January 2025



# Vishwa-Syntharo PharmaChem Private Limited



## Vishwa-Syntharo



- Vishwa-Syntharo PharmaChem Private Limited is a Joint Venture between Vishwa PharmaNexus Corporation of India and Syntharo Fine Chemicals of Germany
- The Joint Venture was established in September 2015 and the company registered in November 2015
- The Joint Venture seeks to leverage the advantages of both entities and the geographical and strategic location of both countries and provide Chemistry Research Services to companies across the globe





## Background – Vishwa PharmaNexus



- The name "Vishwa" originates from the Sanskrit word: "Vishwasam" (Trust)
- Founded in March 2010 by Dr. Sankara Subramanian with more than three decades of experience in leading pharmaceutical and chemical organizations in India
- Incorporated for providing chemistry and related services to the pharmaceutical and fine chemical industry
- Moved operations to Sri Ramachandra University, Chennai, a premier Medical University in October 2012 through a collaborative arrangement.
- Entered into a Joint Venture with Syntharo Fine Chemicals, Germany in
   September 2015 and now operates as Vishwa-Syntharo PharmaChem



# **Background - Syntharo**



- Incorporated near Hamburg in April 1998 for the sale of fine & specialty chemicals
- 2008 2010, located at the Chempark, Leverkusen
- July 2010, relocated to the "Industriepark Troisdorf" (a former site of Dynamit Nobel) located between Cologne and Bonn
- ✤ 8,000 sq.ft. facility in Troisdorf with a warehouse
- Customers include catalogue companies, R & D departments of research-intensive chemical companies
- Annual revenue: Mio EUR 4-5
- Syntharo Fine Chemicals USA, Inc. located in NY, with a warehouse in NJ



## **Mission & Vision**



### <u>Mission</u>

Be a **TRUSTWORTHY** provider of products and services to the

Pharmaceutical and Speciality / Fine Chemical industry in all its fields of operations

### <u>Vision</u>

To be **GLOBALLY** renowned for excelling in Quality of Work, Integrity, Innovation, Business processes, Technologies developed, and Services offered



# **Quality Policy**



ISO 9001 Certified

At Vishwa-Syntharo PharmaChem we shall continuously strive to provide our customers the best and timely delivery of products and services, through:

- Adopting a Business Process Flow that satisfies applicable requirements;
- Continuous improvements to our business processes;
- Developing and using the most appropriate technology that is efficient, cost effective and has least impact on environment;
- Maintaining a transparent and timely communication chain with the customer;
- Deploying appropriate human resources for the projects and continuously upgrading their skill and efficiency levels through periodic training and mentoring.

# Dr R Sankara Subramanian

### Education:

B.Sc – Vivekananda College, Chennai; M.Sc – Loyola College, Chennai Ph.D – IIT Madras (Chennai);

Post Doctoral – Univ. of Bath, UK

#### Previous work experience:

Recon Limited (now Hikal)

Shasun Chemicals & Drugs

- Head of R&D
  - Head of Corporate Quality Assurance & Regulatory Affairs
  - Strategic Business development

-Process development for APIs

- Structure and commission CRAMS activities

-Establishment of Research Laboratories

Sanmar Speciality Chemicals / ProCitius Research

**ProVentus Life Sciences** 

- Establish and lead the API division through FDA inspection
   Establish and manage the Contract Research division ProCitius Research
- -Co-investor
- -Restructure of business activities
- Establish and manage API and CRAMS business activities





# Lars Müller

Lars Müller was born in Hamburg, Germany, in 1971.

After completing his training as a wholesale and foreign trade merchant at Helm AG in Hamburg (1991-1993), he joined his father's company RAIMUND MÜLLER GMBH, an agent/representative for speciality chemicals In the following years, Lars Müller gained in-depth sales knowledge and technical expertise, when working for various associated companies in the USA and England.

Of the company's three main pillars - raw materials for printing inks, raw materials for hair colours and bromine chemicals - he took over responsibility for sales of the latter two.

- In 1998, Lars Müller founded the company "CHEM-TRADE", which focused on international trade of fine chemicals.
- Accompanied by continuous organic growth and the ongoing diversification of the organization into additional areas of activity, the company was renamed to SYNTHARO FINE CHEMICALS GMBH in 2008.

The fascination for chemistry and its processes is and remains a key driver for current and future challenges.

As Managing Director as well as Marketing and Sales Manager, Lars Müller always manages the company with an eye on the latest developments and future topics.

 Since the founding year 2015, Lars Müller has therefore also been Director of the India-based JV "Vishwa-Syntharo PharmaChem Pvt. Ltd





## **Research Advisor**

### Prof K K Balasubramanian

Education:	PhD: University of Madras	
Post Doctoral:	Wayne State University, Detroit	
	(Amino- and keto- sugars with Prof Carl Stevens)	
Background:	Dept. of Chemistry, Indian Institute of Technology Madras (1971 – 2001)	
Industrial :	Executive Director, R&D, Shasun Chemicals and Drugs (2001 – 2011)	
Currently:	INSA Emeritus Scientist at Department of Biotechnology, IIT Madras	
Expertise: Synthetic Organic Chemistry		
	Molecular rearrangements	
	Organic photochemistry & Electro-organic chemistry	
	Carbohydrate chemistry	
Publications:	150	
Students guided	for PhD: 32	
Key Awards:	Lifetime achievement award CRSI Gold Medal 2012 Fellow of the Indian Academy of Sciences	



## **Business Associate**

### Dr. K Vijayakumaran

M.Sc – University of Madras (Chennai); PhD & Post Doctoral Research – University of Nancy (France)

### Areas of Expertise:

Education:

Carbohydrate Chemistry

Oxidation reactions

Multi-step organic synthesis

Synthesis of mono and polysaccharidesDeuterated sugars

Chromium based reagents in organic oxidation of complex organic molecules

Several compounds synthesized for laboratory chemical companies





# Key Personnel .. 1



Name	Department	Ed. Qual.	Prior Experience	
Sasikumar Malayandi	Technology	M Sc Chemistry	- Tagros Chemicals - GVK Biosciences - Jubilant Chemsys - ProVentus Life Sciences	
lyyasamy Sangudurai	Analytical	B Sc Chemistry	<ul> <li>Shasun Chemicals &amp; Drugs</li> <li>Strides Shasun Ltd</li> <li>Venkatnarayana Active Ingredients</li> </ul>	
Mahesh Kuppam	Research & Development	M Sc Chemistry	<ul> <li>Fischer Chemicals</li> <li>ProVentus Life Sciences</li> <li>Syngene International</li> </ul>	

# Key Personnel .. 2



Name	Department	Ed. Qual.	Prior Experience
Saruhasan Balakrishnan	Technology / Kilolab	Diploma in Petrochemial Engineering	<ul> <li>Piramal Healthcare</li> <li>Malladi Drugs &amp; Pharmaceuticals</li> <li>East Coast Organics</li> <li>Alchymars ICM</li> </ul>
Dhamodharan Devaraj	Technology / External Manufacturing	B.Tech Chem Engg	<ul><li>EID Parry</li><li>Sun Pharmaceuticals</li></ul>
Rajini Rajappan	Quality Assurance	M Sc Chemistry	<ul> <li>Syngene International</li> <li>ProCitius Research (Sanmar Group)</li> </ul>
Vanitha Palanisamy	Project Management	M Sc Chemistry	- Vishwa-Syntharo PharmaChem

## Areas and Activities of Focus





**cGMP** Manufacturing

#### **Route Selection & Technology Development**

Retrosynthesis Literature screening **Route Selection Design of Experiments** Laboratory Experiments for Development Preparation of Technology Package

#### Scale-up for a Robust Process

Scale-up to check the performance of technology Identify the critical parameters Verify the robustness

#### Kilo-lab manufacturing

Manufacture and supply of kilo-quantity materials either for pre-launch tests or continuous supply of small volume chemicals

#### Speciality Chemicals / cGMP Manufacturing

Transfer of technology to the appropriate manufacturing site and supply commercial quantities on a continual basis



Kilo-lab Manufacturing

## **Key Chemistry Capabilities**



Asymmetric Compounds	<ul> <li>Chiral Compounds &amp; Ligands</li> <li>Carbohydrates as synthons</li> </ul>
Oxidation	<ul> <li>Classical (Jones, KMnO<sub>4</sub>, K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>, Na<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>, CrO<sub>3</sub>, MnO<sub>2</sub> etc)</li> <li>Transition Metal Catalyzed</li> </ul>
Reduction	<ul> <li>Hydrogenation (normal and high pressure)</li> <li>Homogeneous &amp; Heterogeneous catalysed</li> </ul>
Halogenation	<ul> <li>Fluorination (NFSI, DAST, selectfluor, deoxo-fluor)</li> <li>Chlorination</li> <li>Bromination</li> </ul>
Others	<ul> <li>Hydroxylation</li> <li>Amidation</li> <li>Azidation</li> <li>Amination (by several methodologies)</li> <li>High Pressure reactions</li> </ul>
Organometallic	<ul> <li>Butyl lithium</li> <li>Suzuki coupling</li> </ul>
Polymerization	<ul> <li>Raft polymerization</li> <li>Co-polymerization</li> <li>Nano-copolymers preparation</li> </ul>
Blue font refers to ch	emistries performed at commercial scale (100s of Kilos to MT lots)

**Chemistries not performed - Reactions involving Phosgene; Cyanation** 



# **Key Areas of Focus**

### **Carbohydrates**

- Basic monosachharides
- Polysaccharides
- Protected amino-sugars
- Configurational inversion
- Carbohydrate-derived chiral synthons

### Fluorinated Chemicals

 Typical fluorinating agents used: NFSI, DAST (at small scale only), Selectfluor, Deoxo-fluor, Other inorganics

### Chiral Molecules

- Chemical Resolution
- Asymmetric / enantioselective synthesis
- Stero-selective synthesis using enzymes

Chiral purity estimated by: Chiral HPLC, Optical rotation, NMR using chiral shift reagents





## **Research & Development**



TUVINDIA

ISO 9001 Certified

Fume Hoods:	4	
Rotary evaporator	Buchi	
Scale:	5 ml to 5 litres	
Temperature range:	- 70 to + 250 deg C	
Vacuum:	Diaphragm pump:	~ 5mm Hg
	Oil vacuum pump:	~ 0.1 mm
High pressure	5 lit SS 316L (Amar Equipment)	Design Temp: 300 °C Working Temp: 250 °C Design pressure: 100 bar (kgsc)
Capabilities:	<ul> <li>Column chroma</li> <li>Eractional distill</li> </ul>	tographic purification

- Fractional distillation
- Cryogenic reactions
- Organo-metallic reactions





## **Analytical In-house**



TUVINDIA

ISO 9001 Certified

	- Agilent GC 7820A with FID
GC:	- Agilent GC 6890 with FID
	- Scion 436i GC with FID
HPLC	- Shimadzu LC-20AD (UFLC) with PDA Detector
(Analytical)	- Shimadzu LC-20AD (UFLC) with UV Detector
HPLC (Preparative)	Shimadzu LC-20AP
UV-Vis:	Agilent UV 8453
Auto-titrator:	SPECTRALAB Automatic Potentiometric Titrator (Model: AT38C)
Polarimeter (digital)	ATAGO AP-300
Melting Range	Stanford Research System - Optimelt
Water purification	Siemens Evoqua LaboStar TWF UV 7 (Capacity: 9 lit / hr)





# **Analytical Outsourced**



FT-IR:	Shimadzu IR Spirit (Tamil Nadu Test House)
NMR (Multi-nuclear)	Bruker 500 MHz (SRM University)
Residue on Ignition	Neoscience Labs / Monarch Testing Laboratories
GC-HSS:	Agilent 7890B (Neoscience Labs)
GC-MS/MS:	Agilent 7000D (Neoscience Labs)
LC-MS/MS:	Agilent 6495 (Neoscience Labs) / Shimadzu LCMS 8040 (SPINCO)
ICP-OES	Thermo Fischer iCAP™ 7400 (Monarch Testing Laboratories)
ICP-MS	Agilent 7800 (Neoscience Labs)
Pesticide analysis	LC-MS / GC-MS (Neoscience Labs)
Microbiology	Neoscience Labs



Bruker 500 MHz NMR



Agilent 7890B GC-HSS





Agilent 6495 LC-MS-MS

- 100 T

## Kilo-lab 1



Low-level fume hoods for 5 to 20 litre flasks - 2

### **Operating conditions:**

Temperature: -70 to + 250 deg C Vacuum: 1 mm Hg Pressure: Ambient



### <u>GMP</u>:

Ante-room, change-room and clean-room Area classified as Class 100,000 GMP for N-1 compounds of APIs



# Kilo-lab 2



100 Lit all glass unit	2
20 Lit fractional distillation (Glass)	1
20 Lit Rotary evaporator	1
Vacuum tray dryer (4 trays / 5 to 10 kgs) (SS 316)	1
Nutsche filter (PP)	1
Pressure Nutsche Filter (SS 316)	1
Column Chromatography set up (Glass)	1

#### **Operation conditions:**

Temperature: -70 to + 250 deg C Vacuum: 1 mm Hg Pressure: Ambient

#### <u>Area</u>:

Ante-room Air conditioned Clean area (Not classified) Can be converted to GMP if required in ~ 3 months





## **Commercial Manufacturing**





#### Unit 1 (Speciality Chemicals)

SIPCOT Industrial Estate Ranipet Tamil Nadu

120 Km from Chennai

#### Unit 2 (Speciality Chemicals)

APIIC Industrial Estate Athivaram Andhra Pradesh

125 Km from Chennai

#### Unit 3 (Pharmaceutical Ingredients - cGMP)

SIPCOT Industrial Estate Ranipet Tamil Nadu 120 Km from Chennai



# Manufacturing Unit 1 – Speciality Chemicals

Location: in Ranipet, Tamil Nadu (140 Km from Chennai)

Manufacture of Specialty Chemicals developed by Vishwa-Syntharo

мос	No of reactors	Total Capacity	Reactor Sizes
SS 316	5	11 KL	1,000 - 3,000 Lit
MS-GL	4	8 KL	1,000 - 3,000 Lit





# Manufacturing Unit 2 – High Pressure



Location: APIIC Industrial Estate, Athivaram, Andhra Pradesh (140 Km from Chennai)

Manufacture of products developed by Vishwa-Syntharo involving high pressure or hydrogenation

мос	No of reactors	Total Capacity	Remarks
SS 316	10	30 kL	1,000 - 5,000 Lit
MS-GL	2	7 kL	3,000 - 4,000 Lit
			1,000 - 3,000 Lit
SS316L	3	6 kL	Design Pressure: 78 KgSc –
			Operating Pressure: 55 KgSc





# Manufacturing Unit 3 - cGMP



- Location: SIPCOT Industrial Complex, Phase 3 Ranipet, Tamil Nadu (140 Km from Chennai)
- Manufacture of Active Pharmaceutical Ingredients developed by Vishwa-Syntharo for Animal Toxicity, Phase 1, Phase 2, Phase 3 clinical trials and commercial launch
- ✤ US FDA Inspection target 2025

Kilo-lab	All Glass vessels
Manufacturing	SS 316
	MS-GL
	Hydrogenation & High-Pressure Reactors







## **Key Achievements**



Product	Other Manuf.	Status	Customer
Nutraceutical for weight loss (under license of patent)	Exclusive	Commercial	USA
Cross-linker for a novel catalyst	Exclusive supply	Commercial	Germany
Two novel emollient for cosmetic application	Exclusive supply (for end use)	Commercial	Germany / Global
Two small-scale cosmetic ingredients	Exclusive supply	Commercial (kilo-scale)	Germany
Two Pharmaceutical intermediates	From China	Licensed to US-FDA inspected API company	India
Stabilizer for API		Commercial (kilo-scale)	Japan



## **Products .. 1 (Commercial Scale)**



	Chemical Name	CAS #
1	2,6-Dipicolinic acid	499-83-2
2	(4-Carboxybutyl)-triphenylphosphonium bromide	17814-85-6
3	10-Chloro-1,1-diethoxydecane	1221273-58-0
4	3-(4-Chlorobenzylidene)-phthalide	20526-97-0
5	trans-Styrylacetic acid sodium salt	439801-60-2
6	trans-Styrylacetic acid	1914-58-5
7	Tetrabutylammonium nitrite	26501-54-2
8	Sodium 2,3,3-Trimethyl-3H-indole-5-sulfonate (5-SulphoTMI Na-Salt)	287188-58-3



# **Products .. 2 (Commercial Scale)**



	Chemical Name	CAS #
9	6-Chloro-2,4-dimethylaniline	63133-82-4
10	2-(Aminomethyl)quinoline Hydrochloride (Currently Manufactured on Exclusive Basis)	18004-62-1
11	2-Amino-4-hydroxyanisole	29644-12-0
12	2-Hydroxystearic acid (Currently Manufactured on Exclusive Basis)	629-22-1
13	2-Hydroxydecanoic acid (Currently Manufactured on Exclusive Basis)	5393-81-7
14	Oleoylethanolamide (Currently Manufactured on Exclusive Basis under license of patent)	111-58-0
15	Triethylmethylammonium octanoate (Currently Manufactured on Exclusive Basis)	170275-23-7





# **Products .. 3 (Technology-ready)**

	Chemical Name	CAS #
1	2-lodoethanol	624-76-0
2	Bisphenol S Diglycidyl Ether	3878-43-1
3	5-(Ethylthio)-1H-tetrazole	89797-68-2
4	2-Acetoxyisobutyryl bromide	40635-67-4
5	Tetrabromophenol Blue	4430-25-5
6	2,6-Dimethoxy-3,5-Pyridinediamine HCI	56216-28-5
7	Bis(triphenylsilyl)chromate	1624-02-8
8	5-Bromo-m-xylene	556-96-7
9	1,3-Dimercaptobenzene	626-04-0
10	1,3-bis(Methylamino)benzene	14814-75-6



# **Products .. 4 (Technology-ready)**



	Chemical Name	CAS #
11	2,6,7-Trichloroquinoxaline	41213-31-4
12	6,7-Dichloro-2-Quinoxalineacetonitrile	1821129-18-3
13	(±)-exo,exo-2,3-Camphanediol	56614-57-4
14	3-Hydroxy-N,N-dimethylamino-aniline	99-07-0
15	3-(Dimethylamino)-acrolein	927-63-9
16	Schwesinger P4 Base	111324-04-0
17	[1,3-Bis(diphenylphosphino)propane]- dichloronickel(II)	15629-92-2
18	2-Naphthoyl chloride	93-09-4



# **Products .. 6 (Technology-ready)**



	Chemical Name	CAS #
19	2-Hydroxy-5-Methoxy Acetophenone	705-15-7
20	3-Hydroxy-2-Methyl Pyridine	1121-25-1
21	Basic Red 76	68391-30-0
22	N-(n-Butyl)thiophosphoric triamide	94317-64-3
23	2,4,5-Trimethyl-4,5-dihydro- cyclopenta[b]thiophen-6-one (2-Methylthiophene-Tiglic acid adduct)	1256451-40-7
24	1,2-Bis(1-indenyl) ethane	15721-07-0
25	1,2-Bis(3-indenyl) ethane	18657-57-3



# **Products .. 7 (Technology-ready)**



	Chemical Name	CAS #
26	6,6-Diphenylfulvene	2175-90-8
27	1,8-Diaminonaphthalene	479-27-6
28	1,8-Dinitronaphthalene	602-38-0
29	1,5-Diaminonaphthalene	2243-62-1
30	1,5-Dinitronaphthalene	605-71-0
31	Tris(hydroxymethyl)aminomethane (Tromethamine)	77-86-1
32	1,6-Dibromohexane	629-03-8
33	Theobromine	83-67-0
34	R-Xyl-BINAP	137219-86-4



## Gallery





















Stability Program



**Quality Assurance** 

## **Quality & Regulatory**



### ✤ ISO 9001:2015 certified

- Site is registered with U.S. Food and Drug Administration (US FDA) for supply of nutraceuticals
- ✤ 100 % Export Orient Unit (EOU)





## Contact

### Vishwa-Syntharo PharmaChem Private Limited



#### **R&D**:

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### **Syntharo Fine Chemicals**

#### Syntharo Fine Chemicals GmbH

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https://syntharo.com

#### **Syntharo Fine Chemicals USA Inc**

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