



Regulatory Affairs Intern

Available Positions: 1

Summary

Lyndra Therapeutics is seeking an intern to join the Regulatory Affairs/ Quality Assurance (Good Manufacturing Practices - GMP) department. The role will focus on supporting Regulatory Strategy and Operations and will have the opportunity to support the RA organization, program strategies, health authority meeting preparations and exposure to Program Management and Quality.

Tasks & Responsibilities

- Assist in organization of regulatory strategies and meetings in support of Lyndra R&D portfolio
- Assist in RA document preparation
- Research regulatory precedence in US and outside of the US for RA leads
- Assist in the development and/or revision, implementation, and maintenance of policies, SOPs, and forms to ensure they reflect current practices and are in compliance with FDA and other regulatory requirements and guidance
- Collaborate with other departments to implement improvements and support development of RA strategy
- Additional responsibilities assigned within the Regulatory Affairs group

Essential Requirements

- Enrolled in BS/BA (or equivalent degree) in science related field
- Solid computer skills using Word, Excel, PowerPoint, and SharePoint
- Good organizational, verbal, and technical written communication skills
- Able to execute multiple tasks
- Good interpersonal communication skills/able to work in a team environment

Educational Outcomes

- Will gain knowledge and application of good documentation practices
- Will gain knowledge and understanding of Good Clinical Practices
- Will be able to navigate the FDA Code of Federal Regulations Title 21 and FDA Guidances

More About Us

Lyndra Therapeutics is a clinical-stage biopharmaceutical startup company based in Watertown, MA that aims to make daily pills a thing of the past. Our team has developed the first ultra-long-acting pill that lasts a week or longer to improve medication adherence and health outcomes and help lower the cost of care.

For further information, please contact sholar@lyndra.com