Regulatory Affairs Impact Players

We are currently representing the following candidates:

Senior Director Regulatory Affairs

- Global Regulatory Strategy and Global Regulatory Team lead leader for more than both marketed products and ones in development
- Director and US Regulatory Lead for a portfolio of four marketed products and three new products in development including two that are currently under FDA review
- Managed a team of 30+ North American Regulatory Product Development Consultants assisting clients with product development and product lifecycle management activities.
- Acted as Regulatory point of contact between US office and global headquarters for multiple initiatives
- Sat on Legal, Medical and Regulatory review committee that commented on and approved all marketing materials for us in US market

Associate Director Regulatory Affairs

- Lead the development and provide global strategic guidance on preparation of submissions including but are not limited to IND/CTA, SPA, PSP/PIP, Orphan Designation Application, Brand Name Application, Fast Track, etc
- Developed and implemented global regulatory strategy for assigned biologic including a Phase 3 Rheumatoid Arthritis program, a Phase 1&2 Asthma program, and an early development Lupus program
- Develop and execute development strategy to support combination product marketing application and labeling extension; Lead interactions with FDA OCP (Office of Combination Product), CDRH, and CDER DPARP
- Provide strategic guidance to preparation of IND, CTA, BLA/sBLA, DSUR, Meeting Briefing Packages, and responses to Health Authorities inquiries

Director Regulatory Affairs

- A seasoned biopharmaceutical professional with 20 years of experience in Regulatory Affairs, QA, QC and CMC
- Currently a Director of Global Regulatory Affairs at a CRO where he directs, assists, and executes the production of high quality written deliverables including INDs, agency meeting packages, NDAs, 510Ks, PLAs, and BLAs
- Significant experience in authoring CMC and other sections of IND applications for submission to the FDA and global agencies
- Trained in CMC Regulatory compliance for Biopharmaceuticals and Biologicals
- Strong understanding of CMC strategy and compliance with respect to FDA and ICH guidelines
- Maintains up-to-date knowledge base for all pertinent US and International regulations
- Has a PhD in Biochemistry, a Masters in Biochemistry and a Bachelors in Biochemistry

Director Regulatory Affairs

- Currently the Director of Regulatory Affairs at a leading research-based biopharma company where he manages three direct reports.
- In this role he has led several INDs for early and late phase biologic programs and led several FDA pre-IND meetings.
- Previously was a Sr. Director of Regulatory Affairs at Enzon where he led all clinical and post market submissions.
- In addition to his industry experience, he spent two years at the FDA as a CBER immunogenicity reviewer and six years at the NIH as a Fellow.
- He has a PhD in Cellular & Molecular Biology and a BS in Biophysics.

I look forward to speaking with you and sharing more about these, and other valuable regulatory professionals. Please let me know your availability for a conversation this week.

Dennis Partners www.DennisPartners.com **(508)394-9700**