Job Title: Alliance Manager & Regulatory Affairs

Telethon is a major Italian charity focused on rare genetic diseases. Founded in 1990, its mission is to advance biomedical research towards the cure of rare genetic diseases otherwise neglected by major public and private investments. The ultimate goal is to make therapies available to all patients in need.
Telethon has so far funded 2570 projects for an overall amount of 451 million Euro with the purpose of progressing research from the lab bench to the patient bedside.

We are currently looking for a person to fill the double role of Alliance Manager and Regulatory Affairs Officer.
The candidate will provide support to the Head of Alliance Management & Regulatory Affairs working at the San Raffaele Telethon Institute for Gene Therapy (SR-TIGET) in Milan.
SR-TIGET is a joint venture between Telethon and the San Raffaele Institute established to perform innovative research on gene transfer and cell transplantation to be translated into successful therapies for genetic diseases.

Job Description

Academia and non-profit organizations are increasingly active in areas of emerging and translational science in rare diseases. A model they are using to translate an excellent research to a potential reality for the patients is to establish Strategic Alliances with Pharmaceutical Industries, whose skills and resources can address the regulatory hurdles and manufacturing needs to bring new therapies to registration. When the Strategic Alliance is established, the alliance manager plays a major role in ensuring a thriving collaboration. Having knowledge of the regulatory path from the drug development to registration and market access is key to maximise the management of the alliance.

OBJECTIVE
Reporting to the Head of Alliance Management & Regulatory Affairs, the Alliance Manager and Regulatory Affairs Officer will support the assigned alliances with multiple SR-TIGET partners and collaborators and will support the assigned projects in the Regulatory Affairs strategy and needs. Responsibilities include supporting strategic and regulatory discussions and decision-making processes anticipating and addressing contract and business issues to effectively manage the partnerships.
The successful candidate will be dynamic, well-organised, team oriented, with an innate senve of urgency, able to partner well with all functional management and to think across disciplines.
The successful candidate understands the complexity of the pharmaceutical R&D and regulatory process and its financial and strategic implications for drug development, registration and market access.

RESPONSIBILITIES/ ACCOUNTABILITIES:

Responsibilities will include, but may not be limited to the following:

- *Management of the industrial alliance :*
    - Planning and management of the operational aspects of the alliance, including joint governance committee, ensuring appropriate communication and coordination of the activities. Providing a single point-of-contact for partners for business/contractual issue resolution or other business-related matters
    - Management of joint team meetings and/or on-site collaborator visits to stay abreast of joint team progress and to track contractual obligations
    - Proactively track, monitor and communicate contract milestones, obligations and any financial payments to project team leaders and management. Proactively monitor the economic value of each assigned collaboration

- Review and approval of material financial payments and routes of payment requests through the Finance department
- Work with Legal, TTO, IP and other internal stakeholders, as well as alliance partners, to review and execute contract renewals and amendments
- Work with project teams and stakeholders and alliance partners to evaluate and resolve any business/contractual issues in an equitable and timely manner. Present recommendation to the Senior Management team.

➢ *Development of business relationships with existing and potential partners functional to the alliance:*
- Establish and grow working relationships with existing and new partners
- Understand SR-TIGET 's strategies, objectives and goals and their potential impact on collaborations
- Set specific and measurable performance objectives, standards, and accountabilities for each assigned collaboration or service contract
- Educate team members on contract terms, obligations, milestones and roles and responsibilities

➢ *Regulatory Affairs role:*
- Orphan Drug Designation (ODD) planning, preparation, submission and management to the approval and annual report management.
- Scientific Advice/Protocol Assistance planning, preparation, submission to the completion of the procedure
- Pediatric Investigational Plan (PIP) planning, preparation, submission and management to the approval

EDUCATION, COMPETENCIES AND SKILLS REQUIRED

- A Bachelor's or Master's degree in a scientific discipline (Biology, Pharmaceutical Chemistry, Pharmacy or related).
- 3+ years experience in the Biotech or Pharmaceutical industry is a must
- Previous experience with Preclinical, Clinical Research, Regulatory Affairs preferred.
- Solid understanding of the cross functional drug development processes (CMC, Clinical operations, Data Management, Biostats and Regulatory).
- Project management experience, preferably in the Biotechnology or Pharmaceutical industries.
- Experience with management of partnerships, post-deal execution preferred.
- Experience with management of interactions with Regulatory Affairs Bodies
- Knowledge of project management techniques and tools, including project management software is a plus.
- Proficiency with standard desktop computing programs (e-mail, Word, Excel, PowerPoint, Adobe Project and Adobe Acrobat Professional).
- Excellent oral and written English communication.
- Self-motivated, highly organized, detail-oriented and able to deliver multiple tasks working under strict timelines.
- Strong interpersonal skills. Capacity to work cross-functionally and to influence people without direct authority.

Please, send your CV including copies of academic credentials, together with names, addresses and fax numbers/e-mail addresses of three referees to:

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