Regulatory Affairs Internship

Waltham, MA

About us:

The Regulatory Affairs department at Nightstar Therapeutics is offering an internship opportunity for a motivated graduate student in a Master's of Regulatory Affairs program in the Boston area to join our team this summer. In this internship, you will observe and participate in the role Regulatory Affairs plays in clinical development and manufacturing activities.

Job Responsibilities:

- Become familiar with FDA and EMA regulatory submission requirements and participate in compilation of both clinical and technical regulatory submissions.
- Catalog and archive regulatory correspondence records.
- Review and optimize regulatory commitment tracking or database tool through review of agency meeting minutes, informal correspondence, guidance requirements, etc.
- Develop and implement a process outlining best practices for creating reviewing, approving and tracking regulatory documentation.
- Attending department meetings with regulatory colleagues to gain exposure to regulatory department and drug development activities; and have the opportunity to interact across the organization to gain exposure to other fields in pharmaceutical development.
- Participate in other projects as needed.

Critical Competencies:

- Must have a Bachelor's Degree in physical or life sciences and have completed at least 1 year in a Master's Degree program for Regulatory Affairs
- Excellent communication skills (written and verbal)
- Ability to work independently once instruction given
- Detail-oriented with strong computer skills (Word, Excel, Sharepoint)
- Hard-working, energetic and passionate about making a difference
- Highest integrity and commitment to ethics and scientific standards

Intern sessions are considered temporary employment, with a predicted ending point. No full-time employment commitments are made.