Regulatory Affairs Impact Players

We are currently representing the following candidates:

Director Regulatory Affairs

- Since their inception into regulatory, they have filed and received approval for two major NDA's, lead four oncology and immunology programs with FDA, in addition to saving their employer over 500k in savings due to creating solutions with existing vendors in support of eCTD submissions.
- Interact directly with FDA and other major health authorities to achieve timely drug / submission approvals.
- Represent regulatory as either Team Leader for RA on International Core Project Teams charged with efficient development/implementation of regulatory strategies for assigned products within Oncology, Virology, Immunology, and Urology therapeutic areas.
- As Team Leader, they are responsible to form and lead RA Sub-team for development of global regulatory submission strategies.

Regulatory Affairs Senior Manager Global Labeling

- Global labeling experience across broad array of therapeutic areas including oncology, cardiovascular, inflammation, bone, general medicine/supportive care
- Provides tactical and strategic guidance's to internal labeling teams, senior management, and external business partners, regarding label content development and maintenance for single or multiple complex products, ensures that global
- Expertise in Global Labeling Process. Leads development and continuous assessment of global labeling work processes to improve operational efficiency, productivity, and quality
- Manages corporate labeling development and maintenance process; global labeling process/tracking design (CDS, Regional Labeling with emphasis on US and EU, Target Product Labeling, Global Labeling Negotiation Document)
- Labeling team leadership/supervisory experience; including management of multiple direct reports in addition to own product/project assignments, recognized strength as a mentor/coach of junior GLL staff

Senior Director Regulatory Affairs

- Responsible for delivery of regulatory strategy and execution of agency filings, including FDA (BLA) approval of first-in-class treatment for hypercholesterolemia
- Successful track record in new drug and biologic development, from Phase 1 to Phase 3b, in a diverse range of therapeutic areas including dyslipidemia, infectious disease, oncology, and rheumatology
- Highly effective at providing strategic and tactical guidance to cross-functional project teams dealing with complex scientific and regulatory issues
- Has led submissions for world-wide marketing applications: US BLA (approved), EU MAA (with CHMP positive opinion), J-NDA, and applications in Canada, Australia, Brazil, Mexico, Russia, and Switzerland
- Masters in Molecular Biology and is RAC certified

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**