Käthe Byrström Regulatory Affairs / Drug Development Consultant

The company provides consulting service to the pharmaceutical industry in the areas of Regulatory Affairs and drug development strategy. The service includes regulatory activities and strategy, advice on development plans and planning/preparation of clinical trial application within drug development.

Description

The company was established in August 2007 by Käthe Byrström, MSc Pharm, and provides consulting service to the pharmaceutical industry in the areas of Regulatory Affairs and drug development strategy.

Assurance of quality

I have held a number of management positions within KabiPharmacia, Pharmacia Upjohn, AstraZeneca, Orexo and Avaris AB. During 2007 I worked on a consultancy basis as the interim Head of Regulatory Affairs for the Nordic Area in a large pharmaceutical company. I have gained a commercial awareness and have a sound understanding of the environment for the pharmaceutical industry. I have been working with global drug development including Toxicology, Regulatory Affairs and Project Management. I have experience of a broad range of therapeutic areas including Cardiovascular, CNS, Pain, Diabetes, Gastroenterology, Cell therapy, Malignant Disorders, HIV, Peptide hormones, Nutrition, Plasma Products and OTC.

More than 25 years in the pharmaceutical industry have given me extensive experience of global drug development, proactive regulatory support and agency interactions. I have worked for big pharmaceutical corporations as well as small startup companies, both in Regulatory Affairs and Project Management.

Services

I am available for temporary managerial positions within Regulatory Affairs and project management. The service includes regulatory activities and strategy, advice on development plans and planning /preparation of clinical trial application within drug development. I am competent in planning and execution of agency meetings in Europe, including EMEA scientific advice as well as meetings with the FDA. I have experience of a variety of tasks such as:

- Preparation of briefing documents /background package and rehearsal for agency meetings
- Review and evaluation of licensing opportunities
- Review of medical/scientific reports, IB, study protocols
- Preparing target labelling and claims, review of promotional material

Practical information

For further information please contact me at kathe.byrstrom@gmail.com.

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