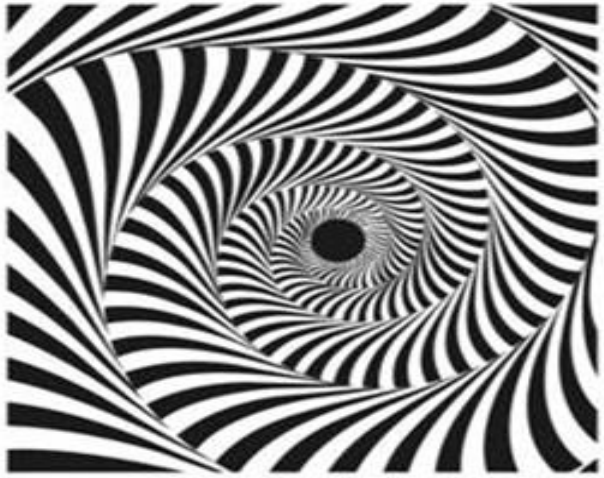
# Etico Lifesciences Pvt. Ltd.

Excellence Through Innovation

KNOWLEDGE
PARK

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# Mission Statement

*Our mission is to become a global leader in developing critical and innovative parenteral products at affordable cost for the benefit of the society.*

# Salient Features

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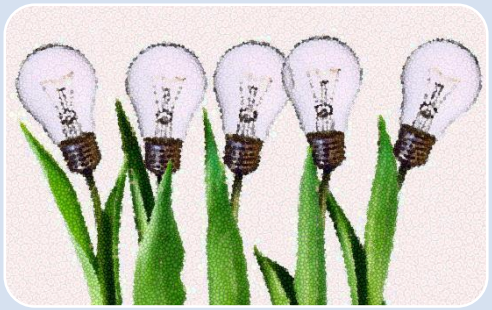

## Quality & innovation

- Specialized in parenterals
- QbD Approach
- Innovative technologies

## Infrastructure

- State of the art R&D centre
- Dedicated potent suite
- Experienced research staff

## Niche business

- Critical and complex parenterals
- 505(b)2 formulations
- Less competition
- High value products

## Customer satisfaction

- Timely deliveries
- Dedicated PM
- Flexible business model
- Regulatory support

# Corporate Overview

- Established in Aug’2016 in Hyderabad, India
- Facility setup expected to be completed by Jan’2017 in IKP Knowledge Park
- Distinguished state of the art R&D lab for handling oncological and non oncological molecules.
- Identified land to set up a US FDA & PMDA Japan compliant commercial manufacturing plant in Genome Valley, Hyderabad, India.
- Founded and run by pharmaceutical professionals having cumulative experience of more than 25 years in Pharmaceutical product development, manufacturing, regulatory filing and commercialization.
- Engaged in the business of developing specialized oncological and non oncological parenteral dosage forms.
- Injectables & ophthalmic products handling capability - Solutions, emulsions, suspensions, lyophilized products, liposomes, microspheres, nanoparticles, etc.
- One stop solution for all your parenteral product development needs.

# Organizational Structure

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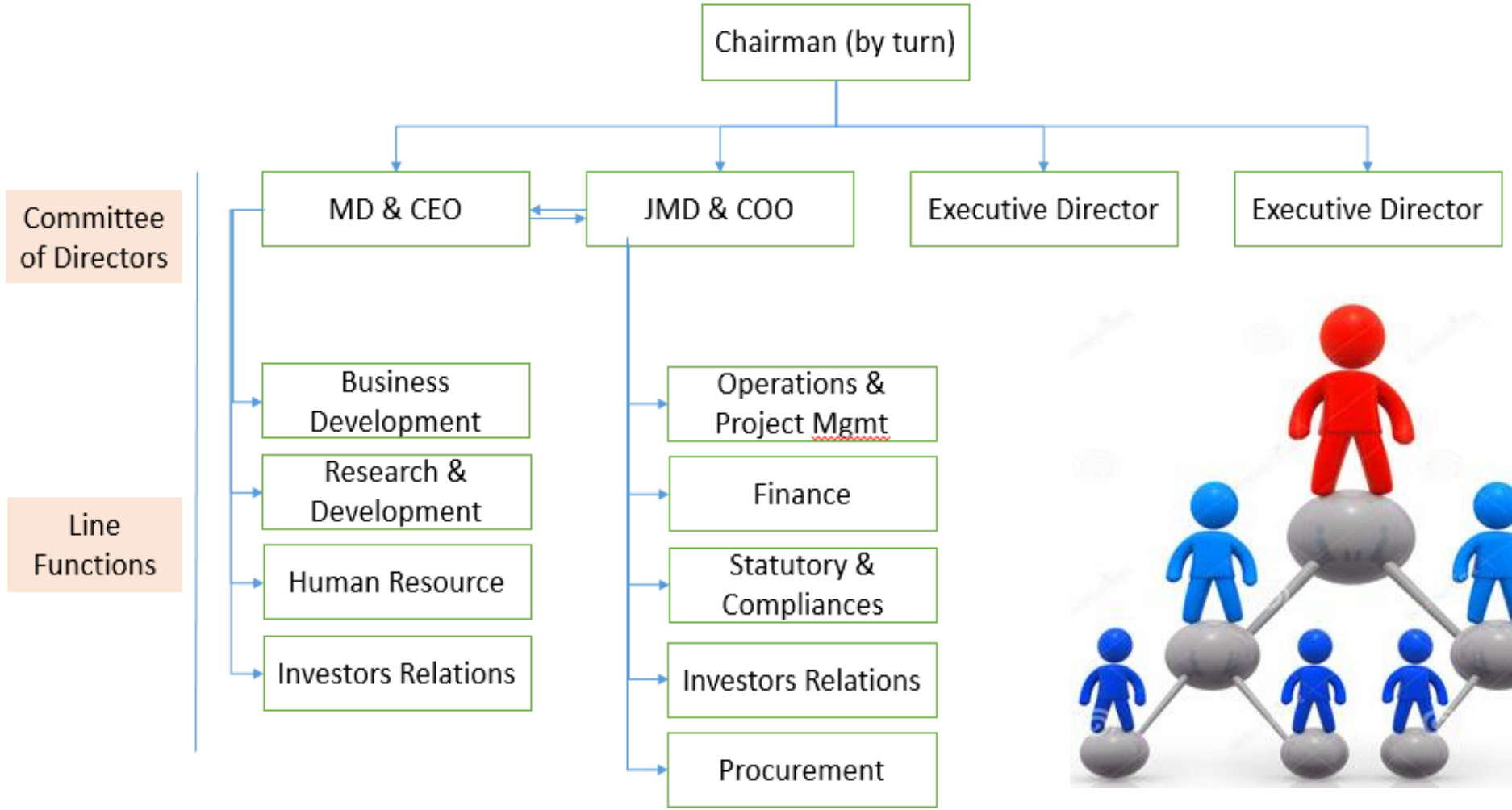

# Key Personnel

| S. No | Name of Key Staff Member | Qualification | Designation | Years of experience | Expertise |
|---|---|---|---|---|---|
| 01 | Dr. Tathagata Dutta | PhD, Post Doc. | MD & CEO | 15 + years | New Product Development of small and large molecules; NCE & NDDS Formulation Development, Analytical Development, Process Development, Regulatory Filling, Approvals and Commercialization. Specially experienced in Depot Injections, Liposomes, Microspheres, Nanoparticles, Ophthalmic products, etc |
| 02 | Dr. Jyotirmoy Tripathi | PhD, MBA, Six sigma master black belt | JMD & COO | 25+ years | Project management, Operations, QbD, |
| 03 | Srinivas Medishetty | M. Pharmacy | Director NPD | 11 Years | Product Development & Process Development of Injectable & Ophthalmics |
| 04 | Aniket Manathkar | MBA, MS | Associate Director BD | 08 Years | Product Development of NCE & Generic Products, Business Development & Out-licensing |
| 05 | Chandramohan Rao G | M. Pharmacy | Manager DRA | 06 Years | Drug Regulatory Affairs |

# Department wise Headcounts

- Employee Breakup

| Department | No. of Full Time Employees |
|---|---|
| FD | 9 |
| AD | 18 |
| DRA | 4 |
| DQA | 2 |
| Microbiology | 2 |
| **Subtotal** | **35** |

**Note**: Support staff HR, IT, Finance, Purchase not included.

# Infrastructure

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- State of the art R&D setup with 10,000 sq. feet of carpet area.
- List of key instruments & equipment -

| Formulation Development Lab Key Instrument & Equipment List | |
|---|---|
| Mechanical stirrer | Viscometer |
| Magnetic stirrer | Weighing balance |
| Vacuum Pump + Filtration Assembly | DO + HO meter |
| Lyophilizer | Rotary evaporator |
| Hot air oven | High pressure homogenizer |
| Autoclave | Homogenizer |
| Stability chambers (All 4 ICH zones) | Laminar air flow |
| Photostability chamber | Isolator |
| pH meter | Deep freezer |
| Osmometer | Refrigerator |

# Infrastructure…..cont.

| Analytical Development Lab Key Instrument & Equipment List | |
|---|---|
| HPLC | Conductivity meter |
| Water Purification System | pH meter |
| Micro Balance | Bath Sonicator |
| Weighing Balance | Electronic desiccator |
| UV Spectrophotometer | Viscometer |
| Gas Chromatography | Dissolution Apparatus (USP Type I, II & IV) |
| Nitrogen Generator | Density meter |
| Melting Point Apparatus | KF Titrator |

# Infrastructure…..cont.

| Microbiology Lab Key Instrument & Equipment List | |
|---|---|
| Laminar Air Flow | Autoclave |
| Hot Air Oven | Deep Freezer |
| BOD Incubator | Weighing balance |

# Core Expertise

**Formulation Development**

**Analytical Development**


**Developmental QA**

**Stability Testing**

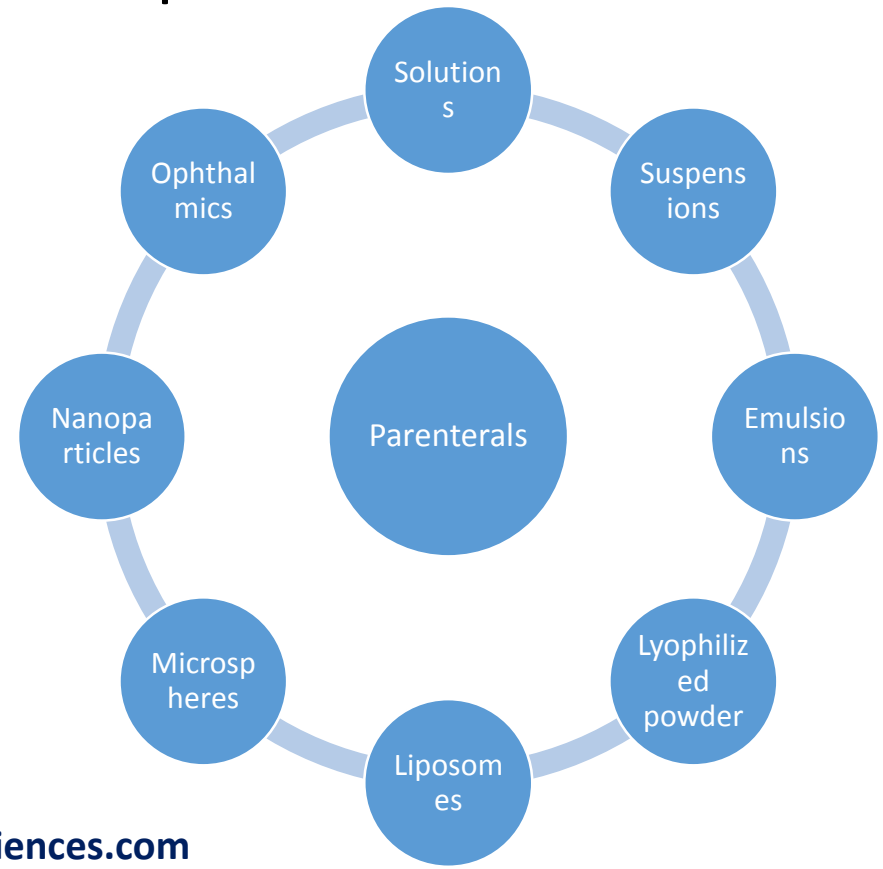
**Microbiology**


**Regulatory**

**IPR**

# Formulation Development Capabilities

- Parenteral formulations (Oncological and non oncological)
- Dedicated area with isolator to handle potent molecules.
- Dosage form development
  - Injectable solutions
  - Injectable suspensions
  - Injectable emulsions
  - Lyophilized powder for inj.
  - Ophthalmic preparations
  - Liposomes
  - Microspheres
  - Nanoparticles



# Analytical Development Capabilities

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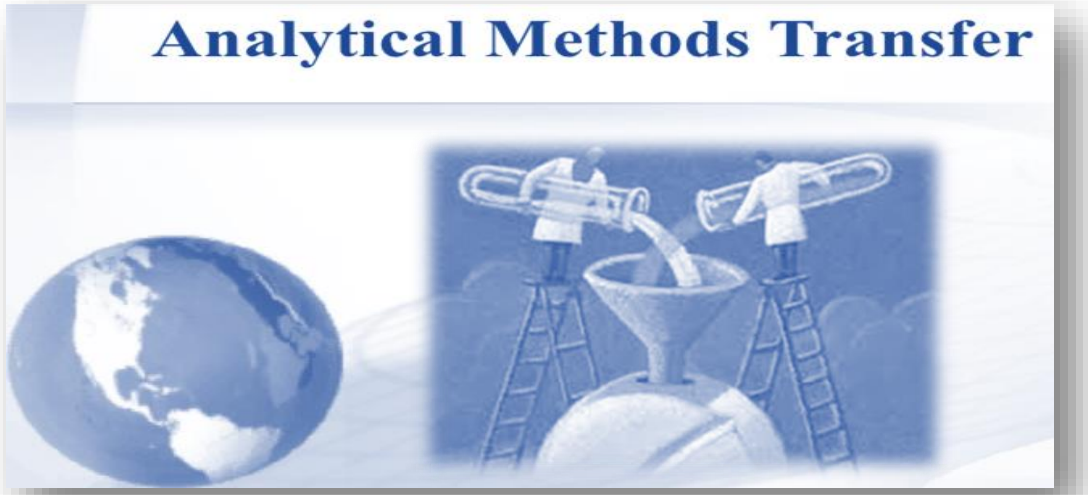

# Developmental Quality Support

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- Quality assurance
- Regular quality audits (internal & external)





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# Stability Testing Capabilities

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- Stability testing (All ICH Zones)
- Protocol development
- Data monitoring
- Stability testing reports
- OOS/OOT Analysis

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# Microbiology Testing Capabilities

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- Preservative efficacy test (PET)
- Bacterial Endotoxin Test (BET)
- Sterility test

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# Regulatory Support Capabilities

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- Dossier compilation
- Dossier submission
- Handling regulatory queries
- Pre-NDA meetings
- Supporting regulatory audits and approvals
- Post approval changes


## Role of Regulatory Affairs

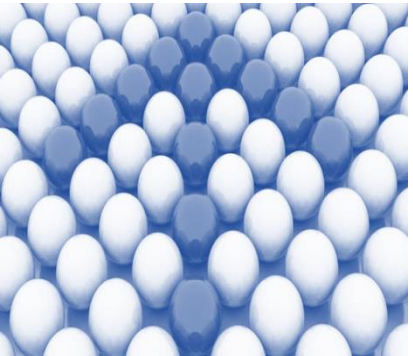

***Helping you stay ahead of regulatory change***

# IPR Capabilities

- Patent landscaping
- Non infringement analysis
- Drafting & filing patents
- Litigations


# Business Strategy

- Become a key global player in parenteral (oncological and non oncological dosage forms) development, manufacturing and registrations.
- Product portfolio selection
  - Competitive advantage
  - Develop novel, critical, difficult to make parenteral formulations
  - Para IV
  - Complex Para III products
  - 505(b)2 products
- Maintain zero conflict of interest with clients



# Business Models

- Fee for service
  - ✓Milestone based contract development
- Dossier out-licensing
  - ✓Upfront fee with profit sharing
  - ✓Upfront fee without profit sharing
- Out-licensing of products at POC (proof of concept) stage
  - ✓Upfront fee with profit sharing
  - ✓Upfront fee without profit sharing
- Co-development
  - ✓Split of expenses & profit with pre agreed %

# Contact Us

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thank you
danke
謝謝
ngiyabonga
рахмат
teşekkür ederim
спасибо
gracias
dank je
tapadh leat
Баярлалаа
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