LGM PHARMA

LGM Company Presentation

The API Specialists

Expert Operational Capabilities. Extensive Market Experience.

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Expert Operational Capabilities
Extensive Market Experience
Assured cGMP Excellence

LGM Pharma is an innovation-driven API company, involved in distribution of quality cGMP pharma ingredients to leading pharmaceutical companies

We specialize in streamlining the API supply chain management throughout all development and commercial stages while providing complete technical capabilities and expert regulatory support.

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About LGM Pharma

- Established in 2005
- ISO:9001-2015 QMS certified company
- GMP systems in accordance with ICH Q7 – Good Manufacturing Practices for Active Pharmaceutical Ingredients (relevant parts for distributors)
- Main business segments (US centric):
  - R&D / Biotech / CDMO / Specialty Pharma Companies
  - New Drug Delivery Technologies (NDA/505b2) – with heavy concentration on injectables, transdermal, inhalation, nasal, ophthalmic & sublingual drug deliveries
- 37 employees across 5 locations. Affiliate offices in India, China & Israel

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Supply Chain Focused

- Temperature controlled API warehouse in Erlanger, KY (~10,000sqf)
- Validated freezer (-20C) & fridge (2 – 8C) storage available
- Expansion planned towards controlled substances storage & distribution (2018)
- 175 different APIs in US stock regularly – JIT door-to-door services
- 1,720 importations (US) during 2017
- Fully qualified facilities/equipment. Complete documentation of API supply chain
- Focus on streamlining API procurement and ease of supply chain

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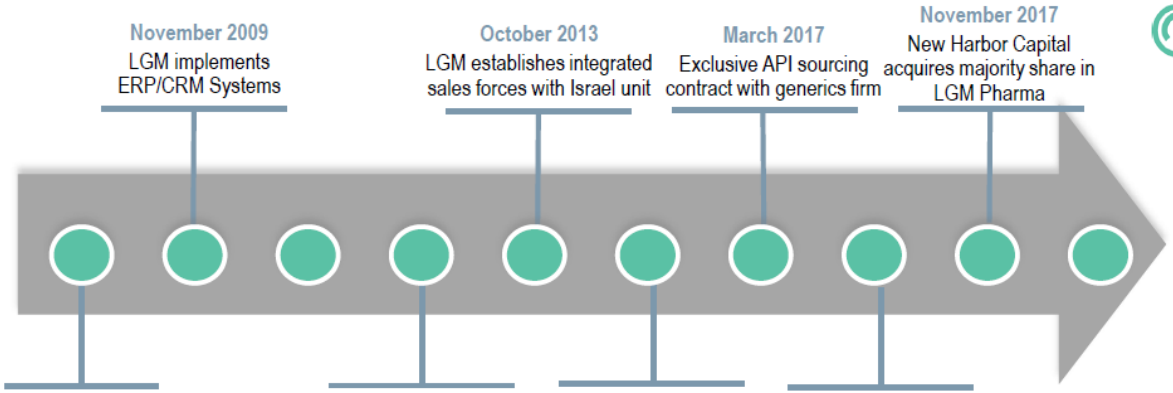
LGM History & Milestones



NEW HARBOR CAPITAL

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INSIGHT & INTELLIGENCE

REGULATORY

DIVERSE API PORTFOLIO

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INSIGHT & INTELLIGENCE

- Possessing unparalleled competitive intelligence on API resources and pharma market positioning
- Leveraging our intelligence resources and market insight to assist our clients in making the most informed choices regarding primary and secondary API sources
- Close collaboration with many world-class cGMP compliant, EU & US-FDA inspected and approved manufacturers gives us several key advantages in the scope of knowledge, technical expertise, cutting-edge market trends and quality

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REGULATORY

- We ensure full regulatory documentation & complete technical capabilities from the outset
- Our API manufacturing partner sites are fully accredited, inspected and certified by all major regulatory authorities
- Our regulatory team has extensive experience towards product submissions (IND, NDA, ANDA, 505(b)(2), etc.)
- Jan 2016 – Successful US-FDA routine GMP inspection (Zero 483's)
- LGM is fully licensed/permitted by all applicable state board authorities

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DIVERSE API PORTFOLIO

- LGM maintains a wide range of APIs, covering all major therapeutic classifications
- Our API portfolio is with access to complete documentation - available upon request (DMF/CTD/CEP/ASMF)
- Extensive experience working with various formulation developments, technologies and drug delivery systems

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OUR CUSTOMERS

At LGM Pharma, our clients' needs are our top priority

Our client base consists of a diverse array of pharmaceutical companies, including:

- Contract Research, Development & Manufacturing Organizations
- Specialty Pharma and NDDS Companies
- R&D & Biotech Companies
- Generic Pharma Companies
- Chemical Catalog Companies
- OTC & Private Label Manufacturers
- Academic & Government Laboratories
- Pharmacy Compounding Industry

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CONSULTATIVE APPROACH

LGM Pharma provides APIs for initial research and more complex development work towards product commercialization by providing raw materials from top quality GMP certified manufacturers. Our manufacturing partners have the necessary regulatory credentials and are able to provide technical packages, letters of access (LoAs) to registered DMFs as well as complete documentation towards any regulatory filings.

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QUALITY COMMITMENT

When it comes to purchasing your APIs, we believe that quality is key

That's why our number one priority is providing our customers with the highest quality pharmaceutical ingredients. Our APIs originate from manufacturing partners with full compliance to strict cGMP guidelines and who are inspected and approved by the leading regulatory authorities, such as EDQM, TGA, UK-MHRA, PMDA and US-FDA.

Our continuous evaluation towards improved quality and GMP processes assures you of the highest degree of confidence in the quality of our products. We work directly with QA, process engineers, scientists, and IP specialists, in order to resolve any analytical, quality or regulatory issues.

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Inhalation **Ophthalmic** **Transdermal** **Sublingual** **Injectables**

APIs FOR DRUG DELIVERY SYSTEMS

The area that excites LGM more than anything is working with other innovation driven companies that are focused around new drug delivery technologies.

Nasal devices, fast dissolving film strips, sublingual spray, microscopic ophthalmic stents, topical patches and orally disintegrating tablets are all amazing drug delivery technologies that our business development team is involved with regularly.

We supply APIs that are tailor-made to suit your application

We work to solve your challenge - API solubility, nano-particle size, taste masking etc – Our dedicated team has years of experience dealing with these same technical issues

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Thank you for your attention!

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