



Role Profile- Draft

Job Title	Senior Programme Manager	Reports to:	General Manager Wales
Date	June 2015	Location	Wales/South East tbd

Role Purpose

This role is directly accountable for driving all aspects of the assigned programme/s to meet critical clinical timelines across phase I,II and III as agreed by the RN Board.

This is a pivotal and high profile role where the job holder must take direct ownership right across the programme, pro-actively coordinating all the necessary resource and taking **personal accountability** for:-

- Ensuring the high level programme strategy is translated into clear and visible operational delivery plans that match agreed timelines
- Defining and managing the project budget
- Delivering on all aspects of the programme, working through the resource teams to ensure they understand and meet the agreed dates, on budget and in compliance with in-house and external regulatory requirements.

The job holder therefore takes personal responsibility and ownership for the programme meeting it's time, cost and quality targets

Key Responsibilities

- Own the Target Product Profile for all Products. This will involve leading the preparation of this document, working with the department heads and presenting it to the exec team as appropriate during the product development.
- Working with the Executive team, ensure that the strategy on the assigned programme is translated into a high level operational delivery plan. Gain clarity and agreement on this plan that fixes clinical delivery milestones to meet agreed timelines. Ensure these plans and decisions are recorded in the Project Strategy File (see below).
- Drill down from the high level plan to increasing levels of detailed project

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plans in order to assign project tasks and expectations on deliverables to the resource teams, right across the programme covering non-clinical studies, clinical trials, regulatory submissions etc. Ensure that these work packages are clearly defined in terms of deliverables and timelines and that detailed project plans are up to date, accessible and visible to all parties concerned. Determine and manage critical paths, inter dependencies on activities etc.

- Draw up and gain agreement on a programme budget both at the high level and drilled down to the work package level. Manage or ensure management of all aspects of this budget to avoid overspend once agreed.
- Maintain an active risk register for the programme continuously assessing risks to either notify the Exec of high level risks or to manage and mitigate risk to ensure project delivery stays on plan.
- Take ownership for creating and maintaining the Project Strategy File which includes the Risk Register, the Project Rationale, the Project Plan, the Budget (costs and FTEs)and the Target Project Profile. Keep these documents up dated so that they “tell the story” of all decisions and events on the programme from first adoption of a development candidate. Ensure that all sections are suitable for presentation to external bodies and the board as appropriate.
- Work with line managers to ensure appropriate resource to the project, and jointly select individuals to lead the teams in the various specialist areas and to sit on the project strategy team. Raise to the Exec any issues with shortage of resource or lack skills/capabilities that might jeopardise project delivery or quality
- Manage the “project team” both in-house project teams and external contributors to stay focussed on the project and project delivery. Set up communications lines to ensure project delivery information is constantly streaming. Take personal responsibility for seeing that roadblocks are identified and removed and for resolving conflicts.
- Ensure the wider project team is kept informed of relevant information and project performance. Keep the plans up to date and publish and notify all levels from Exec down of any significant variations from plan.
- Be the programme champion for project delivery to the appropriate quality standards. Maintain an understanding and provide support to ReN’s QMS and ensure all work complies with standard operating procedures (SOPs), Guideline for Good Clinical Practice (CPMP/ICH/135/95), EN ISO 14155: 2003 (device studies), EU Directives (2001/20/EC; 2005/28/EC), Annexe 13, EU regulations specific to Advance Therapy Investigational Medicinal

Products (ATMPs), UK Statutory instruments and applicable local regulatory requirements.

- Ensure that all activities have a clearly mapped process where necessary to support GXP compliance. Where processes are not defined, actively work with the team and put them in place.
- Own all of the reports and agreements and other relevant documents for the projects, ensuring these are relevant, covering all the gaps, completed to plan, maintained as appropriate and correctly filed.
- Work hands on to support the team any area as necessitated and appropriate to achieve the required deliverables and quality.

Person specification

Skills:

- Excellent skills (super user) in all Microsoft office applications particularly an MS Project-advanced level user.
- Ability to analyse complex project information and present to project team and exec team to enable clear decision making and assessment of performance against budget and project baselines and other metrics.
- A born project manager with innate planning skills and a natural desire to take control. Proactive, energetic, hardworking, , infectious enthusiasm
- Sound understanding of commercial, regulatory environment for ATMP clinical development.
- Able to lead change and improvement by example rather than expecting systems to be in place, a can-do attitude without the need to gold plate.
- Excellent and disciplined meeting chair.

Experience:

- Proven experience of managing complex biologicals development programmes from preclinical to license and a proven track record of having brought a number of these projects to conclusion on time and budget .
- Long experience of using MS project at an advanced level to give company wide visibility of project plans . Experienced at rapidly adjusting and updating plans as circumstances change without loss of integrity..
- Experience of working in a small biotech environment, leading teams onto next phase of development,
- Experience of matrix management across multiple stakeholders including
- Proven track record of managing large project budgets , establishing budget processes and managing , including assessing accruals etc.

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