LUPIN

LUPIN
MANUFACTURING
SOLUTIONS

CDMO BY DESIGN. PARTNERSHIP WITH A PURPOSE.

Flexible engagement.
Focused execution.
Formidable results.

Lupin Manufacturing Solutions (LMS) is a purpose-built CDMO, created to partner with global pharmaceutical and biotech innovators across the full development and manufacturing lifecycle. Backed by Lupin's science-led legacy and global manufacturing footprint, Lupin Manufacturing Solutions (LMS) combines deep chemistry expertise, integrated development capabilities, and phase-appropriate manufacturing to help programs move confidently from early development to commercial supply.

We do more than manufacture molecules. We design pathways, mitigate risk, and integrate science, scale, and supply into a single, accountable partnership model.

OUR CDMO APPROACH

PARTNERSHIP-LED ENGAGEMENT

Flexible business models aligned to program maturity and long-term goals

SCIENCE-FIRST EXECUTION

Strong foundations in chemistry, formulation, and analytics

INTEGRATED DELIVERY

Seamless transition from early development to manufacturing

QUALITY BY DEFAULT

Compliance-driven systems aligned with global regulatory expectations

END-TO-END CDMO PLATFORM

LMS offers both integrated and standalone services across the pharmaceutical development continuum including:

- **Building Blocks & Advanced Intermediates**
- **Drug Substance Development & Manufacturing**
- **Drug Product Development & Manufacturing**
- **Analytical & Stability Services**
- **Integrated Drug Substance-Drug Product (DS-DP) Programs**
- **Specialized Modalities: Peptides, ADCs, Oncology**

ONE PARTNER. ONE PROGRAM STRATEGY. ONE ACCOUNTABLE DELIVERY.

WHY LMS?

- Backed by Lupin's global manufacturing and quality legacy
- Focused CDMO with selective, high-engagement partnerships
- Oncology and complex modality readiness
- Deep chemistry and formulation expertise
- Integrated, phase-appropriate solutions

Building Blocks and Intermediates → Drug Substance → Drug Product → Commercial Supply

BUILDING BLOCKS & ADVANCED INTERMEDIATES

LMS supports innovators and generic companies with reliable, scalable access to key building blocks and advanced intermediates, laying the foundation for robust downstream API manufacturing.

Capabilities

- Custom synthesis of intermediates at lab, kilo, pilot, and commercial scale
- Route scouting and synthetic pathway optimization
- Process intensification for yield, cost, and sustainability
- Multi-step synthesis and impurity-controlled intermediates
- Chiral synthesis and resolution
- Controlled substances and complex raw materials

Value To Partners

- Reduced development risk through early route selection
- Supply continuity from early development through scale-up
- Cost-efficient, scalable chemistry aligned to long-term manufacturing goals

Route scouting → Kilo scale → Commercial intermediate supply

DRUG SUBSTANCE DEVELOPMENT & MANUFACTURING

LMS offers end-to-end API development and manufacturing services designed to support programs from early development through commercial supply.

Development Capabilities

- Route scouting and synthetic strategy design
- Process development and optimization
- Impurity identification, control, and mitigation
- Process safety studies and scale-up readiness
- Phase-appropriate GMP development batches

Manufacturing Capabilities

- Integrated lab-to-commercial scale manufacturing
- Multi-step synthesis across diverse chemistries
- Chiral chemistry and complex transformations
- Robust technology transfer and scale-up execution
- Commercial manufacturing with regulatory readiness

Quality & Compliance

- Integrated lab-to-commercial scale manufacturing
- Multi-step synthesis across diverse chemistries
- Chiral chemistry and complex transformations

Lab → Kilo Lab → Pilot → Commercial API scale-up flow

HPAPI MANUFACTURING

LMS is a strategic CDMO partner for high-potency and oncology-focused programs, offering dedicated infrastructure and containment expertise.

Capabilities

- Dedicated HPAPI suites with OEB 5 containment
- Safe handling of cytotoxic and cytostatic compounds
- End-to-end HPAPI development and manufacturing
- Specialized isolator-based operations
- Integration with analytical and formulation teams

Partner Advantage

- Early risk mitigation through containment-by-design
- Seamless transition from development to commercial manufacturing
- Oncology-focused expertise aligned with regulatory expectations

DRUG PRODUCT DEVELOPMENT & MANUFACTURING

LMS provides comprehensive drug product development and manufacturing services designed to support clinical programs and commercial launches across dosage forms.

Formulation Development

- Pre-formulation and developability assessment
- Excipient compatibility and stability studies
- Bioavailability enhancement strategies
- Phase-appropriate formulation development

Dosage Forms Supported

- **Oral solids:** Tablets, capsules, modified-release systems
- **Liquids:** Syrups, suspensions, emulsions
- **Injectables:** Sterile formulations and complex injectables
- **Drug-device combinations:** Auto-pen injectors, nasal delivery systems

Manufacturing & Clinical Supply

- GMP clinical trial material (CTM) manufacturing
- Packaging and labeling
- Global distribution support
- Scale-up to commercial manufacturing

ANALYTICAL & STABILITY SERVICES

Analytical science is embedded across every LMS program, enabling informed decision-making and regulatory confidence.

Formulation Development

- Method development, validation, and transfer
- Impurity profiling and characterization
- Solid-state and physico-chemical characterization
- In-process, release, and stability testing
- Support for DS, DP, and complex modalities

Stability Services

- ICH stability studies (all phases)
- Forced degradation and stress studies
- Shelf-life estimation and re-test extensions
- Stability support for regulatory submissions

Integrated Analytical Support

- Phase-appropriate analytical strategies
- Seamless transition from non-GMP to GMP testing
- Alignment with CMC and regulatory timelines

INTEGRATED DRUG SUBSTANCE-DRUG PRODUCT (DS-DP) OFFERING

LMS is purpose-built to deliver integrated DS-DP programs, thus, reducing interfaces, timelines, and technology transfer risk.

Integrated Advantages

- Single program governance and accountability
- Reduced tech-transfer complexity
- Accelerated development timelines
- Improved data continuity and quality alignment

Ideal For

- Emerging biotech programs
- Complex molecules requiring close DS-DP alignment
- Accelerated clinical development strategies

SPECIALIZED MODALITIES

Peptides

- Custom synthesis of simple to complex peptides
- Expertise spanning GLP-1 analogs and therapeutic peptides
- Integration from peptide API to finished dosage forms
- Strategic supply-chain partnerships for key starting materials

Antibody-drug Conjugates (Adcs)

- Linker and payload synthesis
- Conjugation process development
- Analytical method development for ADCs
- Scale-up support aligned with oncology programs

Complex Chemistry & Conjugation

- Innovative conjugation chemistries
- Handling of challenging payloads and linkers
- Integrated analytical and manufacturing support
- Complex chemistry reactions:

Alkylation
Amidation & Azidation
Ammonolysis
Cross-coupling Reactions
Deuterated Chemistry
Enzymatic Conversions
Flow Chemistry
Fluoromethylation
Halogenation & Hydrogenation
Hydrothermal Reactions
Organometallic Chemistry
Krapcho Decarboxylation
Oxidation & Phosphorylation
Wittig Reaction
Condensation & Reduction
Steroids

ANIMAL HEALTH DRUG SUBSTANCE DEVELOPMENT & MANUFACTURING

LMS can support Animal Health innovators with scalable, cost-effective drug substance development and manufacturing, leveraging our existing infrastructure, technical expertise, and commercial manufacturing footprint. Our integrated model enables rapid transition from development to commercial volumes, ensuring timely market access across regulated and semi-regulated markets.

From early development to sustained commercial supply, our capabilities are designed to address the diverse chemistry, containment, and volume requirements of modern Animal Health APIs.

Therapeutic Coverage

Our platform supports a wide range of Animal Health therapeutic segments, including:

- Anti-parasitic, Anti-fungal & Insecticides
- Antiemetics
- Anesthetics
- Sedatives
- Oncology (High-Containment APIs)
- Feed & Nutritional Actives
- Human / Dual-Use APIs

This broad coverage allows us to support both standalone Animal Health products and dual-use molecules, ensuring flexibility as portfolios evolve.

A Reliable Partner for Animal Health Growth

Our Animal Health API capabilities are designed to support:

- Portfolio expansion into new therapeutic areas
- Lifecycle management of existing products
- Smooth transition from development to commercial supply
- Long-term partnerships across global markets

PARTNER WITH LUPIN MANUFACTURING SOLUTIONS

For end-to-end CDMO solutions, backed by science, speed, and scale.

Lupin Manufacturing Solutions Limited (LMS), a wholly-owned subsidiary of Lupin Limited, is a leading manufacturer of active pharmaceutical ingredients (APIs) and a global contract development and manufacturing organization (CDMO) offering standalone & integrated solutions across drug substance, complex chemistry, drug product, and advanced modalities including ADCs and peptides. Leveraging Lupin's legacy of scientific rigor and regulatory expertise, LMS supports biopharma innovators from early development to commercial scale. With state-of-the-art facilities, a client-first approach, and a team of 250+ scientists, LMS accelerates the path to market for transformative therapies.

LMS is where science meets speed, and innovation meets execution.

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