FERA PHARMACEUTICALS' PUERTO RICO PRODUCT LAUNCH

An inside look into Five Rivers RX's advanced Puerto Rico compliance process

Five Rivers RX offers superior Puerto Rico Solution services to clients that range from international conglomerates with over \$20 billion in revenue to specialty start-up pharmaceutical companies. We tailor our services to your unique business requirements and objectives to enhance your company's operational activities and mitigate risk, all while maintaining cost-effectiveness. Our services are based on a strong foundation of consulting services that can help your firm adapt to any unique business challenges and situations.

Attempting to organize all the necessary compliance requirements for your business is time consuming and can lead to costly oversights. Each Board of Pharmacy are constantly updating their requirements which makes compliance a minefield to navigate through without a guide. Tackling Puerto Rico compliance is a separate beast. When handled without the proper tools, it is impossible to properly achieve the compliance needed to sell on the island. Luckily, Five Rivers RX industry experts provide the necessary tools and information to handle your compliance with ease.

The first step for any business is achieving proper registration and licensing on the island.

Registration is accomplished by filing a Certificate of Authorization to do business directly with the Department of State. This naturally leads to the licensing stage where the Puerto Rico Office Associates complete license applications and directly submit them to the Department of Treasury.

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The next piece of Puerto Rico compliance is essential and impossible for most businesses to achieve on their own. Every company must have a representative agent on the island.

This agent is authorized and registered by the Department of Health to represent a manufacturer or distributor of medicines in their marketing, without storage, distribution or dispensation. Manufacturers and distributors of prescription products, OTC products, controlled substances, and devices containing active ingredients are all included. The final compliance step which is needed on a continuous basis are product registrations. Each new NDC that a company plans on using must be independently registered on the Island. Five Rivers RX has associates that are authorized and responsible for requesting and obtaining registration for clients on the island.



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Kevin Moctezuma has been a Project Manager with Five Rivers RX since February 2019, based in their Puerto Rico office.

During his career, Kevin has developed extensive experience in regulation of the pharmaceutical supply chain. Through his time working for Five Rivers RX, Kevin has become the expert on all Puerto Rico requirements, and has formed personal relationships with members at the Department of Health and inspectors. This allows him to expedite the process for his clients and receive important information first hand.

HEAR FROM FERA

Fera Pharmaceuticals has dedicated themselves to providing cost-effective treatment options that meet the needs of their patients and healthcare communities. They began with eye care and are expanding their treatment portfolio, offering high quality products at affordable prices.

When Fera was looking to expand their business into Puerto Rico, they ran into some speed bumps. With the tight regulations and strict requirements Puerto Rico has, breaking into the Island's market is difficult. This is where Fera turned to Five Rivers RX for guidance.

"The Five Rivers RX team was easy to work with and they got our **Puerto Rico registration done** quickly, allowing us to do business on the island. Their service, expertise and professionalism all added up to a very positive experience for Fera." -Susan McDougal, Vice President of Fera Pharmaceuticals

Navigating Puerto Rico requirements can prove to be a headache. Five Rivers RX full process Puerto Rico compliance services allowed Fera to remain cost-effective and start business on the island quickly.

Five Rivers RX expertise and personal relationships on the Island make it easy to do business on the island. We provide costeffective solutions while maintaining high quality services by leveraging technology and years of industry experience.

THE SOLUTION

