

Pearl Pathways™

Quality Compliance Advisor

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. Our mission is to deliver superior services that effectively enable our clients to accelerate life science product development.

Pearl Pathways' service offerings include:



REGULATORY

- Regulatory Strategy and Global Filings
- Submission Support for IND, NDA/BLA, 510k, CE mark, PMA, CTA, MAA, etc.
- eCTD Submission and Publications
- Clinical, Non-Clinical, and CMC Development
- Due Diligence of New Product Platforms/Technologies



QUALITY COMPLIANCE

- GXP Quality Systems
- Auditing
- Validation Support
- Remediation
- Supplier Management
- Training
- Contract staffing services



CLINICAL SERVICES

- Niche CRO Services
- Medical Writing
- On-demand Clinical Research Staffing
- GCP Support Services
- Research Site Support
- Pharmacovigilance
- Biostatistics



INDEPENDENT REVIEW BOARD

- IRB Board Review Services
- Expedited and Full Board ICF/Protocol Reviews
- Patient Recruitment Materials & Advertisements
- Exemption Determination
- Annual Review
- IRB Consulting Services
- AAHRPP Accreditation Consulting

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 has 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 the Director Quality/Regulatory

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
- 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

Send inquiries and your resume to recruiting@pearlpathways.com

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Company Description

Pearl Pathways is a comprehensive life science regulatory, quality compliance, and clinical services consulting company providing strategic guidance and project-based support for emerging to mid-size biopharmaceutical, medical device, and diagnostic companies. As the recognized trusted advisor and preferred partner for enabling innovative and expedited life science product development, our nimble and flexible team of experts provide custom solutions that help our clients deliver lifesaving products to market.

Our consultants collaboratively leverage decades of clinical, scientific, industry, FDA and global regulatory authority experience to help our clients successfully navigate a highly complex regulatory environment while balancing risk, speed to market, and cost to achieve their business goals. Pearl Pathways supports all aspects of human research through its full-service central independent review board, Pearl IRB. Founded in 2010, Pearl Pathways is headquartered in Indianapolis, IN and is proud to be a certified Women's Business Enterprise. For more information, please contact us at info@pearlpathways.com or visit us at www.pearlpathways.com.