Regulatory Affairs Impact Players

We are currently representing the following candidates:

Regulatory Affairs Director

- Direct interaction with FDA and Ex-US health authorities
- Major NDA filings achieved timely drug & submission approvals
- Formed and led Regulatory Affairs Sub-team for development of global regulatory submission strategies
- Led the direction for Pre-NDA meetings with FDA for multiple oncology programs
- They are described as a major contributor in mentoring junior regulatory teams
- Holds accountability with executive staff
- Has a “hands on” attitude & ability to have an immediate impact related to clinical stage programs
- Their experience working with FDA and ROW agencies allow a quick turnaround of deliverables

Regulatory Affairs Executive Director Global

- Full life cycle regulatory leader
- 10 years’ experience efficiently moving drugs through clinical trials to registration
- Worked on early stage Bio marker thru to PhI, II, III along with success filing with NDA and drug / Device combination products
- Provides expert strategic regulatory guidance on the discovery and development of innovative drug, biologic, and cellular/gene therapies for cancer and immune-inflammatory diseases
- Adaptive to spectrum of organization size, structure, and stage of development, partner across functions to creatively evaluate risk and solve problems
- Has a broad foundation that will be a high value addition to organizations with platforms that will develop agents that will build on the drugs currently in clinical development

Regulatory Affairs Director Operations

- Master of Science, Drug Regulatory Affairs and Health Policy
- 15+ years in the pharmaceutical and biotechnology industries
- Experience with Code of Federal Regulations, ICH Guidelines, WHO and ISO 9001 Matrices US/EU GMPs, EU Annex, PMI practices
- Develops regulatory timelines, which identify all activities, resources and timing needed to meet regulatory submission deadlines
- Executes submission plan, ensuring coordination of all activities between relevant functional groups
- Successfully lead multidisciplinary project
- Liaise with document contributors and e-CTD System vendors

These are just three Regulatory Affairs professionals we have built relationships with. Let’s get in touch to discuss these and many others that may help impact your organization!

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