

Posting Title: Large Molecule Project Expert
Job Title: Senior Principal Scientist

Posting Locations

| Country | State | City |
|----------------|--------------|-------------|
| GBR | | Sandwich |

Responsibilities:

This position offers several exciting opportunities in the growing field of Vaccines and Biologics within Sandwich PDM. The opportunities are dependent on experience and include; i) oversight and general PDM support of an individual Vaccines project, ii) a leadership role with strategic contribution to offer PDM support for a range of Vaccines projects iii) a leadership role in bioanalytical support for Vaccines, biologics and biomarkers.

Within Vaccines project support opportunities, you'll be responsible for the oversight of one or a number of vaccine projects within a range of TA groups and, depending on experience, will provide input across the entire course of a projects life from project inception and vaccine optimization, through to filing and beyond. You'll provide oversight and PDM input in areas such as PK, PKPD, ADME, IVIVC. Working with a scientific mentor you will communicate strategic direction to assigned projects on a regular basis, and implement PDM best practices in the area of vaccine and biological discovery and development. You will liaise with other groups and members of the vaccine COE requesting and interpreting data provided by the groups, liaising with project team members on project progression, issue identification and providing direction to the project. With relevant experience you will also act as scientific mentor to more junior colleagues and will be responsible for both developing strategies for communication with your and others projects, and development of PDM best practices for large molecules.

Bioanalytical skills and experience in large molecule assay method development as well as practical knowledge in the biologicals area are essential for all opportunities within large molecule project support. You will develop, validate and use a range of bioanalytical measures to determine immunological effect (eg ELISA, ELISPOT), working closely with the Sandwich Vaccines Centre of Emphasis (CoE), and with relevant experience will influence and develop best practices for interpretation of data.

Recognized expertise in bioanalytical chemistry, including immunochemistry, with relevant industrial experience of a wide range of analytical techniques (eg LC, ELISA, DELFIA), will allow you to take a leadership role in the development of a Bioanalytical/PDM group to support the Vaccines CoE at Sandwich where you will be responsible for characterization of new fit-for-purpose methods for bioanalysis and bring expertise to overall bioanalysis of biomarkers and biological compounds in biological matrices.

Although there are no direct supervisory responsibilities associated with the leadership

opportunities, if you have the relevant experience to take on either of these roles you'll be expected to provide technical coaching and scientific direction for the junior scientists in the group as well as participating in organization of the departments activities and appropriate deployment of resources. Strategic planning for the development of PDM activities within biomarker and biologics disciplines will also be a part of these leadership roles.

Main duties include:

a) for PDM Support Roles for Vaccines Projects;

- Provide oversight and PDM input with consultation with supervisor or mentor where appropriate to a vaccine project in PDM areas including PK, PKPD, ADME, IVIVC, operating confidently in areas of uncertainty (Leadership role will provide independent oversight of multiple projects).
- To develop, validate and use the range of assays required to determine the biological effectiveness of a candidate vaccine.
- Implement PDM best practices in the area of vaccine discovery and development, including data interpretation (Leadership role will play a major part in influencing and developing best practices).
- Co-ordinate, prioritise and agree progression with project(s).
- Provide direction to the project on the development of a suitable vaccine.
- Work efficiently as part of a matrix team to initiate experiments and to bring together the data provided by these groups to guide the project towards its stage gates.
- Maintain effective communication on project status with the TA liaison leader.
- Represent PDM as a core member of the Research project team. Within and out with team meetings present findings, interpretation and propose future studies in a confident and timely manner.
- Ensure all work activities are carried out in compliance with standard operating and safety procedures.
- Actively collaborate with Core discipline groups within PDM, the vaccine CoE and interact with the Project Leader and scientists in Biology departments, DSRD and Pharm Sci and clinical departments as necessary.
- Work with supervisor and/or mentor to identify innovative solutions to PDM problems, particularly in the area of vaccine discovery / development and drive PDM science in this and other areas (Leadership role will independently provide innovative solutions).
- Seek to widen knowledge of the principles of vaccine discovery and development by using the current literature and by attending appropriate meetings, conferences and training courses.
- Contribute to the scientific community (internally and externally) by presentations and publications.
- The Leadership role will provide mentorship to colleagues in all areas of vaccine discovery and development including assay development and interpretation.

b) for the leadership role in Bioanalytical Support for Vaccines, Biologics and Biomarkers;

- Provide efficient, timely bioanalytical leadership for support of all assigned Vaccines CoE projects.
- Lead the development of state of the art assays that are fit for purpose to support the quantization of biomarkers, and provide innovative solutions to the quantification of novel macromolecule drug candidates.
- Ensure all work activities are carried out in compliance with Good Scientific Practices (GSP), promote high level of safe working practices within the laboratory.
- Make work more efficient by providing adequate training and constructive feedback to people of the team to help them improve performance and productivity.
- Contribute to bioanalytical technology advances at the global PDM level through participation in cross-site networks and global bioanalytical technology teams. Liaise with PDM Biologics CoE for method and technology transfers.
- Identify and support external sourcing of bioanalytical work for biomarkers and biologics. Contribute to the strategic sourcing decisions for appropriate utilization of contract research organizations in support of bioanalytical work.
- Improve turnaround of data by encouraging the development of sensitive analytical methods, simple and easy to run, that involve the use of both automation capabilities and on-line sample preparation techniques available in the group.
- Keep abreast of current and advancing technologies in the area of biomarker and biologics bioanalysis, so that state-of-the-art instrumentation is available to optimize efficiency of assay development, sample analysis and issuing of reports
- Facilitate interactions with other bioanalytical groups for workload sharing, resource allocation and technology exchange.
- Contribute to the scientific community (internally and externally) by presentations and publications.

Qualifications:

You'll have a BSc. or MSc. in Analytical Chemistry, Biochemistry, Pharmaceutical Sciences or Life Sciences based subject or equivalent, with a high level of lab based experience. A PhD in these areas with relevant post doctoral studies is desirable.

Your experience of project liaison and project support, in all phases from inception to initial human studies, will allow you to demonstrate the achievement of results in a matrix environment.

Your knowledge base will include ADME science and drug discovery and development, pharmacokinetics and use of appropriate tools (e.g. Watson), and basic knowledge of PKPD including dose response modelling. You'll also have proven experience in the area of large molecule assay development using a broad range of techniques.

Taking a rational, innovative and creative approach to problem solving, you'll be able to show sound judgment in own work and in problem solving. You'll be able to identify and

resolve complex PDM project issues, and be able to apply learning's from prior experience to new situations and problems.

With proven oral presentation abilities, you'll be able to interact well with other teams and be pro-active in making things happen. With the ability to work independently, but also be a member of a team, you'll be able to evaluate information from a broad range of sources and be able to prioritize based on urgency and importance of tasks. Ideally you'll have developed coaching skills, and be able to inspire others to perform with own energy and drive.

For the leadership role in biologics and biomarkers bioanalysis, you will need a wide breadth of knowledge of analytical techniques (LC, ELISA, DELFIA, general immunochemistry), you'll be able to take a rational, innovative and creative approach to bioanalytical assays troubleshooting, and you'll be able to design the strategy for assay method development in an independent manner. You'll have a positive leaning towards the application of new technology. You'll have sound physicochemistry and immunochemistry judgment in own work and in problem solving, and be able to apply learning's from prior experience to new situations and problems.

All opportunities require excellent interpersonal / communication skills, which will enable to consult key stakeholders, coach and mentor other colleagues, and make contributions at a wider project team level. Being organized with an ability to plan own work and the work of others for extended periods, you'll be able to prioritize based on urgency and importance of tasks and also initiate change and take action rather than waiting for a situation or problem to develop. Attention to details is also key.

PDM is a multidisciplinary department whose work involves studying the fate of potential new medicines within the body. In broad terms, this entails characterizing the absorption and excretion of novel drug molecules, their distribution into body tissues to elicit a pharmacological effect and how they are modified by enzymes to form metabolites. Within the drug discovery process, PDM scientists work closely with chemists, biologists and clinicians to design molecules with optimal pharmacokinetic and pharmacological properties for their intended medicinal use.

PGRD's aim is to provide equality of opportunity in the recruitment process by avoiding discrimination on the grounds of: age, sex (physical characteristics you were born with), marital status, gender (self identity), sexual orientation, religion or belief, disability, colour, national or ethnic origin, political persuasion or trade union membership.

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