Smith Associates Now Offering Initial Importer Services for Global Manufacturers

Smith Associates has created dedicated resources to help manufacturers register with the FDA, import their products to the US and comply with all regulations.

CROFTON, MD, USA, September 5, 2018 /EINPresswire.com/ -- When selling regulated medical devices, it is necessary to register your facility with the FDA, adhere to GMP (Good Manufacturing Practice Regulations), integrate appropriate importing procedures and comply with specific reporting requirements. Smith and Associates has been dealing with these issues for many years and has created a support program enabling global manufacturers to gain access to the United States medical market. Their newly formed Initial Importer service will handle registration with the FDA and adherence to required standards to ensure a company's devices are compliant to import and sell in the US. Additionally, they have relationships with national organizations that can aid in the distribution of the device including manual rewrites, qualified testing in labs, customer service programs, marketing services and sales.

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>
> *Yolanda Smith*

Yolanda Smith of Smith & Associates has stated, “We are committed to support businesses who import FDA regulated products and proudly work with companies here and abroad to make distribution easier. Marketing can be daunting when you have to go through regional distributors, independent sales representatives, and others for approval. This is why Smith & Associates understands the need to give global manufactures the ability to choose an Initial Importer as their central receiving warehouse and ensure they are registered with the FDA to simplify the process of importing their product. Other issues such as complaint file handling is something we offer as well, this guarantees the manufacturer is compliant with FDA requirements to offer their device in America.”

About Yolanda Smith
Yolanda Smith is a co-founder of Smith & Associates specializing in FDA regulatory services for the medical industry. With over 24 years of experience, she has worked with medical manufacturers for in vitro diagnostics, cosmetics, blood products, and medical devices to safeguard their adherence to FDA standards. She has a Master’s degree from Old Dominion University and Bachelor’s degree from Mount Saint Agnes College along with many years of personal experience needed to thoroughly examine FDA compliance regulations to guarantee her clients follow requirements precisely.

About Smith & Associates
Since 1994, Smith & Associates has specialized in regulatory services in relation to medical manufacturers of specimen and products such as biologics, blood, in vitro diagnostics, and other medical devices. Under the direction of E.J. Smith, President, they have been pioneers of regulating product distribution with services in 510(k) submission (PMA), the most common route to clearance. They can assist small and large companies in writing, enhancing, and implementing their quality systems to conform to regulatory requirements. Smith & Associates also handles Pre-Submissions, Pre-IDE, PMA, and Human Factors studies required for validating

devices intended for inclusion in 510(k)s. Their standard operating procedures, forms and instructions have been implemented, audited and inspected by the FDA to fulfill their requirements. With an extensive background in sales, marketing and business ownership, the Smith & Associates team understands many facets of the measures it takes to help manufacturers get started in the United States.

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