Remedica

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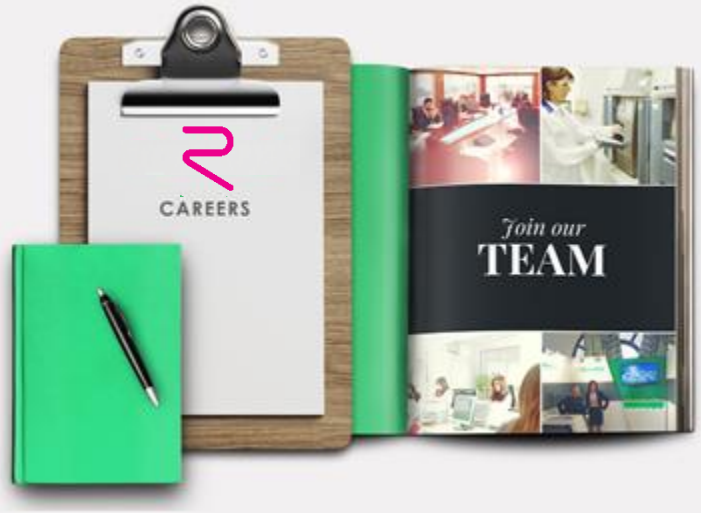

Senior Clinical Operations Scientist

Role

Reporting directly to the Regulatory Affairs and Clinical Operations Manager, the Senior Clinical Operations Scientist will be responsible to lead and/or support assigned clinical trials.

Duties and Responsibilities

1. Suggest clinical trial designs, provide input to CROs and finalize designs
2. Review and approve the BE/pK study protocols
3. Analyze data, review/evaluate and approve study reports
4. Liaise with pK experts for the assessment of data and reports
5. Collaborate cross-functionally, working closely with R&D for pK data needed for formulation development
6. Provide feedback advice on strategies for establishing IVIVC
7. Manage the BE Study monitoring activities ensuring compliance with Good Clinical Practices (GCP) and applicable regulations
8. Track and obtain approval of clinical operations expenses

Qualifications for the job:

- BSc in Pharmacy, Pharmacology
- PhD with concentration on Pharmacology or Pharmacokinetcs will be considered an advantage

Experience:

- At least two years' experience in the generic pharmaceutical industry, preferably clinical trial experience
- Knowledge of Pharmaceutical legislation, Knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial management are mandatory

Required Skills:

- High attention to detail
- Analytical thinking
- Scientific writing experience
- Excellent written and verbal communication skills
- Excellent command of the English Language
- Strong clinical study management skills

An attractive remuneration package depending on qualifications that includes 13th and 14th salary, Provident Fund, medical cover etc. is offered. Interested candidates should apply online through Remedica's website www.remedica.eu