Regulatory 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
Regulatory Advisor

Job Description
The Regulatory Advisor is responsible for creating regulatory strategies, leading global health agency filings, and managing FDA communications on behalf of Pearl clients 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.

Responsibilities include:
- Develop regulatory strategies for global submissions
- Lead regulatory submissions: IND, IDE, NDA, BLA, PMA, 510k, etc…and their global counterparts including CE Marks.

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- Manage FDA and other global health authority face-face communications and via all other communication channels
- Write regulatory documents – for paper and eSubmission
- Lead cross functional teams across clinical, CMC, device engineering, quality, etc.. in gathering and authoring required information for submission
- Reports directly to Director of Quality/Regulatory

Training/Experience Requirements:
- At least 10 years drug OR device quality compliance experience.
- RAC certification preferred
- Bachelor's degree required

Skills
- Strong technical background required
- Some experience in quality assurance roles or auditing preferred
- Track record of leading regulatory strategy and filings for bio-pharma and/or device industry
- Both drug and device experience a plus
- Mix of large sponsor company and small startup experience a plus
- Global filing experience preferred
- Ability to work autonomously
- Exceptional communication skills, both verbal and written

Send inquiries and your resume to recruiting@pearlpathways.com

Company Description

Pearl Pathways (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)*** 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 info@pearlpathways.com or visit us at www.pearlpathways.com.