Pennington Pharmaceutical Services LLC

Proven. Professional. Solutions.

Phone: (901) 896-9450 www.ppspharmrx.com

"Unlike many consulting firms, our services are provided by a certified regulatory affairs (RAC) professional with demonstrated knowledge and expertise within all aspects of the pharmaceutical industry."

Introduction

Pennington Pharmaceutical Services LLC provides start-up, small and medium sized pharmaceutical companies a variety of dependable, cost-effective services for navigating their products through the complex and tightly regulated pathways of the pharmaceutical industry. Our professional services are specifically designed for meeting the regulatory needs of companies with limited regulatory expertise or resources.

Unlike many consulting firms, our services are provided by a Certified Regulatory Affairs (RAC) professional with demonstrated knowledge and expertise within all aspects of the pharmaceutical industry. Whether you need assitance on a specific project or if you require a more comprehensive, beginning-to-end solution, our services are fully customized to meet your needs. By maintaining a manageable portfolio of clients, we're able to build seamless business relationships with all our clients, providing highly personalized service and prompt attention for all their regulatory needs.

Don't put the good standing of your company with federal and state regulatory agencies on the line by utilizing inexperienced or incompetent consultants. In addition to providing superior services customized to your company's specific regulatory needs, our RAC certification provides your company with peace of mind.

- Justin G. Pennington, RAC
  PRINCIPAL

Our Commitment

Regardless if your regulatory needs are related to generic or branded pharmaceuticals, prescription drugs or controlled substances, state licensing or labeling requirements, we are fully capable and committed to providing the the most beneficial, dependable and cost-effective services in the industry.

In addition, we're committed to providing a transparent business relationship with our clients, dedicated to providing accurate statements regarding our capabilities, anticipated cost of services and estimated timelines for projects.

Our Value

Over the years, we have developed strong relationships with pharmaceutical companies and regulatory agencies throughout the United States. As a result, we're able to provide our clients with valuable insight and reccomendations they'd otherwise find very difficult to obtain. This network of industry connections, coupled with the expertise demonstrated by our RAC certification, allows us to provide increased value to our clients.

We bring a fresh and innovative approach to our consulting and regulatory services, enabling our clients to commercialize their products faster, and with increased compliance. We strive to exceed the expectations of our clients through outstanding customer service, increased flexibility, attention to detail, promptness, honesty, transparency and value added services. This formula has proven to optimize the value and cost-effectiveness of our services for our clients.

Whether your regulatory needs are related to generic or branded products, prescription drugs or controlled substances, state licensing or labeling requirements, we offer the most dependable, cost-effective services in the industry.

Professional Experience

Our regulatory knowledge and expertise has been acquired through years of experience directing top-level regulatory initiatives within, but not limited to, the following sectors of the pharmaceutical industry:

- Generic and Branded Pharmaceuticals
- Rx Drugs, Controlled Substances, and OTCs
- Private and Own Label Distributors
- Contract Manufacturing
- Contract Distribution and Third Party Logistics (3PL)
- Contract Auditing and Vendor Qualifications
- Regulatory Consulting
- Analytical Laboratory
- Packaging, Labeling & Marketing Development
- Clinical Trials

Areas of Expertise

Mr. Pennington, as a Certified Regulatory Affairs professional, is profesionally distinguished within the regulatory field for his demonstrated proficiencies and expertise regarding the development, commercialization and distribution of pharmaceutical products within domestic and international markets. Specifically, he is highly trained and skilled in the following technical areas:

- State Licensing Requirements
- Establishment Registration and Drug Listing
- Continuous Process Improvement / Change Control
- Document Control (e.g., batch records, lot releases, etc.)
- Biochemistry / Analytical Chemistry / Bioequivalence and Stability Testing
- Import / Export Regulations
- Product Recalls, Complaints and ADR Reports
- Development and Implementation of FDA/DEA compliant SOPs
- Regulatory Research and Legislative Monitoring
- Regulatory Strategy, Reports and Presentations
- Crisis Management Programs and Resolution Strategies
- Theft/Loss Investigations and Reporting
- Suspicious Order Monitoring Systems (SOMs) and Reporting
- Electronic Records/Signatures Validation (e.g., 21CFR 11)
- Facility/Personnel Security and Access Restrictions
- Due Diligence Screening and Monitoring of Vendors & Customers
- Business Planning / Decision Making
- FDA, DEA, EMEA, and State Regulations
- New Product Development, Registration, and Listing
- Product Labeling and Marketing Compliance (e.g., 21CFR203, DDMAC, etc.)
- Supply Chain Management (e.g., PDMA & Pedigree Compliance, etc.)
- IND, NDA, ANDA, 510k, and DMF Submissions
- Full Product Life-Cycle Documentation
- FDA, DEA, & State BOP Audit Management, Preparation & Response
- FDA, DEA, State BOP & Vendor Negotiations
- Clinical Trial Compliance and Auditing
- Data Trending, CAPA Analysis & Effectiveness Checks
- Regulatory Strategy and Risk/Benefit Analysis
- Development, Implementation, and Enforcement of Regulatory Policy
- Internal/External Auditing and Vendor Selection
- 21CFR, ISO, GMP, GCP, GLP and GDP compliance
- Quality Management Systems (e.g., ICH, GMP/QSR, ISO, etc.)
- SOP Development & Compliance Reviews

"Pennington Pharmaceutical Services LLC provides start-up, small and medium-sized pharmaceutical companies a host of dependable, cost-effective solutions for navigating pharmaceutical products through the tightly regulated pathways of the pharmaceutical industry. Our service offerings are specifically designed for meeting the regulatory needs of companies with limited regulatory expertise or resources."

Our Solutions

We offer a variety of service options for meeting the simplest to the most demanding needs of our clients. By offering both hourly and flat rate services, we're able to work with our clients to develop a customized service plan for meeting both their specific regulatory needs and budget limitations.

All service arrangements between Pennington Pharmaceutical Services LLC and our clients are first initiated by the client's completion and submission of a Request For Quote (RFQ) form. Since any two projects are rarely alike, the RFQ form enables us to thoroughly review all the details of the services requested, and subsequently provide a detailed and reliable price quote, estimated timeline and anticipated completion date.

We like to maintain a two way working relationships with our clients, so instead of just providing a quote based on the service requested, we also provide our clients with the option of providing us with a budget for the services they've requested. Upon receipt of a RFQ with a pre-determined budget, we formulate and provide the client with several different options for satisfying their needs within the established budget.

While our consulting and regulatory services vary from supplemental to comprehensive in nature, the reliability and professionalism of our services remain constant, making us the preferred choice for all your regulatory needs.

Featured Services

Our Featured Services are those which we have found to most benefit start-up, small and medium sized pharmaceutical companies.

- State Licensing Service
- Establishment Registration & Drug Listing (FDA & DEA)
- Product Labeling & Marketing Materials (DDMAC) Development and/or Review
- Full Product Recall Management
- FDA, DEA & State Reporting (i.e., ARCOS, Theft/Loss, etc.)
- SOP Development and/or Compliance Review
- Suspicious Order Monitoring System (SOMs) Development and/or Review
- Vendor Screening, Negotiations & Oversight
- FDA, DEA & State Audit Preparations & Response
- Regulatory & Quality Training Materials Development
- Regulatory, Quality & Compliance Consulting

Contact Us Today

Please contact us today to inquire about any of our service offerings or to request a Free Quote.

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