



Internship Description

Internship Title: Regulatory Affairs Intern, US Regulatory Affairs R&D - Pipeline

Reports To: Manager, US Regulatory Affairs R&D - Pipeline

Department: Global Regulatory Affairs

Office Location: Cary, NC

Target Start Date: February or March 2022

JOB PURPOSE:

The Chiesi – US Regulatory Affairs internship will be an immersive experience that will include exposure to several regulatory projects directly related to the development of drugs and/or biologics. The focus will primarily be on-the-job training experience, with additional education and training including FDA and industry-sponsored lectures.

KEY RESPONSIBILITIES:

- Regulatory document authoring and submission support
- Create templates, databases, trackers to support regulatory activities
- Quality control review of US regulatory submissions and internal documents
- Review and organize resources supporting regulatory processes
- Support regulatory intelligence activities through analysis of approval packages and attendance at project-relevant trainings and webinars

REQUIREMENTS:

- A minimum of a Bachelor's degree in a scientific discipline is required.
- A minimum of 0-2 years of related experience
- Strong organizational and planning skills
- Strong knowledge of MS Office Suite - Word, Excel, PowerPoint
- Exceptional communication in English - verbal and written
- Detail- and goal-oriented and quality conscientious
- An ability to manage changing priorities, multiple tasks, and communicate impact to project teams is required.

KEY COMPETENCIES:

Attention to Detail – Is thorough when performing work; conscientious about attending to detail; few errors in work performed; uses logical thinking that is well organized and methodical.

High Productivity – Produces consistent, high quality and quantity of outputs and meaningful results that contribute to the agency mission and strategic goal. Is efficient in producing results that are delivered on time or before. Able to multi-task productively because is well-organized; applies time management processes and procedures effectively

Organizational Ability – Attention to timelines and deadlines. An ability to review and prioritize organizational commitments to maximize productivity across functional groups

Communication — Speaks, writes, listens and presents information in a logical and articulate manner appropriate for the audience.

Confidential Data: **Yes** **No**