



API Presentation



INNOVATING FOR AFFORDABLE HEALTHCARE

- ∴ Our Commitment & Focus
- ∴ API Manufacturing Facilities & Capabilities
- ∴ Business Segments
- ∴ R&D & Capabilities
- ∴ Regulatory Affairs – Inspection history & Approvals – DMF Filings
- ∴ Analytical Capabilities – Development & Quality
- ∴ EHS
- ∴ API Core Team
- ∴ CSR Activities
- ∴ Awards & Recognition's



Commitment

Innovate for providing affordable healthcare



Focus

Quality for our Customers

Our Journey:

1987 : Established as Shilpa Antibiotics Ltd.

1989: Started its first commercial production of Trimethoprim.

2004: Filed first patent application.

2011: Acquired controlling stake in “Shilpa Therapeutics”.

2012: National Energy Conservation Award by President of INDIA.

2013: Formulations facility became fully operational.

2015: API & Formulation facilities got USFDA Approval.

2021: Partnered with Dr. Reddy’s for Covid-19 vaccine manufacturing

2022: API Business separated as Shilpa Pharma Life Science Ltd.

1987-90

1991-95

2001-05

2006-10

2011-15

2016-20

2021-25

1992: Antibacterial products mfg started for GSK & Bombay Drugs

1993: We are into a Public Limited Company

1995: Listed on Bombay Stock Exchange.

2008: Govt. of India awarded 'Best Entrepreneur Award.

2009: Listed on National Stock Exchange.

2010: Setup Unit-II, 100% EOU (Capex of Rs. 1000 Mn).

2016: First MAH approved in EU & First ANDA approved in USA

2017: Acquired stake in Navya Biologicals Pvt. Ltd.

2018: Bagged Export Excellence Award.

2019 : API production facilities got Approval by USFDA.

2020: API Production facilities got approval by USFDA with zero 483.

Manufacturing facilities:

First company in India to come up with Isolator technology and one of the largest ONCO manufacturing facilities in India.

UNIT-I



- **Unit-1** Located at Deosugur Industrial Area, Raichur, Karnataka, India
- Oncology & non-oncology API Facility
- **7 API blocks with 325 Kilo Liters capacity**
- **USFDA, WHO GMP, KFDA, EUGMP, TGA, PMDA, TPD & Russian GMP.**
- Certified for ISO 9001:2015; ISO14001-2015 and OHAS: ISO45001:2018,ISO50001-2018,SA8000-2014, Implemented OSHA 3132 PSMS, IH Protocol

UNIT-II



- **Unit-II** (100% EOU) located at Raichur Industrial Growth Center, Raichur, Karnataka, India
- Oncology & non-oncology API & CRAMS Facility
- **10 API blocks with 522 Kilo Liters capacity**
- **USFDA, WHO GMP, KFDA, EUGMP, TGA, PMDA, TPD & Russian GMP.**
- Certified for ISO 9001:2015; ISO14001-2015 and OHAS: ISO45001:2018,ISO50001-2018,SA 8000-2014, The company ESG systems assessed by

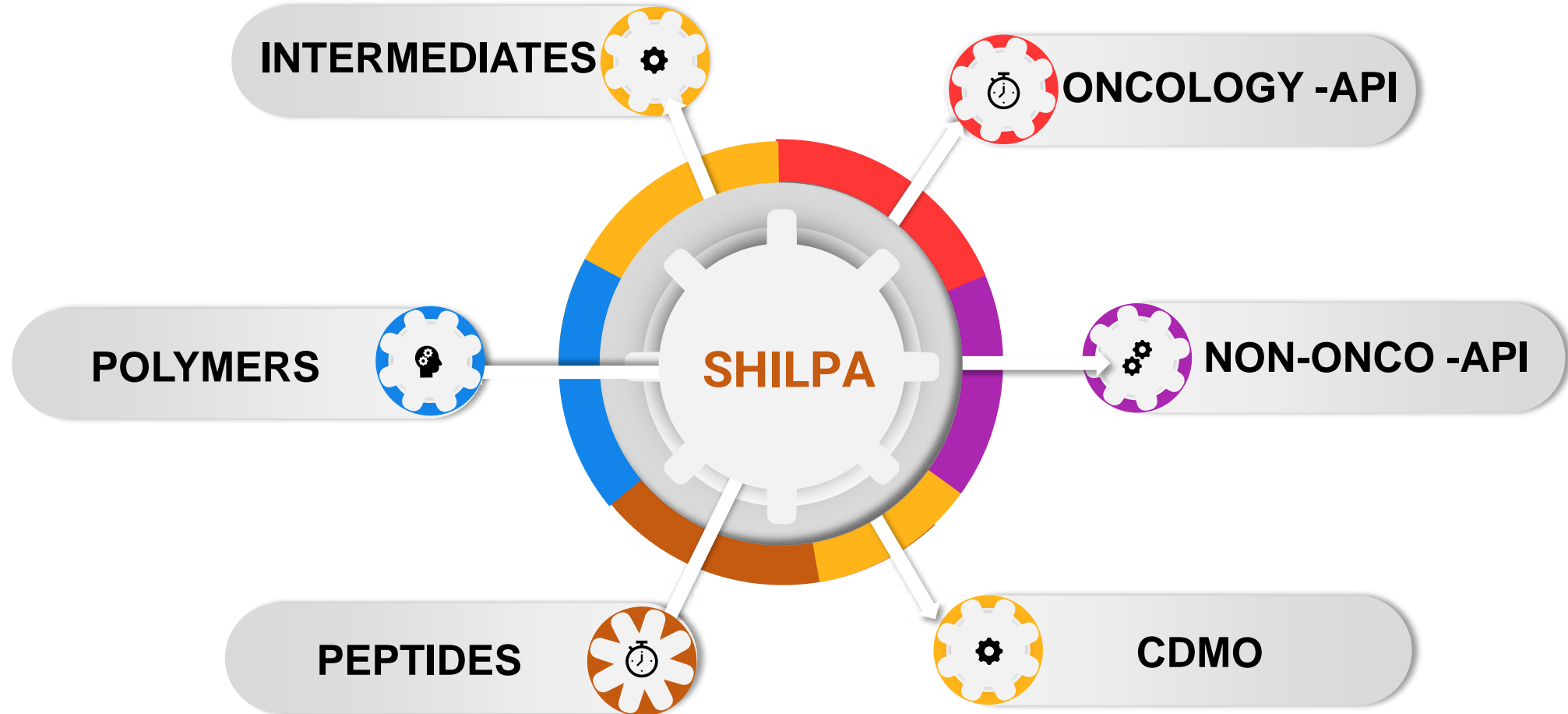
Manufacturing facilities & Infrastructure: *(Continues)*

- One of the largest dedicated oncology manufacturing facilities which can handle from gram scale to multi-ton capacities. Facility can also manufacture various non-oncology, peptide and polymer products.
- Capable of handling broad spectrum of reactions and a wide range of process parameters
- Facility is designed with complete containment (Isolators) to handle oncology products of different OEL categories

Pilot Plant Facility					
Unit	Block	No. of Reactors	Capacity range (L)	Total capacity(KL)	Remarks
EOU	R&D Pilot plant	5	100L-500L	2.0 KL	For scale-up studies and small scale synthesis

Manufacturing Facilities					
Unit	API Blocks	No. of Reactors	Capacity range (KL)	Total capacity (KL)	Remarks
Unit I	7	69	63 L - 25 KL	337 KL	For Mfg. of intermediates & APIs & HP-API.
Unit II EOU	10	138	5 L - 16 KL	525 KL	
Unit-SML	5	33	0.8 KL – 25 KL	152 KL	
Pipeline	1	6	35 KL -40 KL	145 KL	Relocated to Shilpa Biocare
Total Volume (KL)				1159 KL	

BUSINESS SEGMENTS:



- One of the first companies to enter into manufacturing of Oncology API in India.
- About **40 oncology products** in our product portfolio Strong position in regulatory backup.
- **9 dedicated oncology products manufacturing blocks** designed to operate from 300 grams to 350 Kgs per batch scale.
- Blocks are designed in such that, small, moderate, big batches can be accommodated.
- **India's first company** to come up with the **Isolator technology** with Facilities designed to handle oncology products up to OEL-4 category ($<10 \mu\text{g}/\text{m}^3$) considered to be gold standard in Onco API manufacturing.
- Track record of meeting stringent quality requirements for Japan.

ONCOLOGY Portfolio:

Existing Molecules Top-10

- Gemcitabine Hcl
- Capecitabine
- Temozolomide
- Bortezomib
- Irinotecan
- Bendamustine
- Busulfan
- Pemetrexed Disodium
- Azacitidine
- Imatinib Mesylate

Existing Molecules Others

- Axitinib
- Bicultamide
- Cabazitaxel
- Cyclophosphamide
- Decitabine
- Enzalutamide
- Fingolimode
- Ibrutinib
- Lenalidomide
- Lenvatinib
- Melphalan
- Nilotinib
- Pomalidomide
- Sorafenib
- Sunitinib Malate

Pipeline Molecules

- Palbociclib
- Pazopanib Hcl
- Abiraterone Acetate
- Olaparaib
- Methotrexate

U/ Development Molecules

- Ruxolitinib
- Topotican Hcl
- Tofacitinib citrate
- Vismodegib
- Acalabrutinib
- Cytrabrine EP
- Docetaxel (Anhydrous & tri hydrate)

NON-ONCOLOGY :

- Greater impetus on non-oncology segment since past 2-3 years
- About 18 non-oncology products in the product portfolio
- Eight non-oncology multi-products manufacturing blocks designed to operate from 25 Kgs to 2,000 Kgs per batch scale
- Facility designed to comply the global regulatory requirements
- Shilpa is Globally having about 50% Market Share in Ambroxol & about 20% of Tranexamic acid.
- First company in India to start Tranexamic Acid manufacturing using Japanese technology, also First company from India having CEP and DMF.
- Adding high volume products leveraging on our existing products /customers
- Backward integration with flow technology by expanding high volume capacity

NON-ONCOLOGY Portfolio:

TOP Existing Molecules

- Ambroxol
- Tranexamic Acid
- Palmidrol
- UDCA
- Phenylephrine
- Nifedipine
- Citicolin sodium

Other Molecules

- Pirfenidone
- Dimethyl Fumarate
- Varenicline Tartrate
- Terifluonamide
- Montelukast Sodium
- Oxcarbazepine
- Lanthanum Dioxy carbonate
- Eltrombopag

Pipeline Molecules

- Nintedanib
- Oleoylethanolamide

U/ Development Molecules

- Mycophenolate Sodium
- Mycophenilate mofetil
- Feric carboxy maltose

PEPTIDE:

- Independent Peptide R&D Centre and Dedicated peptide manufacturing facility (Unit-1) is in place. Synthesis capability includes solid-phase peptide synthesis (SPPS), Liquid-Phase Peptide Synthesis (LPPS), Microwave-assisted synthesis and Hybrid Synthesis (SPPS + LPPS).
- Highly experienced team of scientists for the development of short as well as long chain Peptide molecules from milligrams to kilograms scale. Comprises Synthesis to Purification by using advanced techniques which are commercially viable and eco-friendly.
- Expertise in Peptide Drug Conjugation (PDC) and various modifications, cosmetic peptide product development
- 2nd Company in India to adopt new Technology (Automated Microwave synthesizer, CEM Microwave SPPS synthesizer) allowing for Kilogram scale production of peptides. It allows major improvements in Peptide purity, synthesis speed and solvent reduction.
- Servicing to various custom made peptides based on client demands (CDMO space) and fulfilling their requirements.
- Two product filled CEP, another GLP analogue process validation is under progress, 3-more product under development in the Lab.

PEPTIDE:- Pipeline

S. No.	Product Name	Stage	Lab Validation	Plant trial	Plant Validation
1.	Desmopressin Acetate			CEP Filed	
2.	Octreotide Acetate			CEP Filed	
3	Liraglutide	LRG –II	Completed	Completed	Under progress
4.	Semaglutide	SMG-I SMG-II	All know impurities prepared. Semaglutide API 20 mmole batch under progress.		
5.	Teripartide	TER-I TER-II	Under development .		
6.	Tirzepatide		Under development .		

- Shilpa is amongst the very few companies in India, which has Dedicated Polymer Research Labs, Pilot scale & GMP Facilities to produce polymeric materials from gram scale to Kg to Ton scale by establishing Novel Techniques of Polymerization methods.
- Our focus is mainly on Specialty Polymers & Polymers for Pharma, Biomedical applications.
- Vision & Strategy of the P R & T Department in the following areas.
 - Scientific services
 - Technology Development
 - Polymer excipients by cGMP
 - Toll manufacturing
- Presently established collaboration with 6 foreign companies (MNCs) and Indian defense DRDO and received award for Development of scalable process for Anionic HTPB

- Integrated, one stop CMC solutions for preclinical, clinical and commercial outsourcing services of both Drug Substance and Drug Product for Small Molecules and Biologicals.
- Servicing to various small biotech companies to mid pharma for new chemical entities (NCEs) for their product development under CDMO space.
- Working on various Oncology, non-oncology, cosmetic, complex chemistry product in R&D and manufacturing under cGMP and non-GMP condition.
- More than ten active program is under progress in CDMO space.
- Developing Complex API and high potent API solutions to Innovator Pharma and Biotech companies in CDMO model.
- Specialized Chemistry one stop solutions from development to cGMP supplies for Solid phase peptide synthesis, Polymers and Flow Chemistry.
- Within one year of decision to commercialize this space, engaged with 4 global innovators for 7 ongoing programs

OUR TOP CLIENTS:

We have associated with them from past 10 - 15 years for their developmental quantities to commercialization.



INTERMEDIATES

- Today Major Pharma companies depended on China or outsider for the Key intermediates & KSM, which Shilpa wanted to capture this opportunity.
- The molecule which can take the additional cost at the at bottom line (whose GM are high).
- To overcome this we are working on In-House Technology (Batch Process/ Conventional) and also made collaboration with Sravathi (for continuous process).
- We have made an internal strategy for outsourcing of KSM's & intermediates considering regulatory & ROW markets.
- In this view we identified two sites, one for regulatory intermediates for DMF filings & another for KSM & ROW intermediates (GMP site).

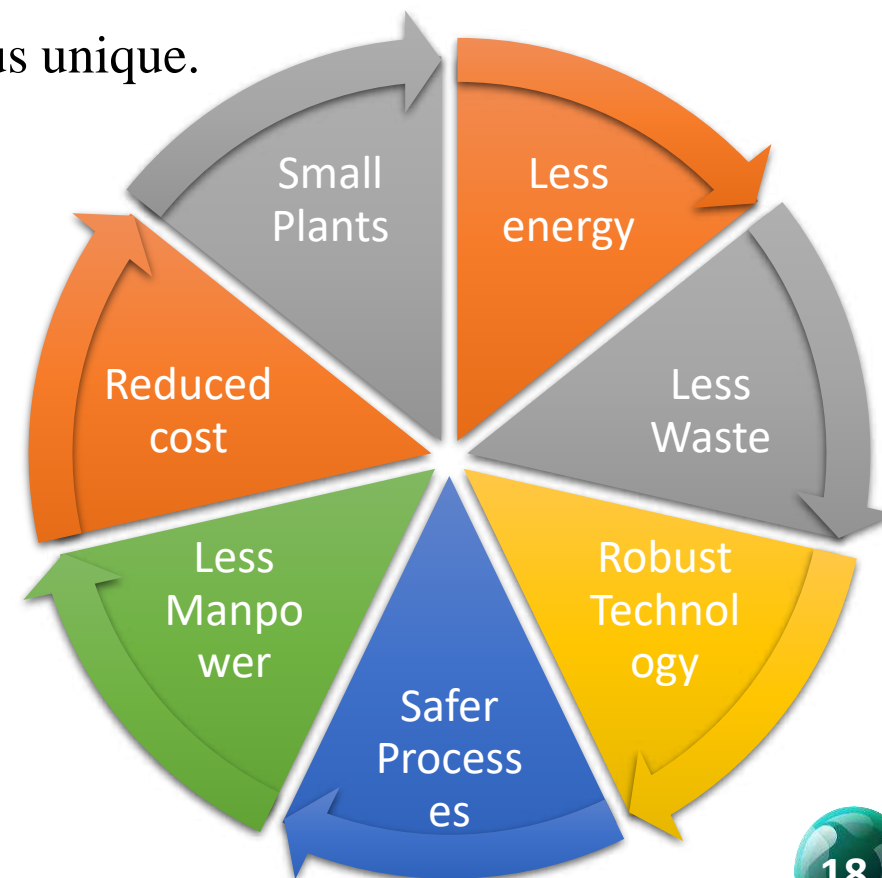
INTERMEDIATES

Products status

- Pilot scale up of Few intermediates like Formamide, Sulfamide, 3-HAP, 10-MISB, AIC, SABAM.HCl, EBP & EFP are completed.
- In-house Validation of Formamide Acetate & Abacavir Sulfate KSM are completed.
- Validation at external site- AIC, SABAM.HCl & EBP were completed.
- Other intermediates like OCBN , OTBN, Citicoline KSM, RPMPA, Montelukast KSM, & Valacyclovir KSM under development.

How are we different

We are working on Flow **technology** for high volume intermediates and KSM's which makes us unique.



Intermediates : Flow Technology

- We develop Differentiated Process Technologies (DPT) using Flow Chemistry & AI/ML
- There are valuable intermediates which are still produced using batch process.
- There are several gray areas in batch process due to long reaction times and cumbersome isolation and purification.
- We will invent new methods of manufacturing of intermediates & API which fully leverages the advances in process intensification with flow technology.
- We focus on improving overall efficiency of process & product using lean manufacturing principles.
- Classes of reactions are few example.

Reaction Types	
✓ Grignard Reaction	✓ Amidation
✓ Oxidation	✓ Diazotization
✓ Nitration	✓ Hydrogenation
✓ Chlorination	✓ Alkylation

Research & Development :

Shilpa initially established with only Chemical Research & development along with required analytical Research development and now it is diversified into different R&D segment's as follows.

- Chemical Research & Development
- Analytical Research & Development
- Peptide Research & Development
- Polymer Research & Technology
- DPI –Differential Process Intensification (Flow & continuous) Innovation & Research.



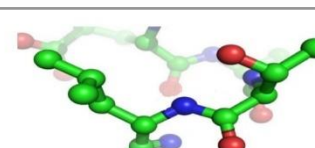
Chemical
Research &
Development



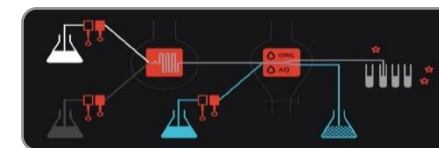
Analytical
Research &
Development



Peptide
Research &
Development



Polymer
Research &
Technology



Flow &
continuous
innovation

Research & Development :

The Research & Development activities at Shilpa are designed to be carried out in full compliance to sound Intellectual Property principles in vogue. The product pipeline and patent portfolio management is efficiently harmonized and overseen by the Intellectual Property Management & Legal Affairs Cell.

We are committed to scale up productivity of our business continuously, marked by a quest for seeding potential opportunities.

- ✓ R&D Facility Can handle 5 Verticals, 5 Teams can work on Different molecules
- ✓ R& D Facility is designed to handle oncology molecules (Isolators / Up to OEL-IV) & non-oncology molecules.
- ✓ Fully in house Supported Analytical Development lab for in process, optimization, method development & regulatory requirement.
- ✓ CR&D & AR&D Comprises about 20+ PhD's and 200+ MSc / M-Tech.
- ✓ Strong dedicated IPM team for patent filing and evaluation.

R&D Capabilities:

Our Reaction Capabilities



Highly qualified team

Professionals ranging from Doctorates in Organic Chemistry and Pharmacy to graduates with **20+ Doctorates, 200+ Masters, etc.**



Molecule selection

Systematic approach involves evaluation of technical and commercial feasibility and customer feedback leading to lucrative return on research spending.



Capabilities

R&D Centre, along with a Kilo Lab, has proven capabilities in carrying out a **wide range of reactions**



Patents

Our IPM team supports development of patent applications, files patents, supports the development of patent applications.

- Shilpa having capabilities in handling of all kind of reactions which comes across different API manufacturing.
- Having specific expertise in handling of **Nitration using Flow**.
- Handling of **Chemo Catalysis Rxn's, Bio catalysis Rxn's**.
- Exploring for **Photo Chemical Rxn's**.
- Capable of handling **Fluorinations**.
- Capable to handle **Long chain reactions**.
- Capable of Handling different polymerizations which are very sensitive for Moisture and Air with Higher scale .
- Capable of handling of High pressure reactions of different scale from 250 Lts to 16000 Lts.
- Having capable of handling High temperature reactions (more than 280°C).

R&D Core Team:

Name	Designation	Shilpa Experience	Over all Experience
Dr. AVSS Prasad	Associated Vice President-ADL	3 Months	30 Years
Dr. Praveen Cherukupalli	Vice President-CR&D	2 Months	25 Years
Dr. K. Dipak	Vice President-CR&D	1 Year	23 Years
Dr. Bhagath Raj	Sr. General Manager –CR&D	11 Years	28 Years
Dr. Doddappa	Sr. Manager –CR&D	1 Year	14 Years
Dr. Girish	DGM (TT)	6 Years	13 Years
Mr. Sivarami Reddy	Sr.Manager (CR&D)	1 Year	18 Years
Mr. Shiva Kumar	Sr.Manager (CR&D)	1 Year	18 Years

Regulatory Affairs:

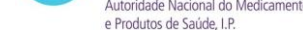
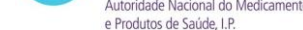
- We are committed to manufacturing products in total compliance with regulatory requirements and customer expectations.
- All process and manufacturing operations are in accordance with cGMP requirements, US FDA and ICH guidelines and regulations.
- Our regulatory department works on the guidelines of CTD and ICH. Our team is engaged in day to day development of dossiers - DMFs, interacting with all the manufacturing sites to keep updating them for regular regulatory developments and features in the international arena. Teams also upgrade day to day operations of the plant, making sure that everything works in sync with the regulatory requirements.

Regulatory Inspection History & Approvals

Regulatory Authorities	Unit-1	Unit-2	Inspection date
PMDA (Japan)	-	✓	Aug-23
Russian –GMP	✓	✓	Feb-22
DSIR, Govt. of India	-	✓	Jun-20
USFDA	✓	✓	Feb-20
WHO-GMP	✓	✓	May-19
Cofepris (Mexico)	✓	✓	Apr-19
EU-GMP (Austria)	✓	✓	Jan-18

Note: Only Recent inspections are tabulated.
(Last 5 Years).

Country /Continent	Regulatory Authority
International	WHO
Europe	EU-GMP
Australia	TGA
US	USFDA
Korea	MFDS
Japan	PMDA
Mexico	Cofepris
Canada	TPD
Russia	GMP

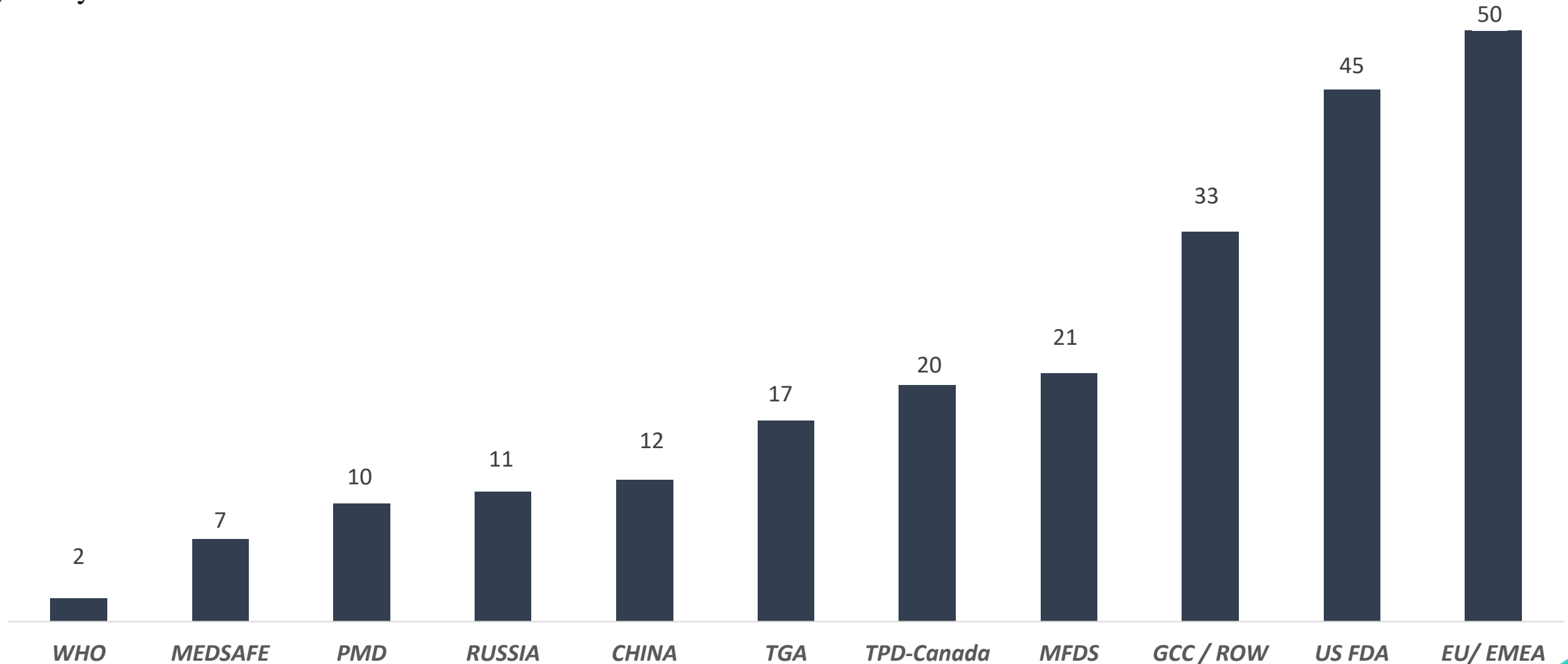


REGIERUNG VON OBERBAYERN



Regulatory Filings

New product introduction and increase in geographical coverage replicated with **228** number of DMF filings done with major regulatory authorities



- Shilpa Created State of art Quality control facilities equipped with the latest Available Instruments for testing the Raw materials, intermediates, Finished goods in house for the release to the market
- Shilpa has in-house stability testing facilities for all conditions like Long term, Intermediate, Accelerated & Zone-IV B and Refrigerated Conditions.
- Both units having dedicated quality testing facilities.
- Shilpa having it's own centralized Microbiology facility.
- Having In-House Analytical Development Lab for supporting the R&D (Analytical Method developments, validations, System suitability & Method Transfer) to transfer the technology to Pilot level as well as commercial level & to support Regulatory requirement.

Analytical Capabilities (Quality Control):



Name of the Instrument	Unit-1	Unit-2
HPLCs with UV detector	10	09
HPLCs with UV/RI detector	-	02
HPC with CAD	-	01
HPLCs with PDA detector	01	-
GCs with Head Space	03	03
GCs with Liquid Injectors	01	03
FTIR (PerkinElmer)	01	01
UV-Vis Spectrometer	01	01
Polarimeter (Autopol V)	01	01
TOC analyzer	01	01
KF Titrators / Coulometer	04/01	03
ICP – MS (Thermo)	-	01
Particle Size Analyzer* (Malvern)	-	01
XRD* (Bruker)	-	01
DSC* (PerkinElmer)	-	01

Analytical Capabilities (Analytical Development Lab):



Name of the Instrument	ARD Lab
HPLCs with UV detector	24
HPLCs with UV/RI detector	02
HPC with CAD	02
HPLCs with PDA detector	04
GCs with Head Space	05
GCs with Liquid Injectors	01
FTIR (PerkinElmer)	01
UV-Vis Spectrometer	01
GCMS Clarus 680 (PerkinElmer)	01
LCMSMS 3200 QTRAP (Absciex)	01
KF Titrator (Metrohm)	01
ICP – OES (Perkin Elmer)	01
Ion chromatography (Metrohm)	01
TGA (PerkinElmer)	01
Particle Size Analyzer (Malvern)	01
XRD (Bruker)	01
DSC (PerkinElmer)	01

Environment, Health and Safety

- SPL has established required processes and putting its efforts to understand and manage EAIA, process safety (HAZOP-Hazard & Operability) and industrial hygiene related aspects/hazards
- SPL has implemented the PSM & IH Protocol to reduce the process safety and exposure related risks.
- SPL has made the Business Continuity plan , Review the Risks & Control Measures available.
- Implemented emergency Preparedness & Response procedures & conducts the Emergency Drills
- The fire Loads are assessed & Fire Hydrant system is available
- The company monitor, evaluate periodically & adhere to the Legal Compliance Requirements
- The Company is UNGC (United Nations Global Compact) participant , Committed to SBTi (Science Based Target initiative)
- The Companies ESG system was assessed by Ecovadis and has Rewarded with a Commitment Badge and the company has obtained a score of 45 & is accepted by all the originator & Other Reputed companies

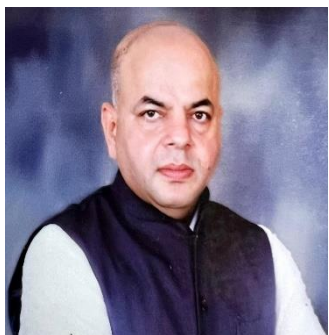
Environment, Health and Safety

- The Company Monitors the scope -1 , Scope-2 & Scope-3(Limited) & is Carbon negative wrt Scope-1,Scope-2 and The company has Registered its Biomass based steam Generation Project with UNFCCC & about 111000 CER's Credited to Company's account
- The company is ISO 9001: 20015 Certified for QMS, ISO 14001:2015 for EMS, ISO 45001:20018 for OSHAS, ISO 50001:20018 Energy Management System, SA 8000-2014 for Social Accountability Management System.
- We are being environmentally conscious all the waste is treated in its ZERO discharge handling facility with all down line supported systems& the solid wastes are Disposed scientifically & safely
- Set the targets for resource conservation , waste minimization, re-Cycling.
- Key Suppliers Environmental& social assessment carried out as apart ESG Commitment in supply chain
- Awareness & Competency trainings are imparted to all the Employees & Workers Including Contractors

Our Team



Mr. Vishnukant C. Bhutada
Managing Director



Mr. Santosh Mahil
CEO



KH Honneshiaiah

Head Operations API
Overall 34+ experience in
Operations.



K.Sharath Reddy

Head Projects
Overall 33+ experience in
Green & Brown field Projects



Dr.Seshachalam

Head Quality & RA
Overall 30+ experience in
Regulatory audits & DMF filings



G.Venu Babu

Site Head- API
Overall 18+ experience in
Pharmaceutical product.



Dr. Dipak Kalita

Head CDMO
Overall 22+ years
experience in Process R&D,



Dr.G.Satyanarayana

Head Polymer
Overall 26+ years experience
in Polymer Research &
Technology



Mrs. Bharti

Head Peptide
Overall 18+ years experience
in Peptide Research &
Technology



Dr. Praveen Cherukupalli

Head CR&D
Overall 25+ years experience
in Chemical R&D

Shilpa Foundation (CSR ACTIVITIES):



Water conservation project

Sujalam Suphalam: To enhance access to community water resource leading to reduction in drought effect and improving the fertility of the agriculture land of the local farmers.



Education Promotion

- Providing infrastructure to Rural Schools.
- Smart class to Rural School.
- Donation for quality education.



Environmental Development

- 21000 Seedling plantation In 03 phase.
- Growth rate of selected plant is 99%.
- Dedicatedly working on tree plantation with a vision of Green RAICHUR' Clean RAICHUR.



Healthcare Promotion

- First time Cancer Awareness, Screening and detecting camp with Team TATA in RAICHUR'.
- 287 screening done and 85% were woman among them.



The Prestigious PEL-HEMSI award presented to Polymer Research & Technology on 26th May 2022 at International High Energy Material Conference organized by Defence Research & Development Organization (DRDO-HEMRL)



FKCCI Export Excellence Awards 2021 held on 15th September 2021 at FKCCI Chief Guest Shri. Murugesh R. Nirani, Honble Minister for Large and Medium Scale Industries.

Recognitions



FKCCI Export Excellence Awards 2020 held on 18th September 2020 at FKCCI Chief Guest Shri. Jagadish Shettar, Honble Minister for Large and Medium Scale Industries.



Outstanding Export performance award for the year 2018-19 from PHARMEXCIL

Recognitions



In year 2016 Patent Award under Bulk Drugs API from Pharmexcil.



In year 2015 Shilpa Medicare bagged UBMs Excellence in R&D Award in category

Recognitions



Awarded first National Energy Conservation Award in Drugs & Pharmaceutical Sector for the year 2012 by **Hon'ble President of India, Shri Pranab Mukerjee.**



Mr. Vishnukant Bhutada awarded "Power of I" from India's best magazine Outlook Business, India. 2017.



Awarded “Best Entrepreneur” 1st National Award from Govt. of India, presented by Late Shankar Dayal Sharma, President of India (1995).

THANK YOU

Wholly Subsidiary of Shilpa Medicare Limited

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