LGM Pharma

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# Corporate Overview & Capabilities

# About LGM Pharma

## Tailored API and CDMO Services for Drug Product Lifecycle Management

LGM Pharma is a leading provider of comprehensive API sourcing and drug product contract development and manufacturing solutions (CDMO) to the pharmaceutical industry. LGM Pharma is your trusted partner in accelerating therapeutics from concept to commercialization.

## Supply Chain Management

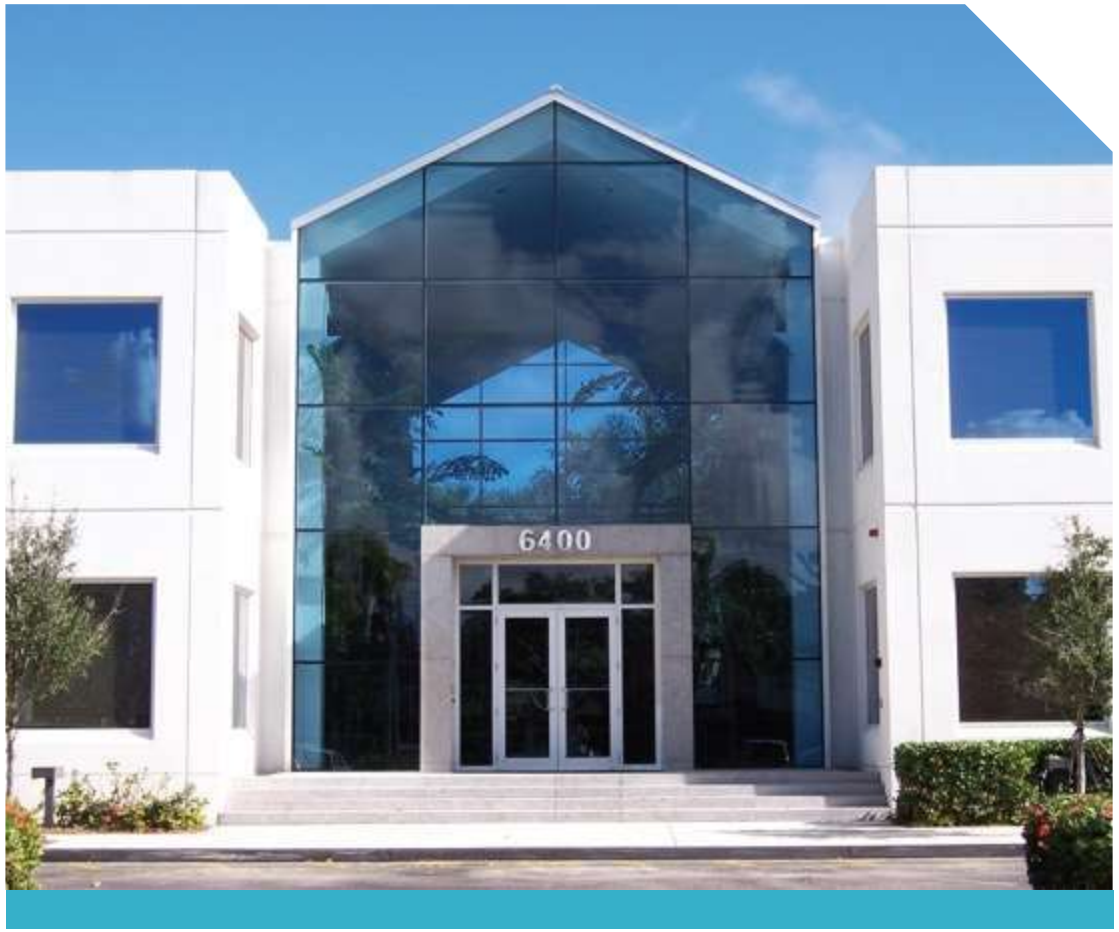
- Access to a robust global network of qualified manufacturers that offer a diverse portfolio of APIs
- Quality & Regulatory documentation support required for submissions in the USA, EU and other highly regulated markets
- Handling all aspects of global logistics, customs and FDA clearance

## Drug Product Development & Manufacturing

- Specialize in solid dosage delivery systems, liquids/suspension, semi-solids, and suppositories
- Services include formulation, analytical method development, commercial scale up and regulatory management
- US based facilities with FDA approval and GMP compliance

## Analytical Testing and Stability Services

- Analytical and microbiological testing for all forms of drug substances and drug products
- Custom, ICH, and registration stability services



# Senior Leadership

**Prasad Raje**
*CEO*

- BS & MS in Chemistry, PhD in Organic Chemistry from Auburn University
- Multiple leadership positions in Life Sciences area:
  - Testing laboratories
  - Drug substance (discovery, development & commercial manufacturing)
  - Drug product (solid dosages, injectables, New Chemical Entities, generics, high potency, controlled substances)
  - Experience in publicly traded companies, individual owned, PE backed, such as Nanotherapeutics, Cambridge Major Laboratories, Smithers Pharma Services, Albany Molecular Research (AMRI), and Abbott Laboratories

**Hamilton Lenox**
*SVP – Business Development & Operations*

**Richard Goitia**
*VP – Finance*

**Shailesh Vengurlekar**
*SVP - Quality & Regulatory Affairs*

**Ian Gibson**
*EVP Operations*

**Deepak Thassu**
*SVP R&D and Regulatory Division*

# Corporate History

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**November 2017**
New Harbor Capital acquires majority share in LGM Pharma

**March 2018**
- Acquired Compounding Business Unit from Zeta
- New CEO (Prasad Raje) appointed

**September 2015**
Established ~10,000 ft² API storage & distribution warehouse in KY

**May 2005**
LGM Pharma is founded

**2020**
LGM Pharma acquires the pharmaceutical division of Nexgen Pharma

**1924**
Anabolic Foods, Inc. is founded in Chicago, IL

**1940s**
Capabilities expand to include pharmaceutical solid dose manufacturing during World War II

**1970s**
Moved to a 50,000 ft² manufacturing building in Irvine, CA and launched private label supplement line

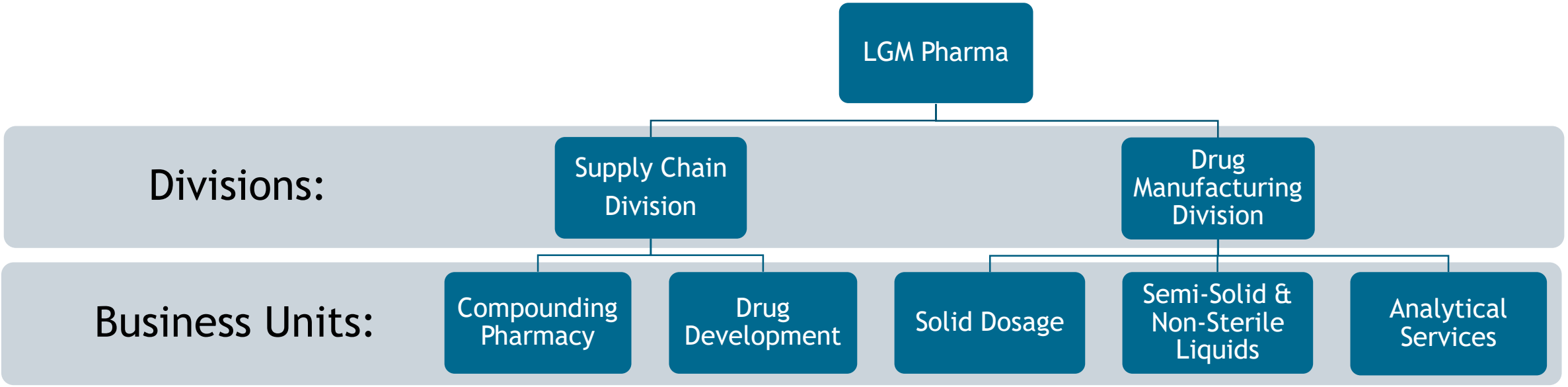
**2007**
Expanded manufacturing capacity with addition of 250,000 ft² facility in Colorado Springs, CO

**2014**
Nexgen acquired Elge, Inc., a liquid / semi-solid manufacturer located in Rosenberg, TX, adding a 50,000 ft² manufacturing site

nexgen pharma®

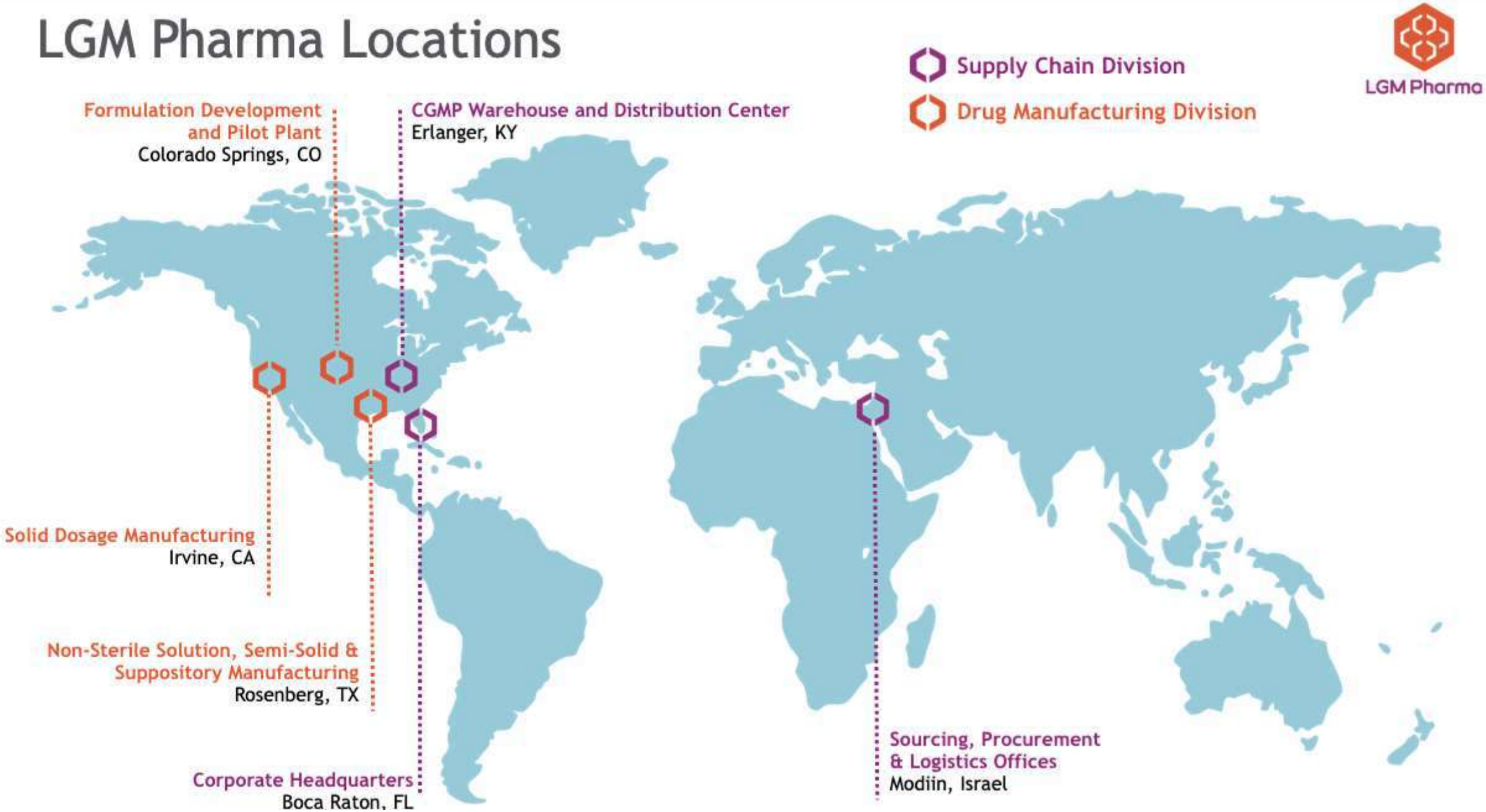
# Corporate Structure




Support clients in managing all phases of development process, from API sourcing to product commercialization

# LGM Pharma Locations



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# Supply Chain Division

# API Supply Chain Management

LGM Pharma is a recognized global leader in sourcing and distribution of quality APIs, providing clients with streamlined API supply chain management from R&D through commercialization. LGM Pharma leverages its extensive network of pre-qualified API suppliers to support hundreds of clients and projects in the 505(b)(2), ANDA, OTC, and compounding pharmacy markets.

Access to a portfolio of over 2,000 APIs from every therapeutic category to support any stage of development, from early feasibility to commercial production.

Consultative approach to understand the unique needs of your project and the timeline for development or commercialization. Our Logistics team successfully handles over 1,500 shipments a year.

Support programs as a primary or alternate source, from R&D through commercialization. Risk mitigation strategies for your supply chain by providing multiple sources from divergent geographic regions.

Global regulatory expertise ensuring a smooth journey from concept to regulatory approval in the USA, EU and other highly regulated markets.

Robust network of 400+ reliable API manufacturers with a tradition of regulatory excellence — holding approvals from leading health authorities — backed by accessible & comprehensive DMF / regulatory documentation.

Sourcing team with technical background, combined 50+ years of experience sourcing products for large pharmaceutical, and specialty generic companies.

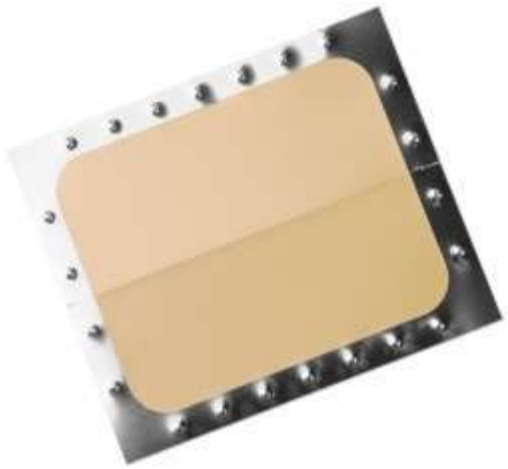
# Supply Chain Support for Novel Drug Delivery Systems

LGM Pharma

LGM is fully aware that innovative drug delivery systems are the bright future of global healthcare.

Nasal devices, fast-dissolving film strips, sublingual sprays, microscopic ophthalmic stents, topical patches and orally disintegrating tablets all are amazing drug delivery technologies that our team currently supports. We supply APIs that are tailor-made to suit your specific application and delivery technology.

We work to solve your challenges — API solubility, nano particle size, taste masking etc. — our dedicated team has years of experience dealing with these same technical issues.

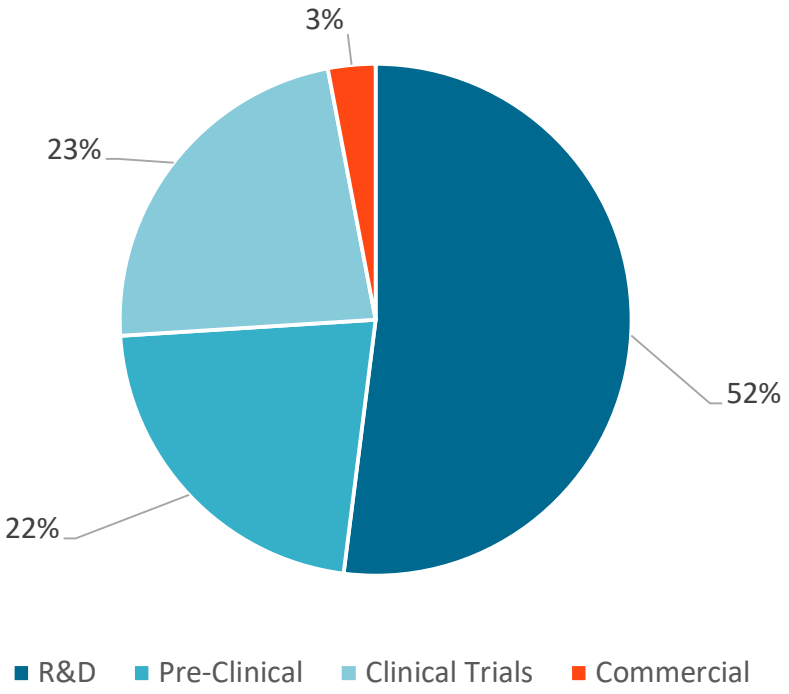


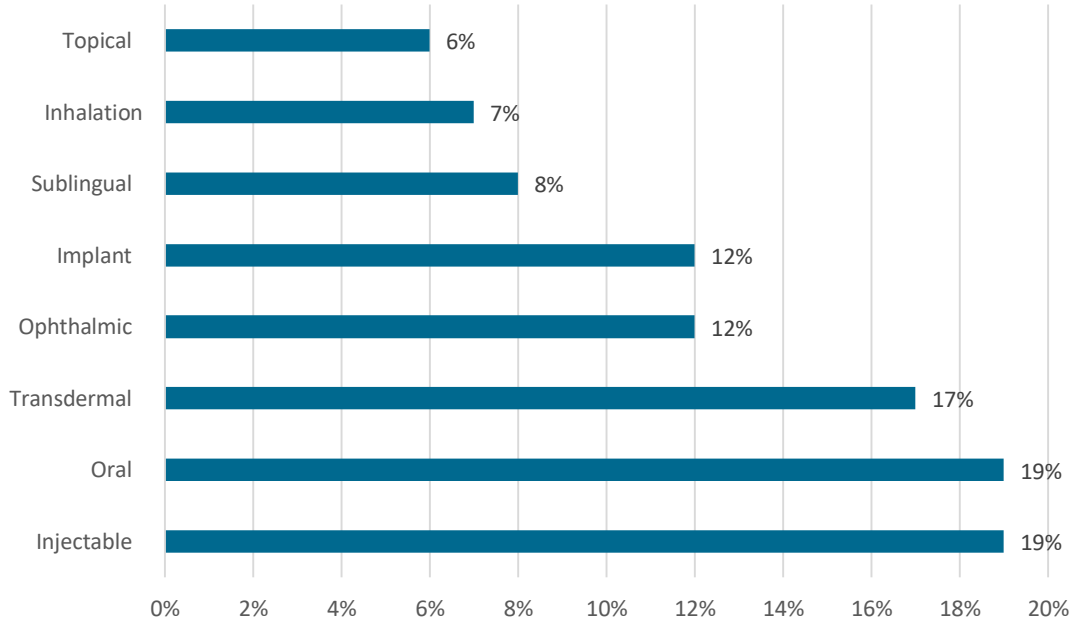
# 505(b)(2) Programs

At present, LGM Pharma supports 120+ drug development programs pursuing the 505(b)(2) regulatory pathway, in a variety of therapeutic categories and at every life-cycle stage (pre-clinical to commercial).

## Programs by Stage of Development




## Programs by Dosage Form

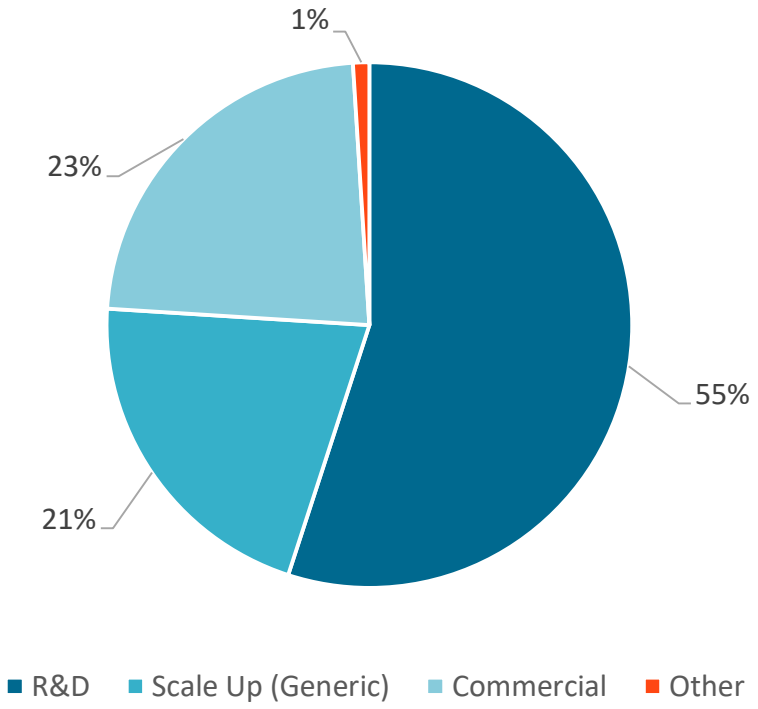


# ANDA Programs

At present, LGM Pharma supports 90+ ANDA programs in just about every therapeutic category and at every stage. Our team understands the need for a high-quality and efficient API source to meet the stringent timelines for a generic filing.

## Programs by Stage of Development

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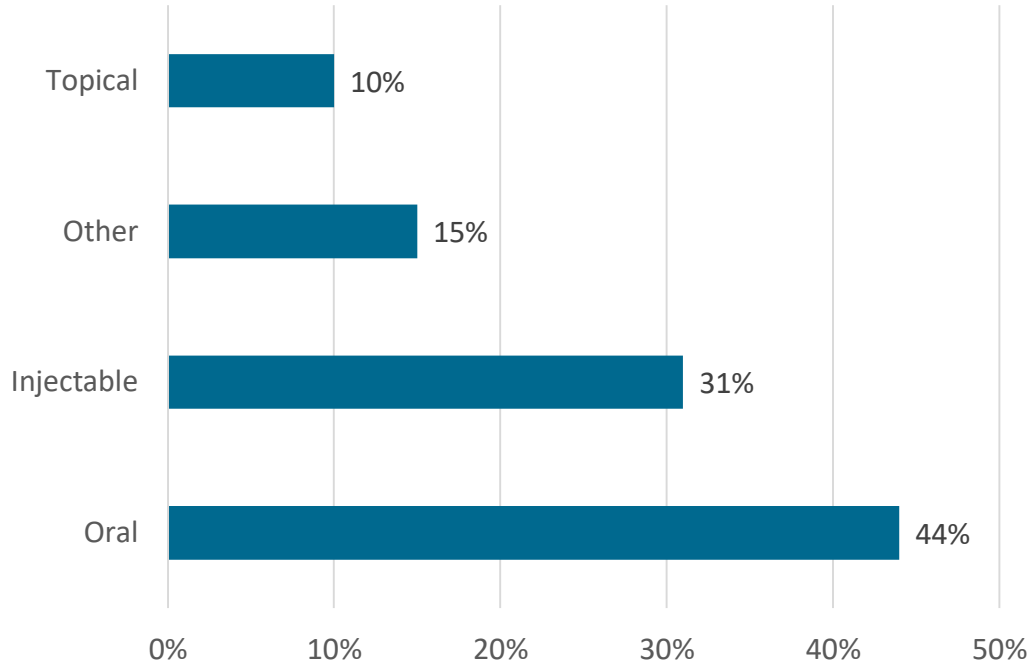
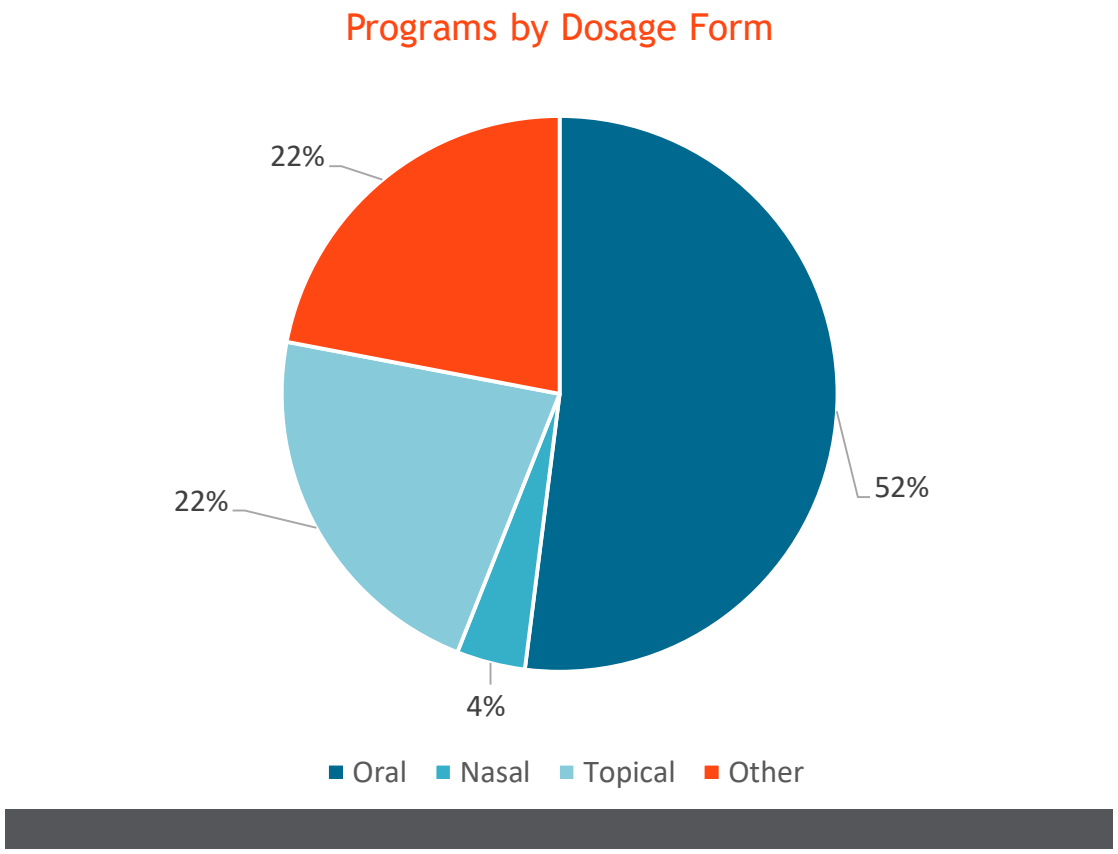


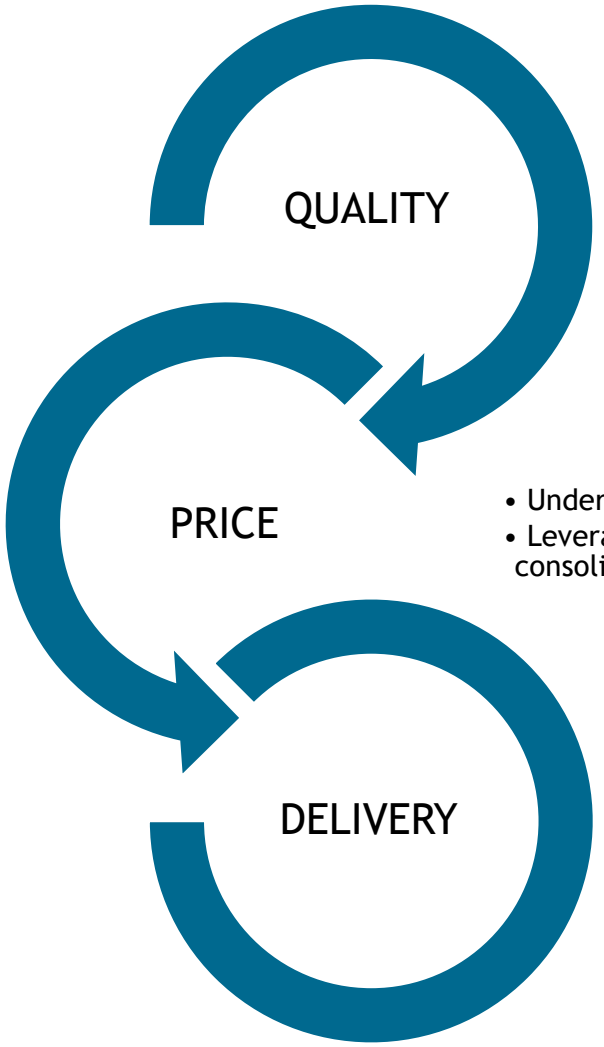
# OTC Programs

At present, LGM Pharma supports 45+ OTC programs. LGM's network of suppliers offer a wide variety of OTC products with the highest quality standards. Our team has extensive experience streamlining the procurement process to best meet your timeline and budget.



# Sourcing & Procurement Expertise




- Compliant with all applicable guidelines and client's requirements
- High quality products, warehouse, and CGMP/GDP services

- Understanding price levels vs. market price
- Leverage negotiation power by supplier consolidation

- Performance measures (on time deliveries)
- Meeting schedules (delivery & performance)
- Flexibility to changes

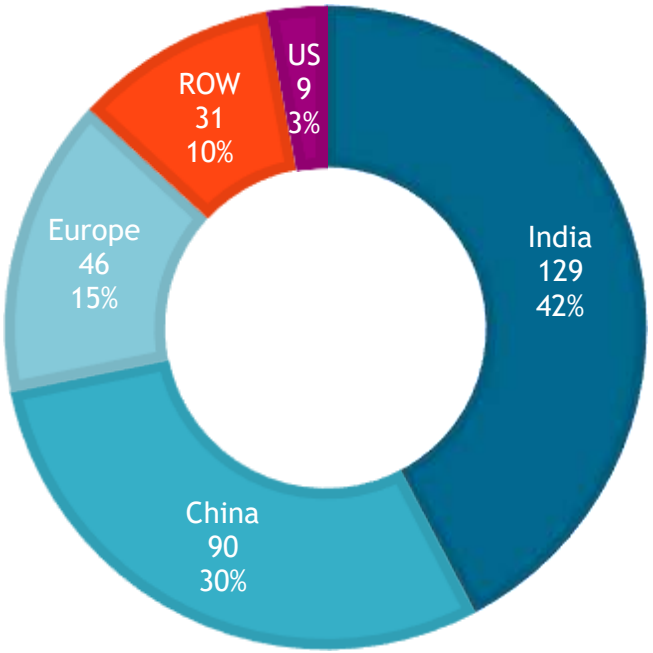
- Sourcing & Logistics departments located in Modiin, Israel
  - Ideally situated between US and European / Asian time zones
  - Handle over 700+ purchases from manufacturers annually
  - 1,500+ deliveries to customers annually

# Vendor Management

- Network of over 400 manufacturers
- Over 300 qualified manufacturers for CGMP APIs
- Focus on building alternate sources from varying parts of the world
- Robust quality-based vendor approval process
- We only work with FDA-registered suppliers with good regulatory standing
- Ongoing and continuous evaluation of API manufactures
- Monitoring of FDA and other regulatory agencies' current standing

LGM Qualified Manufacturers



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# Drug Manufacturing Division

# Formulation Development

## Dosage Forms

- **Oral Solid**: Tablets, Capsules, Beads and Powders
- **Oral Liquid:** Solutions, Syrups and Suspensions
- **Topical Semi Solid:** Creams, Ointments and Gels
- **Suppositories**

## Manufacturing Processes

- Low Shear Wet Granulation Process
- High Shear Wet Granulation Process
- Dry Granulation Process
- Spray Granulation Process
- Spray Drug Layering and Modified Release Coating of Powders and Beads
- Low and Medium Viscosity Liquid Mixing
- Encapsulation of Powder, Tablets and Beads
- Encapsulation of Tablets with Beads or Powder
- Tablet/Capsule Coating
- Bi-layer Tableting (coming soon)

# Formulation Development *(cont.)*

## Batch Size Flexibility

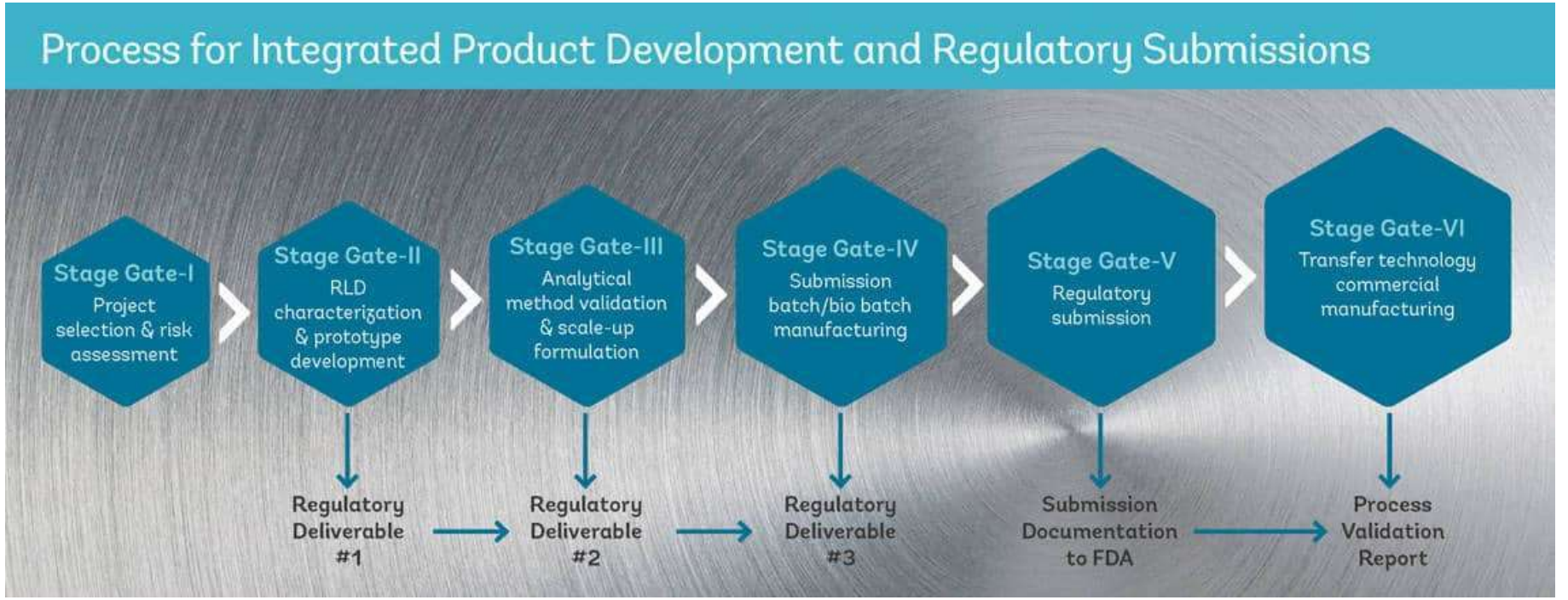
- Small, Medium, and Large Commercial and Clinical Batch Manufacturing for solid, semi-solid, liquid, and suppository dosage forms

## Personnel

- 3 PhDs on the formulation team
- 90+ years of Pharmaceutical Formulation Development Experience
- 90+ years of Pharmaceutical Process Development & Validation Experience
- Experienced Technical Writer and QbD Specialist
- 60+ QA/QC/Analytical specialists

# An Innovative Approach




**4 Regulatory approvals**
(Solids and Liquid)
in past 12 months

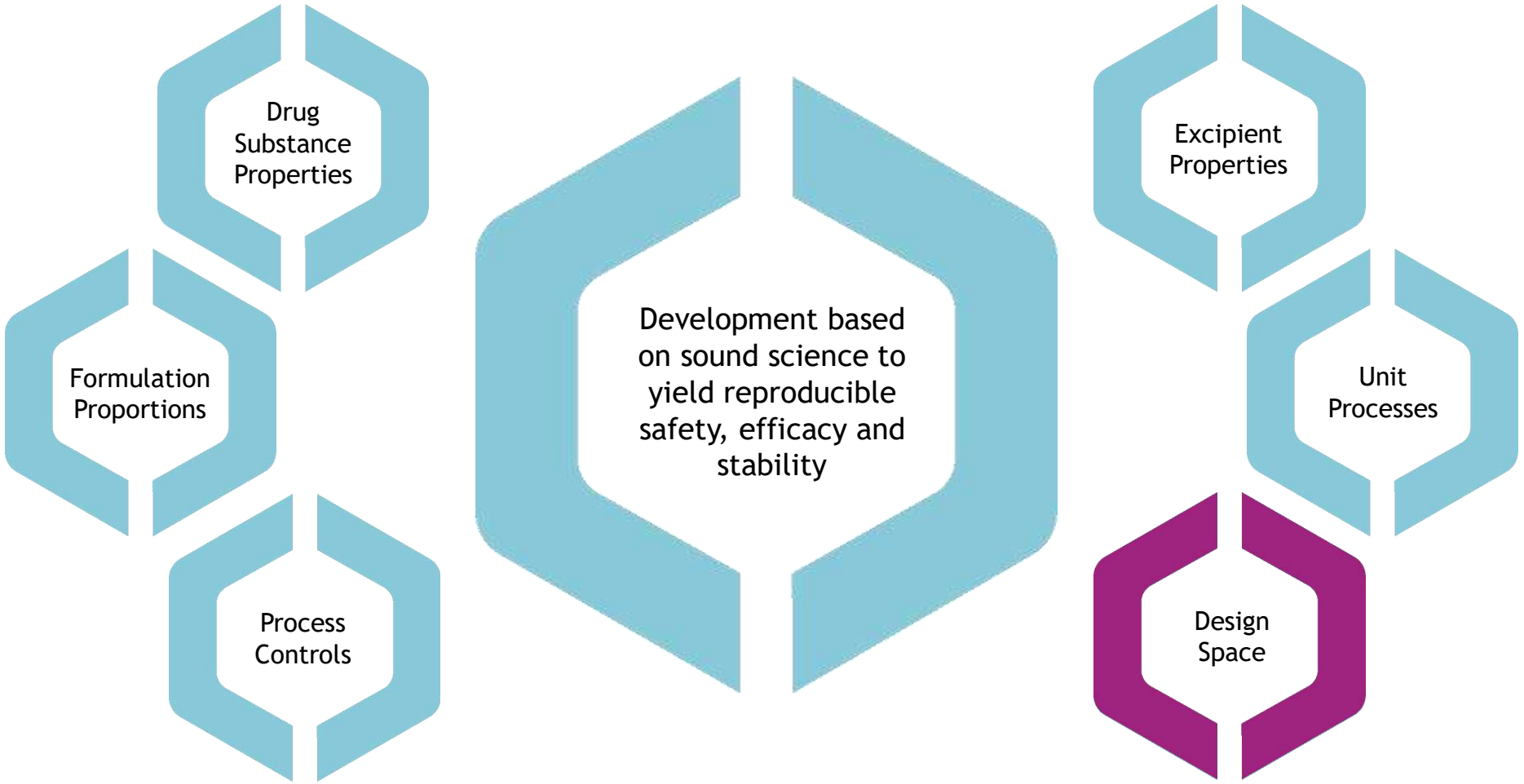
**3 successful commercial launches**
within the last 12 months

Last inspection January 2020 – **Zero 483s**

# Quality by Design (QbD)

Product Development is planned systematically to ensure a robust drug product manufacturing process in which all controls have been identified, understood, and selected to achieve design intent.



# Design Space

Manufacturing processes maintained within the Design Space ensures formation of Drug Product exhibiting all predefined Quality Attributes.

# Solid Dosage Forms

*Irvine, CA*

LGM Pharma

- **Capabilities:** Tablets, Capsules, Beads and Powders
- **Capacity:** 805 Million tablets, 300 Million capsules annually
- **Types of Equipment:** Tablet Presses, Single Encapsulation of Powder, Beads or Tablets, Multi Encapsulation of Tablets with Powder or Beads in a single capsule
- **Batch Sizes:** Small, medium, or large clinical and commercial batches – with tech transfer from pilot to commercial scale. Typical commercial batch sizes of up to 2+ million
- **Packaging:** Bottles
- **Track & Trace:** Serialization equipment operational

# Oral Liquid Dosage Forms

*Rosenberg, TX*

LGM Pharma

- **Capabilities:** Solutions, Syrups, Suspensions and Enemas
- **Capacity:** 1.5 Million Liters annually
- **Types of Equipment:** Piston Filler(s), Cappers, Neck Band/Induction Seal, Labelers, Cartoning, Bundle Packs, Case Packing, Case Labels
- **Batch Sizes:** Small, medium, or large clinical and commercial batches. Typical commercial batch sizes of 500-12,000 Liters. Inline recirculation and homogenization capabilities to manufacture suspension products for batch sizes from 400 to 12,000 liters.
- **Packaging:** Plastic/Glass, Bottles, Jars, Droppers, Syringe, Dose Cup, Packaging Inserts, Coupons, Multi-Layer Labels, Ink Jet, Thermal Transfer, Bundled Carton, Shipping Case
- **Track & Trace:** Estimated Launch Date – Q1/Q2 2023
- **Taste Masking:** Experience with taste masking excipients

# Semi-Solid Dosage Forms

*Rosenberg, TX*

LGM Pharma

- **Capabilities:** Creams, Ointments, Paste and Gels
- **Capacity:** 240,000 kg annually
- **Types of Equipment:** Dual Mixing, Heating, Cooling and Load Cells
- **Types of Packaging Equipment:** Metal/Plastic Tube Filler, Piston Filler, Labeling, Cartoning
- **Batch Sizes:** Small, medium, or large clinical and commercial batches. Typical commercial batch sizes of 1200-6600 kg
- **Packaging:** Plastic/glass, Jars, Bottles, Metal/Plastic Tubes, Multiple Closure systems, Labels, Carton, Bundles Pack, Case Pack, Barcode Labels
- **Track & Trace:** Estimated Launch Date – Q1/Q2 2023

# Suppositories

*Rosenberg, TX*

- **Capabilities:** Suppositories
- **Capacity:** 35,000,000 doses annually (0.5 g – 3.0 g)
- **Types of Equipment:** Form, Fill, Seal and Carton
- **Batch Sizes:** 100 – 1,800 kg. Clinical trial materials and kitting
- **Packaging:** PVC/PE Film, In-House Film Printing, Multiple Packaging Configurations to Meet Customer Needs
- **Track & Trace:** Estimated Launch Date – Q1/Q2 2023

# Chew Tablets

*Rosenberg, TX*

- **Capabilities:** Chewables
- **Capacity:** 35,000,000 doses annually (0.5 g – 3.0 g)
- **Types of Equipment:** SARONG, Form, Fill, Seal and Cartoning
- **Batch Sizes:** 50 – 1,800 kg
- **Packaging:** PVC/PE Film, In-House Film Printing, Multiple Packaging Configurations to Meet Customer Needs
- **Track & Trace:** Estimated Launch Date – Q1/Q2 2023

# Packaging / Serialization

- Strong understanding of DSCSA and GS1 requirements
- Capabilities to support HDA recommended labels or custom labels, as needed
- LGM performs aggregation
- Level 1-2 Optel Linemaster
- Level 4 rfxcel IRIS repository

# Regulatory Submissions (CMC)

Our dedicated expert regulatory services team – embedded in our R&D department – knows how to compile and maintain NDAs, ANDAs, and other regulatory pathways such as 505(b)(2), for a successful FDA review. With two DEA-licensed facilities, we also handle Class II-V controlled substances.

## Write and Review Module-2 and 3

- Technical Writing and Compilation of ANDAs and 505(b)(2) in a CTD format
- Writing Collation and Assessment of Quality/CMC regulatory documentation (Module 2 and 3)
- Critical Writing and Review of Drug Substance and Drug Product documentation

## ANDA Documentation Compliance

- Adhere to CFR regulations and guidance documents to ensure timely approval of new ANDAs, Amendments and post-approval changes
- Expedient response to IRs and CRs prior to due date
- Coordination with clinical trial partners to ensure eCTD compliance (Module 5)

## DEA Compliance for R&D and Commercial Activities

- Licensed for C-I through C-5 and List 1 materials
- Successful, recent DEA audits of all three sites with no deficiencies noted
- Approved vaults and cages at all three sites

# Quality Management System


- Stability Programs
- Batch Release
- Cleaning Validation
- Document Control
- Process Validation
- Controlled Substances
- Vendor Management
- Equipment Validation
- Training
- In Process Control
- Part 11 Compliance
- Deviations
- Complaints
- CAPAs
- OOSs
- Change Control
- Material Management

# Regulatory Inspection History

**FDA**

- **December 2016:** PAI and CGMP Inspection (CA)
- **February 2017:** Part 111 CGMP Inspection (CA)
- **October 2017:** Part 211 CGMP and PAI Inspection (CA)
- **January 2017:** Part 211 CGMP Inspection (TX)
- **August 2018:** Part 211 Pharmacovigilance Inspection (CA)
- **November 2018:** Part 211 CGMP Inspection (TX)
- **January 2020:** Part 211 CGMP and PAI Inspection (CA) – **Zero 483 observations**

**DEA**

- **August 2018:** Compliance Inspection (CA)
- **September 2018:** Compliance Inspection (TX)
- **September 2019:** Compliance Inspection (CA)
- **August 2020**: Compliance Inspection (TX)
- **October 2020**: Compliance Inspection (CA)
- **September 2021:** Compliance Inspection (TX)

Current FDA CGMP status:
VAI (no regulatory or administrative actions pending)

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# Analytical Services

# Analytical Method Development & Validation

- Analytical Quality by Design and Innovative Approach to Develop stability indicating method for all forms of pharmaceutical products (Solid, semi-solid and liquid)
  - Analytical Target Profile Identification
  - Critical Quality Attributes Identification
  - The Validation of Analytical Procedures at LGM is directed to the four most common types:
    - Identification tests
    - Quantitative tests for impurity content
    - Limit tests for the control of impurities
    - Quantitative tests of the active moiety in various samples
- Validated methods include (but are not limited to):
  - Chromatographic techniques such as TLC, HPLC, UPLC, GC
  - Spectrophotometric techniques such as IR, UV, ICP-MS, ICP-OES, AA
  - Titrimetric methods,
  - Microbiological assays
  - Other methods such as fluorimetry, gravimetry, LOD, KF, Dissolution, X-ray Diffraction, Laser Diffraction Particle size characterization, and Sonic/Air Jet Particle size analyzer

 

# Stability Studies

- CGMP Registration Stability Program
- Drug Substance and Drug Product Stability
- Protocol Design (ICH or Custom)
- Real-Time Stability Testing
- Accelerated Stability Testing
- Forced Degradation Studies
- Formulation Stability Studies
- Biologics Stability Studies
- ICH Stability Conditions Available
  - Storage at 2-8 ºC, 25 ºC/60% RH, 30 ºC/65% RH, 40 ºC/75% RH
- Freeze / Thaw Cycle Studies
- Client Specific Reporting (Timepoint and Final Reports)

 

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# Partner Smart

# Types of Partnerships

At LGM, we take the time to understand your project and develop unique collaborations to secure your supply chain and accelerate your new product pathway.

**Fee for Service / CDMO**

- Clinical / Commercial Manufacturing
- Analytical and Stability Services
- Tech transfer (clinical/commercial)
- Regulatory Submissions
- Formulation
- Pilot batches

**Standalone Contract Services**

- API Sourcing
- Analytical Testing
- Stability Services
- Submissions Support

**Joint Ventures / Profit Splits**

- Investment in projects with our partners
- Shared risk
- Allows partners to pursue more projects
- Eight partnership projects currently in the pipeline
- Variety of customers currently utilizing a partnership model
- Partnership model has given us unique insights into various areas of the distribution chain

 

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# Thank you!

www.lgmpharma.com

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