Lupin Manufacturing Solutions

CDMO + API Solutions

March 2025

We are Lupin Manufacturing Solutions

Lupin Manufacturing Solutions (LMS) provides insights, development and manufacturing services for all stages of drug substance development.

Our focus is cost effective supply of molecules with a range of synthetic complexity:

- Small molecules across all the value chain
- Highly potent compounds
- ADC linker-payload
- Peptides
- Fermentation semi-synthetics

LMS builds on the robust performance of its parent

FINANCIALS

$2,300 Mn
Total Revenue From Operations

$452 Mn
EBITDA

R&D

866
Active Patents Applications as of March 2024

442
ANDAs and NDAs filed with U.S. FDA as of March 2024

RANKINGS

3rd
In the U.S. (by prescriptions)

7th
In the Indian Pharma Market

PRODUCTS

25+
Robust Injectables Pipeline for FY25

15+
Robust Pipelines of Respiratory Products for FY25

27 Bn+
Formulation Units Sold Globally (IQVIA MAT Mar 24 Standard Units)

1,420,000+
Patients Reached Through Patient Education Programs

78,000+
HCPs Participated in Doctor Education Programs

21% YoY
Reduction in Scope 1 and Scope 2 Emissions in FY24

Lupin Today

As of 31st March 2024

Our Development and Manufacturing Network

Our world-class facilities ensure we deliver tailor-made solutions to our customers

Dabhasa — 505 — C F T M W

Large-scale cGMP manufacturing facilities and multi-purpose small-scale plants

Pune — 215 — C

Centre of Excellence development & cGMP clinical supply for range of modalities

Vizag — 210 — C F A M W

Large-scale cGMP manufacturing facilities including dedicated facility for potent molecules

Corporate Office: Mumbai 20

Business Development

Employees | C GMP | F FDA inspected | T TGA inspected | M MFDS Inspected | F ANVISA Inspected | W WHO-CDSCO

GMP = Good Manufacturing Practice, FDA = Food & Drug Administration (US), TGA = Therapeutic Goods Administration, MFDS = Ministry of Food & Drug Safety (Korea), ANVISA = Health Regulatory Agency (Brazil), WHO-CDSO = World Health Organization – Central Drug Standard Control Organization (India)

LMS Overview

Enables innovative large pharma, mid-pharma and small pharma companies to develop the next generation of life-changing pharmaceuticals

- Leading developer and manufacturer of cost effective and complex Registered Starting Materials (RSM), Pharmaceutical Intermediates (PI) and Active Pharmaceutical Ingredients (API) for pharma customers
- Focused on cost effective supply of high-quality molecules with a range of synthetic complexity
- Operates across the drug substance value chain of the CDMO market serving two segments, Originators and Generics

Major API Producer

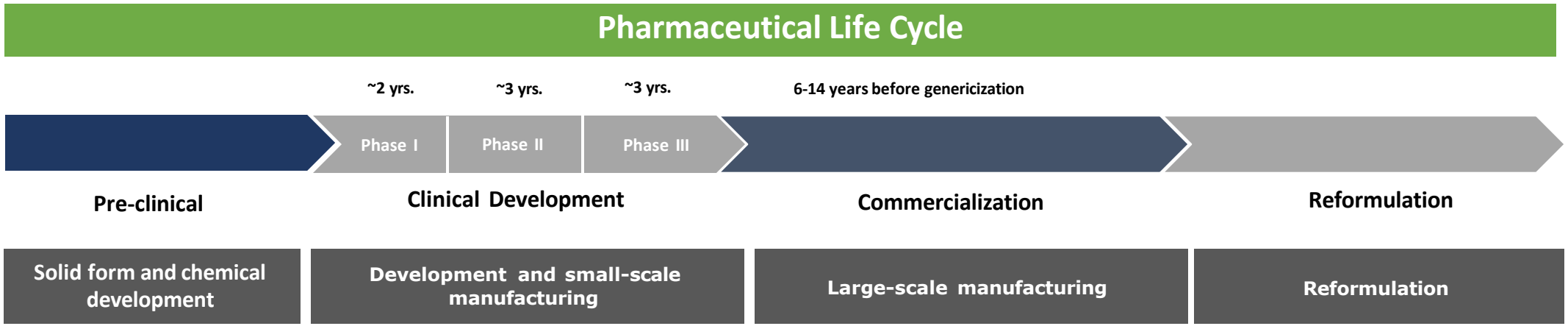
3 Development & Manufacturing Facilities

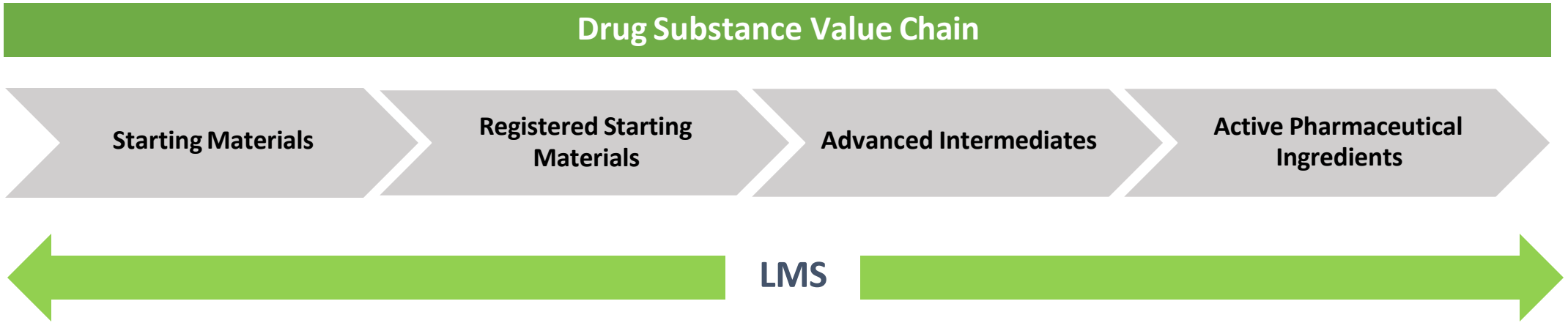
~1000 Global Employees

>200 R&D Scientists

We work with Originators on their Drug Substance challenges

Operating across the complete lifecycle & the full value chain





LMS Executive Management Team

Deep industry experience across all functions and multiple modalities and geographies

Dr. Abdelaziz Toumi
CEO

Dr. Rakesh Ganorkar
CSO

Vijay Ghogare
COO

DVS Varma
CQO

Ajay Tiwari
CHRO

Alok Kumar
CFO

Akhil Varma
VP, Strategy & Portfolio Management

Driving functional excellence across commercial, development, operations, quality, strategy and human resources to ensure customer delight.

Experience across wide range of modalities from key players: Lonza, Catalent, Veranova, Cambrex, Biocon, Sandoz, Hikal, SAI Life Sciences

Technology Platform

Range of platforms to enable supply of cost-effective drug substance

Deep experience across the platform enables rapid development, scale up and validation

Learning over multiple projects enables most favorable cost of goods at commercial scale

Development Center

Labs	Number
Synthesis	7
Analytical	15
Fermentation Development	5
Enzyme Development	2
PECG	1
Containment Lab	1
Steroid & Hormones	1
Peptide Chemistry	2
Process Safety	1
High Pressure	1
Kilo Lab	1

Route Scouting → Small scale synthesis → Process Development → Process Optimization → Kg scale deliveries (GMP) → Process Validation @ Plant → Support Scale-up activities → Cost improvement programs

R&D Services can be offered all through the spectrum of drug development

Development capability

Ability to deploy technology platform to address phase appropriate development & clinical needs

Pune

Development Facilities

- Development Labs and GMP Kilo Lab
- 75 FTEs for chemistry; 25 for biotechnology and 70 for analytical development
- Complete capability for optimization of solid form and product characterization
- Complete capability for chemical, biochemical & analytical development
- Hi-containment lab for handling upto OEL 0.1 µg/m^3
- Peptide development lab (Synthesis & Purification)

Small-Scale Facilities

- 20L – 250L scale glass, steel and Hastelloy reactors (-50 °C to 180°C)
- Centrifuge, Nutsche, pressure filtration and milling, micronization, nano and micron filters

Capacity & capability for rapid development and deployment to clinical supply & technology transfer

Our Manufacturing Facilities

Manufacturing capability

Ability to rapidly scale cost effective processes to address timely market access and commercial volumes

Vizag

HPAPI & Multi-purpose Full Scale Manufacturing

HPAPI:

- Fixed isolators & dedicated detoxification
- Glass, steel and Hastelloy reactors from 0.2M^3 – 1M^3 (-20°C to 150°C & pressure up to 4 Bar)
- Pressure filtration & drying, tray drying, sifting & milling

Multi-Purpose:

- Glass and Hastelloy reactors from 0.1M^3 – 8M^3 (-80°C to 150°C & pressure up to 10 Bar)
- Centrifuge, Nutsche, pressure filtration, milling & micronization
- Specialist unit operations - tangential flow filtration, wiped film evaporation & spray, fluidized bed & Nauta drying

Dabhasa

Multi-purpose Full Scale Manufacturing

- Glass and Hastelloy reactors from 0.25M^3 – 10M^3 (-20°C to 150°C & pressure up to 4 Bar)
- Hydrogenators 0.63M^3 – 3M^3, (up to 10 Bar)
- Specialist equipment for 200°C & 20 Bar operations
- Centrifuge & pressure filtration separation & drying, milling & micronization
- Specialist unit operations - lyophilization, nano filtration, wiped film evaporator, Nauta dryer and column chromatography

Wide range of process operating conditions and unit operations to address needs of cost-effective manufacture

Technology Transfer Teams for internal transfer or external receipt of processes for rapid demonstration and scale-up

Vizag HPAPI Capability

Commercial supply from 1Kg – 30 Kg scale for OEL of 0.05 µg/m³ or higher

Operations undertaken in Intermediates & Clean Room environments – dedicated detoxification area

Intermediate Area Environment

- Dispensing
- Charging
- Reaction 500L SS + 1000L HT
- Reaction 750L HT
- Filter-Dryer ANFD 500L SS + 250L HT
- Dryer VTD 12 Tray

Clean Room Environment

Temperature and Humidity Control (& 1 micron filtered air supply)

- Reaction 200L HT
- Isolation 400L HT
- Filter-Dryer ANFD 250L HT
- Dryer VTD 6 Tray
- Milling Multi Mill 5–30Kg / Hr
- Sieve 18 Inch dia.
- Packing Isolator

Detox.

2000L SS

+

2000L MSGL

The isolators in intermediate and clean area are designed for ISO Class 8 environment (Class 100,000)

Vizag capability on-line in June 2025 – additional existing asset to be brought on stream as needed

MSGL= Mild Steel Glass Lined; SS= Stainless Steel; HT= Hastelloy, ANFD= Agitated Nutsche Filter Dryer

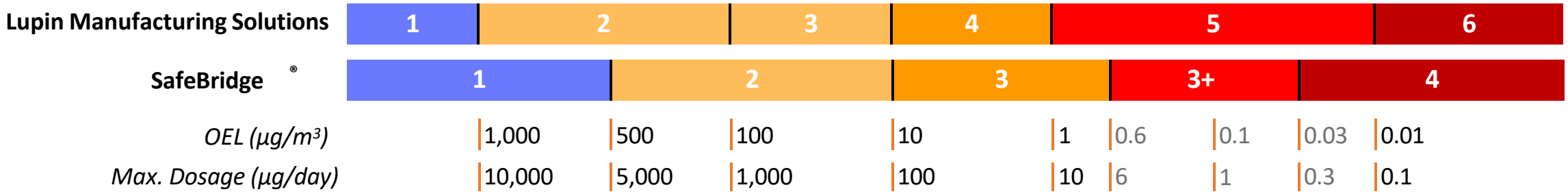
VTD= Vacuum Tray Dryer (3 Kg = Tray capacity)

Non-contained environments

Contained environments

Highly Potent Active Pharmaceutical Ingredients (HPAPI)

Development & manufacturing at OEL of 0.05 µg/m³ (SafeBridge 3+) or higher



SafeBridge®			Lupin Manufacturing Solutions		
Max. Dosage (µg/day)	OEL Range (µg/m³)	OEB (Occupational Exposure Band)		Max. Dosage (µg/day)	OEL Range (µg/m³)
>5,000	>500	1	1	>10,000	>1,000
100 – 5,000	10 – 500	2	2	1,000 – 10,000	100 – 1,000
			3	100 – 1,000	10 – 100
6 – 100	0.6 – 10	3	4	10 – 100	1 – 10
0.3 – 6	0.03 – 0.6	3+	5	0.1 – 10	0.1 – 1
<0.3	<0.03	4	6	<0.1	<0.1

Summary of SafeBridge and LMS' HPAPI banding

HPAPI Capability

Complete range of capability from development through commercial supply for OEL of 0.05 µg/m³ or higher

Pune Development

- Process development
- Non-GMP for toxicology & formulation development
- Synthesis, filtration, drying & finishing
- Fixed isolators & dedicated detoxification

Vizag Kg Labs

- 0.5 Kg scale demonstration
- cGMP for clinical & commercial supply
- Isolators for operation at 3L scale
- Dedicated lab for potent material analysis
- Quality Control lab for in process control and product release

Vizag Production[1]

- 1 Kg – 30 Kg scale
- cGMP for commercial supply
- 0.2M³ – 2M³ reactors with MSGL[2], SS[3] and Hastelloy
- Isolators for all dispensing, charging, discharging, sampling, filtration, drying, milling & micronization.
- Dedicated area for detoxification / decontamination

Wide range of process operating conditions and unit operations to address needs of cost-effective manufacture

[1] Vizag capability on-line in June 2025; [2] Mild Steel Glass Lined; [3] Stainless Steel

HPAPI Manufacturing capability

Ability to rapidly scale Hi-potent molecules at Vizag

INTERMEDIATE AREA

PP AREA

Quality, Compliance and Regulatory Affairs

More than 80 DMFs filed in 10+ countries

- FDA / TGA / ANVISA / MFDS / CDSCO / WHO approved sites in India
- Regulatory Affairs support and submissions
- Active dossiers in China, South Korea
- Validated computer systems for Quality Systems Management
- Regularly audited by our global customer base
- Exemplary audit history

Dabhasa
FDA, 2024 – NAI
WHO-CDSCO, 2023 – Certificate Issued
TGA, 2020 – Certificate Issued

Vizag
FDA, 2023 – NAI
WHO, 2023 – Certificate Issued
ANVISA, 2022 – Certificate Issued

FDA = Food & Drug Administration (US), TGA = Therapeutic Goods Administration, MFDS = Ministry of Food & Drug Safety (Korea), ANVISA = Health Regulatory Agency (Brazil), WHO-CDSO = World Health Organization – Central Drug Standard Control Organization (India)

Commercial Generic API Portfolio

>30 years of combined experience in compliant, cost-effective manufacture at Dabhasa and Vizag sites

> 40 commercial APIs addressing major diseases

- Haematology
- Infectious Disease
- Neurology
- Psychiatry
- Renal
- Respiratory

Enabling affordable medicines for critical treatments

- **Regulatory Affairs ensures access to all key markets**
- **Robust supply chain & systems drives on time deliver**
- **Excellence in quality secures fully compliant product**

Reliable supplier of high quality, cost-effective drug substance and providing access to key markets

ESG: Embedding Sustainability across Manufacturing

LMS fully integrated in the group program, enhancing Lupin's ESG score

100% sites in India successfully covered with ISO 14001 and 45001 certification.

Strong focus on Environment at Manufacturing locations (Decarbonization) – investments on Renewable Energy, Alternate Fuels, Energy Efficiency, Waste Management and Water Recycling.

Integrating ethical practices within our supply chain, emphasizing fair labor practices and responsible sourcing – ESG Assessment for suppliers.

Adopting Green Chemistry Principles – By bringing down product carbon and water footprints, reducing use of hazardous chemicals and solvents and replacing them with renewable green solvents and feedstocks.

Strong performance Year on Year in ESG Ratings

S&P Global ESG Score

17 (2021) → 46 (2022) → 69 (2023)

ecovadis

40/100 (2023) → 69/100 (2025)

CDP

B Climate C Water

Lupin Manufacturing Solutions

Your partner for high quality & cost-effective development and manufacturing of drug substance

Development — *Pune development & clinical supply facility*

- Capacity & capability to achieve timely, phase appropriate process development for optimal manufacturing process

Technology Transfer — *Dabhasa and Vizag demonstration & scale-up facilities*

- Experienced team for robust transfer & rapid deployment of processes

Manufacturing Across Value Chain — *Dabhasa and Vizag manufacturing facilities*

- Ability to scale manufacture of starting materials, intermediates and active ingredients through validation into supply

Quality, Regulatory & Compliance — *Implemented across all GMP activities at all locations*

- Robust quality & compliance systems for confidence in supply supported by global regulatory filings

Supply of Generic Active Ingredients — *Dabhasa and Vizag manufacturing facilities*

- Reliable supplier of high quality, cost-effective drug substance and providing access to key markets

Environmental, Social & Governance — *Lupin Group initiatives fully integrated into LMS*

- Strong & demonstrable commitment to ESG principles with year-on-year improvements across all parameters

Executed with strict maintenance of confidential information and project management excellence

Fast Track to toxicology & clinical API supply

Well defined, confident and cost-effective approach for fast tracking early lifecycle entities

	Features	Benefit for Customers	Value
Pricing	Fixed fee/ FTE model with clear SoW	Clarity on deliverables, timeline & cost (what, when & how much) Ensures costs remain within budget	Clarity, confidence, cost-effectiveness
Solid Form	Flexible solid form exploration as needed, and proactive selection of salt/co-crystal in early development Flag IP opportunities for life-cycle extension	Most viable option in line with formulation Avoid changes in later clinical development	Smooth transition into and through clinical trials Extend market position, revenue / profit
Chemical Development	Expedited familiarization run through & reduction to practice processes Optimized scale-up in Kg Lab	Fast delivery of toxicology or clinical product	Lightspeed deliveries
Analytical Development	Pre-defined SoWs: GMP release; utilize client methods; develop in-house methods; method validation	Customized offer that aligns with program needs and budget	Cost-effectiveness, Speed
Production	Up front clarity on QA standards & expectations Pre-determined in-process controls	Deliverables meet expectations Avoid extra costs associated with rework Agility during execution	Clarity, confidence, cost-effectiveness Speed to market

✓ **Offerings as per the Voice of Customer**

✓ **Cost-effective & Lightspeed Deliveries**

Thank You

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