Regulatory Affairs Impact Players

We are currently representing the following candidates:

Director Regulatory Operations Compliance and Intelligence

- Solid balance of regulatory submissions and publishing related to implementation with EDMS and submissions management processes
- 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
- Tracks and monitors progress against plans effectively managing deadlines
- Leads multidisciplinary project team launch and milestone meetings and documents activities plans and decisions
- Liaise with document contributors and e-CTD System vendors
- Maintains knowledge of current regional regulations and provides leadership to the teams to ensure submissions are in accordance with electronic specifications and/or standard industry practice

Director Regulatory Affairs

- Over 14 years of pharmaceutical industry experience including post-approval regulatory and project management activities that encompassed core labeling, risk registers, artwork, compliance, annual reports, CMC, strategy and issue management for NDAs, ANDAs, 505 (b)(2) ,BLAs and PMAs.
- Experience leading, managing and coaching a team of 8 CMC strategists including Technical Regulatory Leads.
- Global Regulatory Lead for fifty Oncology and Anti-infective drugs in the Pfizer Established Products Portfolio.
- Extensive experience in leading cross-functional teams to address and mitigate internal regulatory/compliance issues and provide aligned responses to various Health Authorities (US, EU).
- Demonstrated ability to provide leadership and manage complex regulatory situations both within organizations and with the FDA.
- Extensive experience in leading cross-functional teams to address internal regulatory/compliance issues and provide aligned responses to various Health Authorities (FDA, EMEA, Swiss medic and TGA).
- Proven ability to work with the FDA including the preparation of briefing packages and management of Type A and Type C meetings.

Senior Director Regulatory Affairs

- Global Lead for dyslipidemia, oncology and rheumatology programs
- 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

Vice President US Regulatory Strategy and Policy

- PhD in Cell Biology and Immunology with a postgraduate Masters in Pharmaceutical Medicine
- Manages both the US Regulatory Strategy and Policy groups
- Regulatory management of four approved Orphan products, two NDAs pending at FDA, and 20 active IND's.
- 20 years industry experience with four filed NDA's
- Experience with NCE's, Orphan drugs and Biologics

These are just the few 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**