Director Regulatory Affairs, Europe

Ref: PSL4043 Attractive Salary Package
Commensurate with experience

Join a highly successful business and market leader to help continue the growth of their focused and ambitious product development pipeline.

Reporting to the Senior Vice President Regulatory & Scientific Affairs you will play a crucial role in the strategic leadership and direction for the scientific integrity of all regulatory submissions and approvals.

You will be a key member of the global leadership team within R&D, accountable for the scientific quality of product submission dossiers, and their successful approval by regulatory authorities.

You will have full responsibility for the scientific content of future regulatory submissions, ensuring that all research and data are of the highest quality standards. This will include incorporating research data that combines traditional scientific methodology, non-clinical and clinical studies, with systems biology, state-of-the-art computational science and disease modelling.

This is a highly strategic position where along with others you will be accountable for the scientific quality and integrity of all EU regulatory submissions and subsequent successful product approvals.

You will have a high level of autonomy, decision making responsibility and be expected to possess excellent communication and management skills in order to develop outstanding relationships with internal and external stakeholders and regulatory agencies.

Crucial to your success will be your ability to work closely with local and international regulatory bodies to agree innovative scientific approaches and provide the leadership to convert this into a regulatory strategy to be followed and implemented.

Scientific standards will be established through a Quality by Design approach to all aspects of the research, including non-clinical and clinical assessment, behavioural studies, manufacture and post marketing surveillance.

Ideally you will have an innovative and pragmatic approach, a desire to make a difference and the ability to lead and motivate others through your passion and enthusiasm. Your communication skills will allow you to interact at all levels, share complex information and work closely with others and senior business leaders. You will provide scientific and regulatory leadership and ensure full compliance whilst appreciating when to consider a more creative and pragmatic approach and ensuring scientific integrity and robust data.

This is an exciting opportunity to join a highly successful global business, within a leadership function, in a highly visible capacity where the long term career prospects are varied and exceptional.