PharmSol

Smart Products, Bespoke Solutions

Jan 2023

PharmSol

18 Years of Excellence

100+ Successful Products & Technologies

1000+ Successful Solutions

PharmSol

MISSION

Committed to the Pursuit of Excellence through Smart & Quality Products and Providing Expert Solutions to meet the needs of Pharma, Biotech.

VISION

To be One of the Worlds' Leading and Most Reliable Products & Solutions Partner

PharmSol

Global Presence

PharmSol GmbH, Germany

PharmSol Europe Ltd., Malta

PharmSol, Hungary *(under formation)*

Pharmaceutical Solutions FZCO, Dubai

Pharmaceutical Solutions DMCC, Dubai

Agile FZCO, Dubai

PharmSol India Pvt Ltd, India

PharmSol (Nanjing) Technology, China

PharmSol - Pharmaceutical Products and Trading, Philippines

PharmSol, Egypt

PharmSol, Vietnam

Eminus eGlobal Institute Pty Ltd., Australia

Our Products

PharmSol

Cooperation Models

- Licensing & Supply
- Contract Development & Manufacturing
- Co-developments
- Tech Transfers

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Track Record

25 (+) APIs
successfully developed
& commercialized

100 (+) FDF
successfully developed

300 (+) MAs

60 (+)
Tech Transfers

55 (+) BE
Studies

Strong bonds with ***50 (+)***
major manufacturer

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Licensing & Supply Products…
List available on request

PharmSol

Co-development Products…
Confidential

PharmSol

Tech Transfer Products…
List available on request

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CDMO Products…
Confidential

Our Solutions

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Our Solutions

GMP Audit

ComplAnce

BIOSIMILAR

Regulatory & Market Access

FDA COMPLIANCE & REGULATORY

EUGMP

Product Development

SOURCING & SUPPLY CHAIN

Facility Design & Project Management

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Our Solutions

GMP Audit

- GMP Audits
- Bulk Audits
- Shared Audits
- GDP, GLP, GCP Audits
- EHS Audits
- Quality Due Diligence

ComplAnce

- EU, AU, WHO, PIC/s GMP Certification
- CAPA Support
- QMS Design & Remediation
- Computer System Validations
- Data Integrity Solutions
- Serialization
- GDP Certification
- GxP Training

FDA COMPLIANCE & REGULATORY

- Gap Analysis Audits
- CAPA Guidance / Assistance
- Training for Inspection
- Post Inspection Remediation (483s / Warning Letters)
- Ongoing compliance monitoring
- US ANDA Preparation & Submission

Regulatory & Market Access

- Dossier Preparations / Submissions
- Pharmacovigilance
- MA Holding
- EU Importation, Batch Control / Release
- Scientific Advice
- GCC Product / Company Registration, Marketing & Distribution

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Our Solutions

Product Development

- Product Developments (API & FDF)
- Patent Evaluation
- Tech Transfers
- Scale ups
- BE Studies
- Licensing In/Out

BIOSIMILAR

- Evaluation of development candidate
- Process Development
- Facility Designs
- Quality System
- Compliance
- Scientific Advice
- Registration in EU/US/AU

SOURCING & SUPPLY CHAIN

- APIs, KSMs
- Finished / Semi Finished Formulations
- Excipients / PMs
- Vendor Qualification
- Technical & Commercial Negotiations
- Pre-shipments Inspections / Approvals
- Supply Chain Management

Facility Design & Project Management

- Facility Technical Assessment
- Due Diligence
- Conceptual Design Review
- Facility Design
- Facility Remediation
- QMS (Multilingual)
- Qualifications & Validations

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Track Record

1400 (+)
GMP/QP Audits

50 (+) Facilities
certified by US / EU

15 (+) Facility
Compliance Remediations
(US/EU)

60 (+)
EU Registrations,
Ongoing ***18 Procedures***

55 (+)
Analytical Methods

200 (+) Clients

Management Team

PharmSol

Leadership

Sunil Doshi

Founder & Managing Director

36 Years of Global Techno-commercial Expertise in Pharma Industry

S. Lakshminarasimhan

Chief Operating Officer

25 Years of Pharma Technology, Compliance & Regulatory

"Leading a global team of **80** committed professionals."

SMEs

Christian Duchow
Senior Business Associate
30 years in European Pharma Business

Borut Strukelj
Senior Scientific Adviser
35 years of expertise in Biotech, Biosimilars & Regulatory

Andrej Gasperlin
Senior Business Associate
35 years in US Pharma Business

Rajeev Patil
Senior Regulatory Advisor
40 years of USFDA Compliance & Regulatory expertise

Ganesh Sangaiah
Director – NDDS
26 years of expertise in NDDS

Ashish Dasgupta
Senior Scientific Adviser
40 years of expertise in Clinical, Quality & Regulatory

Heads – Key Verticals

Manish Rajeshirke
Vice President – Business Development
21 Years in International Pharma Business

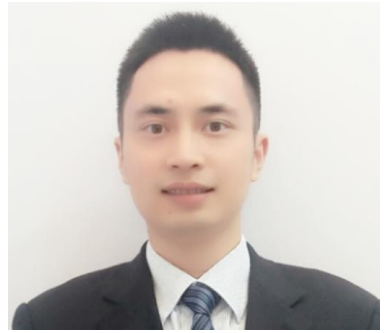
Ravikanth Mandapati
Vice President – Quality Affairs
28 years in Pharma Development, QA & Analytics

Abhay Asthana
General Manager - Technology
19 years in Pharma Formulation Technology & Product Development

Medarametla Rambabu
General Manager - Manufacturing
20 years in Pharma Production & Project Management

Felix Huang
Director – China, BD
10 Years in China Pharma Business

Nancy Yao
Director – China, Technical Operations
11 Years in China Pharma with Compliance



Shawn Xiao
Director – China, BD
15 Years in China Pharma Business – API, Intermediates

PharmSol

Accreditations

BPI Bundesverband der Pharmazeutischen Industrie e.V.

VERBAND DER CHEMISCHEN INDUSTRIE e.V.
WIR GESTALTEN ZUKUNFT.
VCI

ECA ACADEMY

bsi. ISO 9001:2015 Quality Management

ASQ

APIC Active Pharmaceutical Ingredients Committee

cefic

Some Esteemed
Clients

HANSOH PHARMA
Laboratoires Continental Pharm
BIOFARM
CSC
DORRA PHARMA 道尔医药
Velit Biopharma
acino
genepharm
Galenica
ABHILASH CHEMICALS & PHARMACEUTICALS
ADCAN Pharma
TECNIMEDE GROUP
Resproly 瑞思普利
Recipharm good for business
DUOPHARMA
新華 新华制药 XINHUA PHARM.
africure
恒瑞 恒瑞医药 HENGRUI PHARMA
Overseas Pharmaceuticals
深圳华润九新药业有限公司 Shenzhen China Resources Gosun Pharmaceuticals Co.,Ltd.
Evertogen
bcpp
UniMed UniHealth Pharmaceuticals
Healthcare
InterChem
GL Galpha Laboratories Limited
青松股份 GREEN PINE
CTTQ
国药集团 SINOPHARM 国药致君 SINOPHARM ZHIJUN
国药集团所属国药现代成员企业
齐晖 QUALITY HORIZONS
皇隆制药 HUALON
Caelo
HASCO-LEK WROCŁAW
鲁安 Luan
ARISTOPHARMA LTD. Manufacturer of Pharmaceutical Products
SANBE
سبيماكو الدوائية SPIMACO ADDWAEIH
FUKANG
ceva
NATCO
BEXIMCO PHARMA here's to life
SK+F ESKAYEF BANGLADESH LIMITED www.skfbd.com
珍寶島药业 ZBD Pharmaceutical
MCC MAGISTRA C&C CERTITUDINEA CALITATII MEDICAMENTULUI
ADAMED GROUP
齐鲁制药 QILU PHARMACEUTICAL
LIVISTO Along with you
BC Anhui Biochem
Athenex
Sri Krishna PHARMACEUTICALS
aris ali raif ilaç sanayi
UNISON
ELPEN

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Thank You!