Regulatory Publication Coordinator
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 dynamic professional services company that is in an exciting marketplace and poised for success, Pearl has the opportunity for you.

Position
Regulatory Publication Coordinator - Indianapolis

Job Description
The Regulatory Publication Coordinator must work autonomously and across client teams to support eCTD filings, provide literature searches and reference retrieval, and provide other quality control check functions for regulatory submissions. This position will report to the COO of Pearl Pathways. We are looking for a creative, customer focused, flexible, and motivated professional who will support the needs of our clients.

Responsibilities include:
- Serving as regulatory publication coordinator for a pharmaceutical NDA
- Work with eCTD vendor and client
- Scope includes clinical, non-clinical and CMC Modules
- Assist with other literature search needs and medical writing projects as needed
- Quality control check documents
- Work with team at Pearl Pathways and client to accomplish project goals

Skills/Experience
- eCTD experience required
    - Expertise with the format of FDA submissions, documentation and communications
    - At least 2+ years' experience in publishing role in pharmaceutical company or service provide

- Super user of MS Office Suite, Adobe, Endnotes
- Experience in formatting documents, strong web publishing experience including bookmarking, hyperlinking, etc…
- Ability to work autonomously

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- Proven capabilities in working on complex projects across a team of diverse players
- Exceptional communication skills, both verbal and written
- Minimum of a Bachelor's Degree or equivalent work experience

Effort required

- To start 16-24 hours/week, with possibility to increase to fulltime
- This is either a part time fixed duration employee (FDE) or 1099 consultant position.

Send inquiries and your resume contact@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 contact@pearlpathways.com or visit us at www.pearlpathways.com.

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