Global Regulatory Lead (M/F)

About the company

ActoBio Therapeutics, a wholly owned subsidiary of Intrexon Corporation, is an innovative biotechnology company focused on a new class of microbe-based ActoBiotics® biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics. The ActoBiotics® platform produces biologics through oral or topical administration with treatment applications across many diseases including oral, gastrointestinal, and autoimmune/allergic disorders. This cost-effective approach is being developed to provide safer and more efficacious treatments than injectable biologicals. ActoBio Therapeutics has a strong R&D pipeline with the latest stage candidate in Phase 2b and an extensive portfolio of candidates ready for clinical development across a number of potential indications.

ActoBio Therapeutics houses a unique blend of highly motivated and inspired experts, creating an environment of enthusiasm and expertise, which makes ActoBio Therapeutics the game changer.

ActoBio Therapeutics is seeking motivated experts that have a great interest in innovative molecular thinking.

To strengthen our Ghent, Belgium based ActoBio Therapeutics team; we are looking for a
Global Regulatory Lead

Job description

As **Global Regulatory Lead** we are looking for an experienced drug development expert and regulatory professional that will:

- Develop and execute global regulatory product strategies;
- Support and lead regulatory strategies and development of products for project teams across the portfolio;
- Develop Global Regulatory Plans including registration strategies and development plans aimed at achieving optimal regulatory approval;
- Provide regulatory strategic and operational direction in the development of the Target Product Profile in the context of available and expected scientific data, regulatory guidance and precedent;
- Lead the planning and implementing global regulatory filings (e.g. clinical trial applications, IND submissions, PIP submissions, scientific advice);
- Ensure consistency of regulatory submissions across the portfolio;
- Monitor and assess impact of relevant global regulations and guidance;
- Ensure guidance on regulatory mechanisms to optimize product development (e.g. expediting FIH studies, Orphan Drug, Fast Track/Break-through/PRIME, conditional /accelerated approval,

compassionate use and pediatric plan) are assessed and incorporated into the global regulatory strategy;
- Communicate consistently on regulatory strategies and requirements to the organization and external partners and consultants;
- Manage effective regulatory agency communications and relationship by leading and attending key regulatory agency meetings;
- Lead and direct external consultants and providers for execution and delivery of regulatory strategies;
- Grow the regulatory function as needed, in line with the development of the product portfolio of the company;
- Provide education and training on regulatory strategies and compliance issues to other functions

[] Profile

- Master of Science degree in Pharmaceutical or Medical sciences, Chemistry, Biochemistry, Civil, Industrial or Bio-Engineering or related discipline;
- Relevant professional regulatory affairs experience in biotech/pharma R&D, with at least 7 years of experience in a global R&D-focused biotech/pharma environment;
- Preferably with regulatory experience across the life-cycle of development, from early to mid/late-stage;
- Experience from gene therapy or other advanced therapies or is an asset, as well as experience from development of products for immunological diseases;
- Evidence of positively influencing product development strategies through innovative and global regulatory strategies;
- Very good communication (written and spoken), reporting and presenting skills;
- Excellent organization and coordination skills;
- Ability to work independently as well as a member of a team in a dynamic and fast-paced environment;
- Result driven, flexible, creative, assertive, proactive;
- Good problem solving skills;
- Fluent in English, written and spoken;
- Knowledge of relevant legislation and industry standards is expected;
- Willingness to occasionally travel for external meetings

[] We offer

We offer an exciting fulltime job in a dynamic research environment and a competitive remuneration package with attractive fringe benefits.

Do you have the qualifications for this job opening and are you up to the challenge of joining our young and enthusiastic team? If so, please send your application in English by e-mail to: IA.jobs@actobio.com

[] Address

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