



**STAMFORD**  
PHARMACEUTICALS INC

## POSITION DESCRIPTION VICE PRESIDENT, CLINICAL OPERATIONS

**Job Title:** Vice President, Clinical Operations  
**Reports to:** CEO  
**Classification:** Full-Time, Exempt, Salaried

### Company Summary:

Stamford Pharmaceuticals, Inc. is an Austin, TX based late clinical-stage Onco-Dermatology company focused on multiple skin cancers. The Company's lead product, SP-002 is a viral-vector designed to deliver Interferon- $\gamma$  into the tumor microenvironment endowing a wide-therapeutic window. Stamford's near-term clinical program for SP-002 is focused on two Basal Cell Carcinoma indications and will encompass US, Australian and UK sites. The Company will also be evaluating SP-002 in several additional cutaneous cancer indications in early 2024 and has additional candidates that are expected enter the clinic in late 2024 and beyond.

### Position Summary:

Stamford Pharmaceuticals, based in Austin, Texas, is actively recruiting for a VP of Clinical Operations for the management of an effective clinical operations team based in the US and Australia.

### Essential Duties and Responsibilities:

- Represent all aspects of Clinical Operations and communicate with key stakeholders as required (e.g., Executive Committee, Project Teams, Board of Directors and other)
- Recruit, train and lead clinical operations team to ensure quality, timeline, and budget.
- Implement clinical performance indicators to manage the process and clinical goals
- Manage clinical site and investigator identification and study execution
- Manage relationship with CROs, experts and investigators
- Responsible for quality checks of clinical projects and compliance with SOPs, ICH-GCP, regulatory authority regulations and patient safety standards
- Responsible for the operational sections of clinical documentation (e.g., protocols, investigator-brochures clinical SOPs)
- Support regulatory submissions and interactions with FDA, EMA and other regulatory agencies.

### Qualifications:

#### Education/Experience: The ideal candidate will have:

- Bachelors in Life Sciences, Pharmacy, or related field; an advanced degree (MS or PharmD, PhD) is preferred
- A minimum of 15-20 years' experience in clinical operations - developing, and implementing/leading early to late-stage clinical trials (pivotal, multi-site clinical trials)
- In-depth understanding in study planning, execution, data cleaning, database locking, study reports and regulatory inspection
- Experience in developing protocols, SOPs, Clinical Study Reports, INDs, NDAs, & other clinical, regulatory, and safety documents for US and non-US authorities
- Therapeutic experience in orphan diseases, oncology, inflammatory diseases or dermatology

### Knowledge, Skills and Abilities:

- Expertise in clinical operations and a demonstrated ability to effectively lead projects and people
- Demonstrated strong written and oral communication skills



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- Thorough knowledge of clinical research practices, FDA/EMA/other authorities and ICH Guidelines for drug development
- Results-focused team player with strong interpersonal skills and can collaborate at all levels within the organization

**Work Environment:**

Stamford is a rapid growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally is required, it is anticipated that this will be less than 20% of work time. The above job description is not intended to be an all-inclusive list of duties and standards of the position.