



## Quality Compliance Advisor Pearl Pathways

Pharmaceutical and device companies need to navigate through many hurdles as they develop drugs, devices and diagnostics that improve and save human life. **Pearl Pathways** supports companies in their development, manufacturing and marketing of these products.

If you are up for the challenge of a startup company that is in an exciting marketplace and poised for success, Pearl has the opportunity for you.

### Position

Quality Compliance Advisor

### Job Description

The Quality Compliance Advisor is responsible for creating, evaluating and remediating quality system to ensure compliance with federal regulation for devices and biopharmaceutical products. This role will have the day to day responsibility for leading client projects to support product development, submissions, and post marketing activities. This individual must be detail oriented and possess good communication skills.

### Responsibilities include:

- Evaluation of manufacturing facilities, labs, clinical sites, and contract research providers and quality units for compliance with current GXP US and global health authority regulations
- Develop quality assurance systems, SOPs, and plans to ensure companies are compliant and meeting business goals
- Execute internal, external vendor and mock audits to evaluate GCP, GLP and GMP for all phases of development for drugs and devices
- Conduct vendor assessments for quality standards and technical capabilities
- Development of and execution of training modules on Quality Systems
- Reports directly to Pearl Chief Operating Officer

### Training/Experience Requirements:

- At least 10 years drug OR device quality compliance experience. RAC or ASQ certification preferred.
- Bachelor's degree required

### Skills

- Strong technical background required
- Track record of leading quality system strategy and execution for either bio-pharma or device industry

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- Both drug and device experience a plus.
- Mix of large sponsor company and small startup experience a plus
- Ability to work autonomously
- Exceptional communication skills, both verbal and written

### Company Description

**Pearl Pathways** ([www.pearlpathways.com](http://www.pearlpathways.com)) is a comprehensive life science product development services company. Our experienced team is obsessed with expediting life science product development regulatory pathways. We have three business units to serve our clients:

- **Pearl IRB** ([www.pearlirb.com](http://www.pearlirb.com)) is a full service commercial Independent Review Board that provides human research IRB reviews, IRB exemptions and waivers, and also offers support for research protocol/ICF medical writing, site assessments, and monitoring services.
- **Pearl ReGXP** is a regulatory and quality compliance consulting practice that provides regulatory filing guidance, conducts global health authority negotiations, develops/improves quality systems, and delivers GMP/GLP/GCP auditing services.
- **Pearl IDEAS** provides strategic product development assistance, third party vendor selection and management strategies, due diligence services, and sales and marketing services for drug, biologic and device companies.

To learn more, contact us at [contact@pearlpathways.com](mailto:contact@pearlpathways.com) or visit us at [www.pearlpathways.com](http://www.pearlpathways.com).