Manager, Quality Assurance

Responsibilities

- Support development and commercial projects with contract manufacturers (CMOs) to completion
- Review documentation including master batch records, specifications, analytical results, validation protocols and reports
- Maintain quality compliance program for the manufacture of Fera products
- Maintain a quality compliance program for all vendors including an effective change management system
- Coordinate the completion of required documentation for instituting process changes at all manufacturing/packaging/analytical sites
- Participate in vendor audits
- In conjunction with Regulatory Affairs and CMOs, manage and coordinate all product complaints and investigations according to current FDA regulations
- Develop internal SOPs as necessary
- Ensure that Fera and its contract manufacturers comply with all corporate and regulatory cGMP guidelines and SOPs
- Work with internal colleagues to support project plans and evaluation of potential vendors / suppliers

Qualifications

- Bachelor's Degree in chemistry, biology or other related scientific discipline required. Master's, PharmD or PhD Degree preferred
- Minimum 5 years pharmaceutical industry experience in quality assurance with emphasis on CMC
- Working knowledge of chemistry, manufacturing, and controls as needed for A/NDA submissions and approvals
- Resident of Long Island, NY

Send resume to **contact@ferapharma.com**

About Fera Pharmaceuticals

Fera Pharmaceuticals is a virtual, privately held company. The company goal is to realize opportunities via acquisitions, in-licensing, developing, and marketing abbreviated new drug applications (ANDAs), new drug applications (NDAs) and 505(b)(2) NDA products. For more information visit www.ferapharma.com.