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PRESS RELEASE

LGM Pharma Works with Overseas Providers to Assure Quality Control of Pharmaceuticals

BOCA RATON, Florida—As is the case in almost every industry, pharmaceutical manufacturing is becoming an increasingly global business. Between 2001 and 2008, the number of drugs produced outside the U.S. doubled. While this certainly reduces production costs for manufacturers and potentially reduces the costs that consumers pay for pharmaceuticals, the safety of the drugs may be sacrificed in the process. When the manufacturers outsource their production, the level of actual control for both the manufacturer and the Food and Drug Administration (FDA) is effectively reduced.

In today's competitive drug development market, having a reliable and knowledgeable supply chain can make the difference in a project's success. LGM Pharma, a supplier of active pharmaceutical ingredients (APIs) in Boca Raton, Florida, specializes in providing full sourcing options and support for the widest range of rare and new APIs in the research and development community.

According to Mendy Schurder, COO of LGM Pharma, "Depending on a client's regulatory needs, LGM Pharma can provide APIs with full regulatory support from many global manufacturers who are approved by the leading health authorities, such as the Food and Drug Administration (US), European Directorate for the Quality of Medicines & Healthcare, Therapeutic Goods Administration (Australia), and the Medicines and Healthcare products Regulatory Agency (UK). We also work with the FDA and US Pharmacopeia providing ingredients for testing and comparison."

Over the past couple of decades, the pharmaceutical supply chain has become increasingly complex, and medications may pass through many facilities before reaching their final destination in the United States. In fact, as much as 80 percent of active pharmaceutical ingredients in products sold in this country now come from foreign sources. With \$2 trillion worth of products entering the United States, the FDA faces a host of challenges—such as language, laws, and culture—in keeping Americans safe from adulterated drugs manufactured in other countries.

Overseas manufacturing has brought benefits in terms of lowering the cost of producing APIs and excipients used in US drug products, and of many finished drugs sold the US. The dark side of the arrangement, and the one that worries consumers, manufacturers, and regulatory agencies, is that quality

control becomes very difficult when supply chains involve the routing of thousands of products through manufacturers, packagers, and distributors dispersed around the world.

"Our staff perform factory audits around the world for our clients to evaluate the facility for quality," says Robert Hoppes, LGM Pharma Sales Director "We review the processes, regulations, and documentation. The LGM Pharma team has visited sites in South Korea, Germany and China, among others, to ensure that the facilities are qualified to produce products that are safe and effective."

LGM Pharma will shortly be undergoing their first audit for certification from the International Organization for Standardization (ISO), a group that addresses quality management. ISO 9001:2008 is the benchmark that provides a set of standardized requirements for a quality management system, regardless of what the user organization does, its size, or whether it is in the private, or public sector. It is the only standard against which organizations can be certified.

Mr. Schurder concludes, "The quality of pharmaceuticals is a global concern, and the lack of reliable drug quality assurance systems in many developing countries often contributes to the devastation of diseases. Our goal is to contribute to a safe, high-quality supply of medicines. While today's realities have necessitated changes in our approach, we are eager to meet the challenge."

About LGM Pharma

LGM Pharma is a leading supplier of active pharmaceutical ingredients (APIs) to various global pharmaceutical firms involved in the research and development of old and new therapeutic chemical entities. In its commitment to improving health opportunities all over the world, the company has forged partnerships with some of the biggest names in the pharmaceutical industry. Currently, the company supplies over 2,500 active pharmaceutical ingredients to its global clients. For more information, visit www.lgmpharma.com.