MAC Clinical Research

JOB DESCRIPTION

JOB TITLE: Senior Pharmacokineticist

FOCUS OF THE JOB: To lead the Pharmacokinetics team and provide expert PK, PD and PK/PD support to MAC Clinical Research and its customers.
To develop best working practices and Standard Operating Procedures to deliver the portfolio of projects within the PK Department.

- Provide leadership for the PK. PD and PK/PD aspects of projects within the Biometrics department.
- Drive and develop the processes to support all activities within the PK department.
- Serve as a resource for allocated projects and its deliverables.
- Ensure PK deliverables are achieved on time and to high quality.
- Coordinate the PK activities and resources for allocated projects.
- Ensure that all PK activities are performed in line with relevant SOP's and in accordance with GCP.
- To ensure customer satisfaction.

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:

- Educated to Degree level (or equivalent) in an area relevant to the role.
- Considerable demonstrable experience in PK, PD, and PK/PD and an in-depth working knowledge of effective Pharmacokinetics practices. Preferably, a minimum of 5 years in a PK role within the Pharmaceutical or CRO Industries
- Excellent computer skills including expert use of WinNonlin and other PK software
- Excellent oral and written communicative skills. Fluent in oral and written English
- Excellent time management to organise and prioritise workload.
- Ability to lead by example on process development, departmental and project objectives, and overall business strategy and initiatives.
- Ability to work in a collaborative team environment.
- Able to proactively identify risks and issues and be able to devise mitigation and contingency plans and solve problems as they arise. Encourage team members to apply the same approach to seek solutions.
- Knowledge of drug development process including the relationship between the CRO industry and Pharmaceutical companies.
- Knowledge of the regulatory framework that surrounds drug development and the clinical trial process.
- Knowledge of clinical trial process; including the interaction between the PK team with the wider Biometrics team and clinical operations

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RESPONSIBILITIES

- Provide leadership to the PK department and the PK team members assigned to individual projects.
- Oversee the PK team to ensure delivery of high quality outputs on time and in-line with customer expectations to achieve a high level of customer satisfaction.
- You will participate in data focused project team meetings, meeting frequently with the project team to ensure that all deliverables are planned and coordinated within the project team.
- You will work with the project team to proactively identify potential risks and put in place mitigation and contingency plans.
- You will effectively communicate any PK- driven discussions to achieve project deliverables on time and to high quality.
- In addition, your specific responsibilities will include:
    - Serve as the Pharmacokineticist for allocated projects
    - Be responsible and accountable for all PK, PD and PK/PD deliverables per the established timeline
    - Providing leadership to the PK project team and provide instruction and guidance to deliver the project objectives
    - Review the project team's output regularly to ensure the highest quality deliverables
    - Review and, where necessary, adjust the resource allocation within the PK department to ensure that the PK project portfolio can be delivered effectively, on time, within budget and to a high quality.
    - Ensure that all relevant protocols, project plans, SOP's and regulatory requirements are adhered to
    - Develop timelines with the Project Manager for all PK, PD and PK/PD deliverables, in line with the project contract and overall project/business objectives.
    - Communicate risks and issues effectively to the project team and provide regular updates to the project team.
    - Ensure that all PK, PD and PK/PD documentation is generated in a timely fashion in accordance with SOP and project timelines.
    - Maintain complete and accurate records for all PK activities.
    - Generate, review and provide input into project plans and documentation e.g. Protocol, Data Management Plan, Statistical Analysis Plan, PK Report, Clinical Study Report, in terms of PK and PD analysis and study objectives.
    - Develop and drive best working practices and process improvement. Input in writing, reviewing and updating departmental SOPs and associated forms and templates.
    - Perform QC of PK deliverables
    - Identify quality issues and implement CAPA as appropriate.
    - Compile PK and PD analysis datasets
    - Conduct interim PK and PD analyses and interpretation
    - Conduct non-compartmental PK and PD analyses as defined in the project plans

- QC of PK inputs and outputs
- Liaise with the Biostatistics Department regarding the statistical analysis and presentation of the PK, PD and PK/PD data in Tables, Figures and Listings.
- Prepare and/or review PK and PD analysis methodology sections of the Clinical Study Report.
- Provide and/or review interpretation of the PK and/or PD data for inclusion in the Clinical Study Report.
- Attend and provide input to internal, client or regulatory audits or inspections.

Management:

- Responsible for line-managing other members of the PK team.
- Provide training and support for other members of the PK team

Leadership

- Initiate changes in working practices
- Provide practical solutions for problems
- Motivate, encourage and train other members of the PK team

Commercial Awareness and Contribution to Targets

- Work with Head of Contract Research Services to drive and exceed business targets
- Maintain an awareness of our key customers and market competitors
- Actively seek information about new studies and competitors and share with colleagues
- Be proactive in implementing Company strategy and plans
- Contributing to MAC's development of new systems, processes and SOPs
- Expert assistance in the help and compilation of bids and contracts
- Ability to communicate effectively with non-PK Scientists

Professional development

- Maintain a professional attitude and appearance at all times to customers/colleagues
- Identify opportunities for self-development

General:

- Present a positive image of MAC Clinical Research to all external individuals and bodies.
- Set a positive example to all colleagues.
- Share experience and knowledge with colleagues as appropriate and in an appropriate manner.
- Compliance with MAC health and Safety policy
- Compliance with MAC policy on equality and diversity
- To work to the requirements of SI 2004 no 1031 and amendments thereof, which includes Good Clinical Practice
- To work per MAC SOPs, guidelines and policies

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- To work per current data protection standards and practice good information management. Maintenance of strict confidentiality of patient and business related data.
- To maintain a high level of initiative and personal responsibility, liaising appropriately with team members and managers to ensure your job role is efficiently carried out
- To support the aims of MAC and to represent MAC appropriately in a professional way to all our customers

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS: Be available to provide cover for other members of the PK team where necessary (for example due to illness or holidays).

LIMITATIONS AND DISCLAIMER
The above job description is meant to describe the general nature and level of work being performed; it is not intended to be construed as an exhaustive list of all responsibilities, duties and skills required for the position.

Employees signature…… Date……..

Head of Department signature…….. Date……..