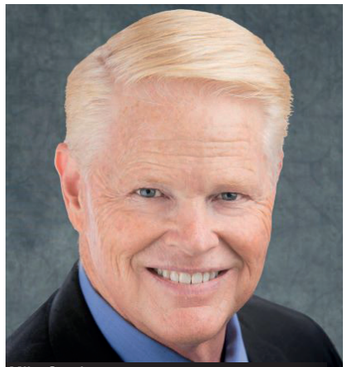
pharma TECH OUTLOOK
ISSN 2644-2787
WWW.PHARMATECHOUTLOOK.COM

ANALYTICAL SERVICES EDITION

LGM Pharma

API and CDMO Services for Complete Drug Product Lifecycle


Mike Stenberg,
Vice President of business development

LGM Pharma is a market leader in offering unrivalled active pharmaceutical ingredient (API) sourcing and contract development and manufacturing (CDMO) services. Whether it is API sourcing or drug product development, LMG's industry-leading service offerings cater to the entire drug product lifecycle, which encompasses a gamut of services.

LGM began operations in the API sector and quickly earned a great reputation for acquiring hard-to-find APIs for drug product developers worldwide. It has an extensive network of 200 to 250 global manufacturers, all dedicated to upholding the stringent regulatory standards of FDI, EMA, and other global bodies, providing custom synthesis for APIs. LGM also excels in comprehensive logistics and supply chain management, handling import-export regulations seamlessly to ensure smooth API delivery to clients.

"In 2020, we expanded from being experts in API sourcing to becoming an end-to-end CDMO through the acquisition of two drug development and manufacturing facilities based in the United States," says Mike Stenberg, Vice President of Business Development at LGM Pharma. "Our facility in Irvine, California, focuses on regulated oral solid doses, while our site in Rosenberg, Texas, deals with regulated and unregulated oral liquid and semi-solid products."

From API sourcing to drug product development, LGM's service portfolio includes pre-formulation, formulation, contract development, regulatory and analytical testing, and commercial manufacturing. Its CDMO Division is a leading producer of over-the-counter tablets, capsules, syrups, lotions, suppositories, and cosmetics. The R&D team, with extensive experience in 505(b)(2) and 505(b)(1) New Drug Application (NDA) projects, supports the facilities and looks after the pre-formulation and formulation stages. They also develop and validate the analytical methods and handle operations like stability storage and testing, and regulatory filing for the products.

Focusing on stability-indicating methods, LGM Pharma also develops analytical testing techniques. This includes formulating analytical target profiles, identifying critical quality attributes, and determining the type of test required among ID, quantitative, limit, and assaying active ingredients. LGM typically develops high-temperature-short-time and gas chromatography methods and uses testing techniques like IR, UV, ICP, and MS. LGM Pharma also tests for particle distribution and size characterization and offers X-Ray and laser diffraction.

"We meet clients' every analytical testing need for drug manufacturing with our robust infrastructure and capabilities. We also offer independent analytical testing services and supply materials for their clinical trials," says Stenberg.

During analytical method validation, if clients are in the animal testing phase of new drug development, LGM Pharma conducts partial validation in accordance with NDA regulations. This prevents clients from incurring full validation expenses if projects don't advance.

It performs in-house microbiological testing, allowing quick delivery of results. In case of unsatisfactory results, it investigates and identifies the root cause.

The company also understands the importance of clean equipment to achieve optimal test results. It validates cleaning methods with regulatory standards and ensures thorough cleaning of all equipment after conducting analytical tests.

LGM Pharma's onsite stability storage and testing capabilities adhere to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Through this, it offers varied storage conditions that meet temperature and humidity requirements for the products.

Having regulatory filing support with the help of its dedicated experts embedded within the R&D team helps create reports that are electronically compatible with the FDA system. Having this capability in-house also enables the company to ensure that the products comply with the regulations at the formulation, development and manufacturing stages.

LGM Pharma's full-service approach is evident as it also provides packaging services after manufacturing any product.

LGM's API capabilities, global drug product development and manufacturing facilities, regulatory and market intelligence services, and efforts to get clients' products faster and hassle-free to market make LGM Pharma a repeated choice of clients. Ph

LGM Pharma

The annual listing of 10 companies that are at the forefront of providing Analytical services and transforming businesses