within and outside the company
- Ideally you will hold a PhD within pathology / toxicology or a related field

Person Qualities

- Dynamic and passionate about science
- Open to new technology and new advances
- An ability to challenge and change the way in which UCB works and provide leadership and direction to others
- Well organised with an analytical approach to work
- A team player who can work independently or as a strong collaborative member of a diverse team, both technically and culturally diverse
- Experienced at maintaining focus on the bigger picture whilst also maintaining detailed analysis as and when required
- Aspiration to provide leadership and further develop strong management skills
- Comfortable working within a scientifically complex area, with the ability to identify solutions to complex problems
- Proven track record of critical data analysis and interpretation
- Strong influencing skills and excellent communication skills, verbal and written
- Ability to foster excellent relationships based upon trust and open communication with project team members and senior leadership teams
- Natural ability to share information and communicate new ideas with others
- Able to think globally and strategically
- Ability to think independently and make decisions, having the courage to follow instincts and ideas
- Maturity to work independently but also as part of a team
- Open to suggestions from others and harbouring an inclusive style
- Ability to adapt easily and take a flexible approach as required and to constantly adapt to a changing environment
- Open and honest with strong, constructive communication and negotiation skills
- Enthusiastic and dynamic, capable of working independently within broad objectives without the need for day-to-day supervision
- Ability to succeed through influence, being persuasive and motivating others
- Comfortable working in a highly visible, high profile role in an organisation with short communication lines and direct access to senior management.
- A proactive team player with good communication skills, comfortable interacting with people at different levels, across functions and internationally
- Ambition and desire for success and personal growth
- Fluent in English and a natural communicator, assertive with well developed presentation, negotiation and persuasion skills

Package

UCB are able to offer a highly competitive salary, dependent on experience plus exceptional additional benefits including:

- Competitive base salary commensurate with experience
- Holiday – 25 days
- Flexible benefit scheme
- Defined contributory pension plan – company contribution 8% (4% min for employee)
- Annual bonus - level dependent upon grade and personal performance
- Life Assurance – 4 x annual remuneration (depending on number of dependants)
- Private Medical insurance (BUPA) for employee only
- Permanent health insurance covers 75% of salary until retirement
- Invalidity insurance
- Disability allowance
- Car/car allowance – dependent on grade
- Employee Assistance Program
- Relocation assistance negotiable - on an individual basis depending of needs