

SUVEN LIFE SCIENCES Ltd

SUVEN Life Sciences

**Partnering Drug Discovery &
Development**

.....and beyond!

Company Background

Vision

To Emerge as a leading player by providing full spectrum services in drug discovery, development, manufacturing and support services under collaboration with leading global life science players



Graduated from Contract Research to Collaborative Research

Suven's Business Model

Drug Discovery

Chem
lib/
comb
chem
hits

Lead
identifica-
tion /
characteri-
zation

Lead
Optimi-
-sation

Pre
Clinical

Clinical
Trials

Process
Research

Custom
Synthesis

Formulation
Developmen
t, Analytical
& regulatory
Services

Clinical
Supplies
Manufac-
-turing &
Packagi-
ng

**Drug Discovery & Development
Support Services (DDDSS)**

C-R-A-M-S

**Collaborative Research Partner (CRP) ...
Seamless transition**

BUSINESS STRUCUTRE

- In operation since 1989 to 2004 as **SUVEN PHARMACEUTICAL LTD.**
- Profitable for the last decade
- Transformed to **SUVEN LIFE SCIENCES LTD** from 2003
- Strong asset base and financial fundamentals
- Pioneering efforts in C-R-A-M-S since 1994
- Initiation of Clinical Research and Data Management operations in 2001 through Asian Clinical Trials
- Pioneering initiatives in DDDSS in 2005
- Relationships with many Global Life Science majors
- IPO in 1995 - Listed on NSE and BSE
- More than 300 scientific professional

High growth potential

Strategic Business Segments

- Contract Research and Manufacturing Services (C-R-A-M-S)
- IP creation in process research
- Drug Discovery and Development Support Services (DDDSS)
- Clinical Research Operations (ACT)
- Collaborative Research Partnerships (CRP)

Full spectrum services in Drug Discovery,
Development and Manufacturing

Facilities

SUVEN LIFE SCIENCES LIMITED

Pharma Solutions Banjara Hills, Hyderabad

- Headquarters
- Biopharmaceutical Research
- Clinical Trials

R&D Center Jeedimetla, Hyderabad

- Process Research
- Discovery R&D
- Analytical R&D

Manufacturing Unit 1 Suryapet, AP

- 300 CM multi-purpose reactors(93)
- 500 L to 10 KL GL/SS
- GMP like Intermediates
- Cyanation

Manufacturing Unit 2 Pilot Plant Jeedimetla, Hyderabad

- Kilo Lab
- Pilot Plant (30 KL)
- 30 CM Reactors(23)

Manufacturing Unit 3 Pashamylaram, Hyderabad

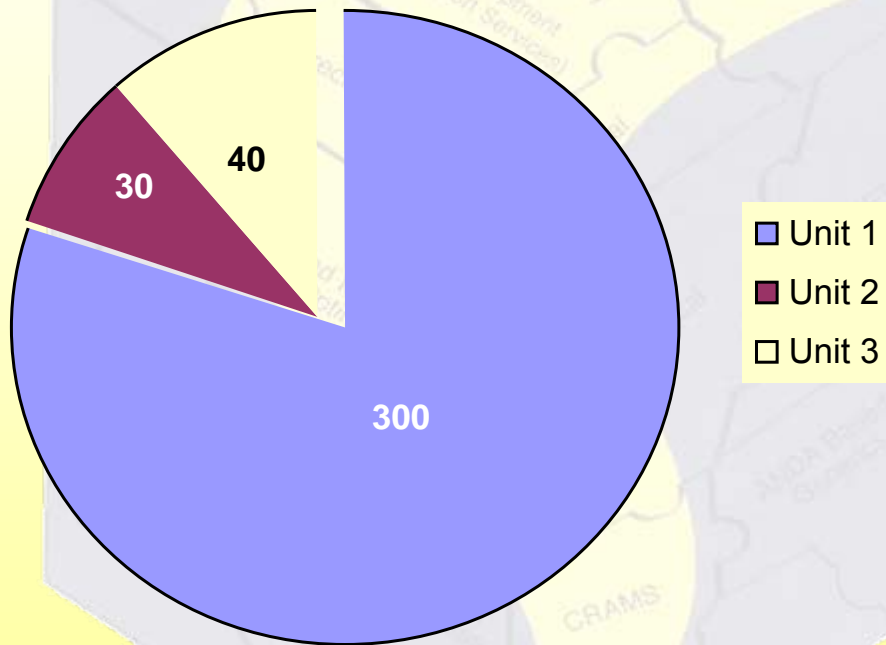
- 40 CM Reactors(23)
- 100 L – 3 KL GL/SS
- cGMP APIs
- DMF/ FDA compliant

SUVEN USA New Jersey

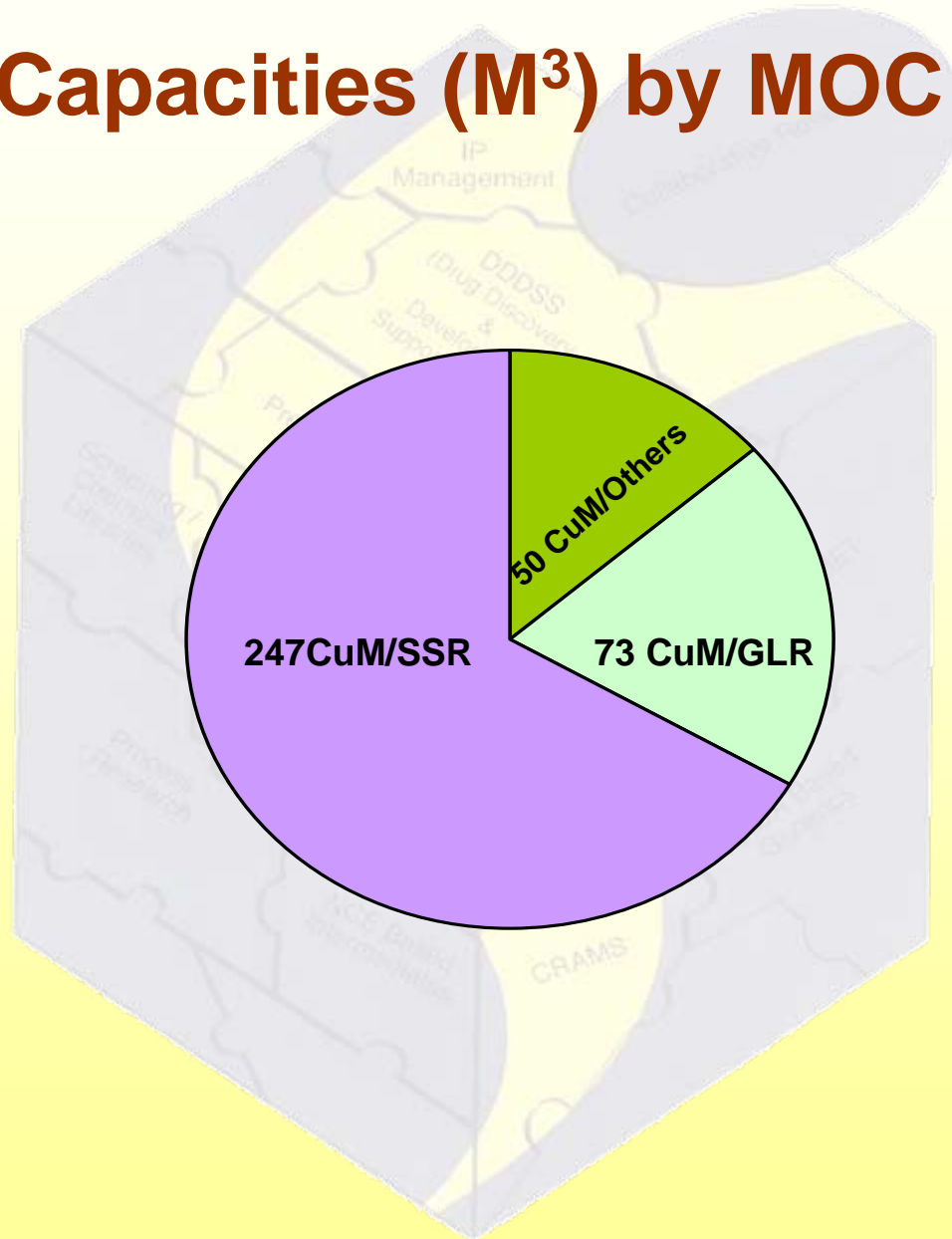
- Business Development
- Project Management
- Intellectual Property Management

Any stage scalable at short time

Reactor Capacities (M³) across Suven's facilities



Reactor Capacities (M³) by MOC



Regulatory Information

SN	Product	DMF	Number	Date of submission
1.	Gabapentin USP	•US FDA	17063	29.12.2003
		•Portugal Health Authorities	33/2005	20.01.2005
2.	Entacapone	US FDA	19092	06.01.2006
3.	Iron Sucrose Complex	US FDA	18261	11.04.2005
4.	Sodium Ferric Gluconate Complex	US FDA	18541	29.07.2005
5.	Glycopyrrolate	US FDA	19026	10.12.2005
6.	Divalproex Sodium	US FDA	19266	18.03.2006
7.	EPEB an intermediate of Tamsulosin HCl	US FDA	19336	07.04.2006
8.	MAS HCl an intermediate of Tamsulosin HCl	US FDA	19397	29.04.2006
9.	Tamsulosin HCl	US FDA	19647	02.08.2006
		Ph.Eur.	R0-CEP 2007-014; Rev.00	---
10.	Nitazoxanide	US FDA	19752	05.09.2006
11.	Fenoprofen Calcium	US FDA	20498	26.04.2007

Business Activities

**In Research & Development, Process Optimization and
Production of...**

- ❖ Organic Fine Chemicals and Pharmaceutical Intermediates
- ❖ Active Pharmaceutical Ingredients (API's)
- ❖ Generic API's and Orphan Drugs
- ❖ Chiral Synthesis / Separation
- ❖ Racemic Switches
- ❖ Customers include 22 Global Life Science majors
- ❖ 460+ C-R-A-M-S projects completed till date and 72 are currently being executed.

Custom Synthesis and Toll Manufacturing are our core competencies

More than 65% of revenue from USA & Europe

Human Resources

Total Employees **577**

- R&D **256**
- Manufacturing & Services **278**
- Administration / Sales **43**

Human Resources


<u>R&D</u>	-	256
- Analytical Development -	38	
- Clinical	-	35
- Discovery	-	118
- Process R&D	-	65

Human Resources

Qualifications:

PhD's / MD	-	25
MS / M Phil / M Tech	-	296
BS / B Tech / Engg. Diploma	-	256
Total	-	577

Quality/Safety Systems

- 
- **cGMP**
 - **ISO 9001:2000**
 - **ISO 14001:2004**
 - **OHSAS 18001:1999**

R&D PROFESSIONAL

- ❖ **Highly qualified and experienced scientific professional manpower.**
- ❖ **State of the art DST approved R&D facility**
- ❖ **Willing to accept challenging product development opportunities**
- ❖ **Fast technology transfer from laboratory to industrial scale**
- ❖ **New product / process development in collaboration with leading global pharmaceutical / fine chemical companies**

RESEARCH & DEVELOPMENT ACTIVITIES

- ❖ Synthetic organic Chemistry
- ❖ Building Blocks, Scaffolds and Intermediate compounds for generating analogues
- ❖ Custom Synthesis of lead compounds in grams and kilograms.
- ❖ Intermediates in Multi-kilograms
- ❖ R & D for process optimization
- ❖ R & D for hazardous chemical Reaction
- ❖ Collaborative research
- ❖ R & D for clean technologies

PRECLINICAL AND CLINICAL DEVELOPMENT SUPPORT

- ❖ Contract Research – Laboratory
- ❖ Custom Synthesis – laboratory
- ❖ Process Research– optimization of process
- ❖ Custom manufacturing– Pilot plant
- ❖ Scale–up of synthesis to provide quantities from grams to kilograms
- ❖ Synthesis of reference compounds, fully characterized to meet GLP requirement

SCALE-UP/COMMERCIAL SUPPORT

- ❖ Scale-up of established processes
- ❖ Process optimisation
- ❖ Identification of alternate viable synthetic methods
- ❖ Scale up synthesis of gram/ kilogram quantities of building blocks
- ❖ Manufacture of intermediates

MEDICINAL CHEMISTRY CAPABILITIES

- ❖ Support for:
- ❖ Lead optimization
- ❖ Synthesis of reference compounds
- ❖ Starting materials
- ❖ Intermediates / Building blocks
- ❖ Preparation of compound libraries

RESEARCH & DEVELOPMENT CAPABILITIES



PROJECT MANAGEMENT

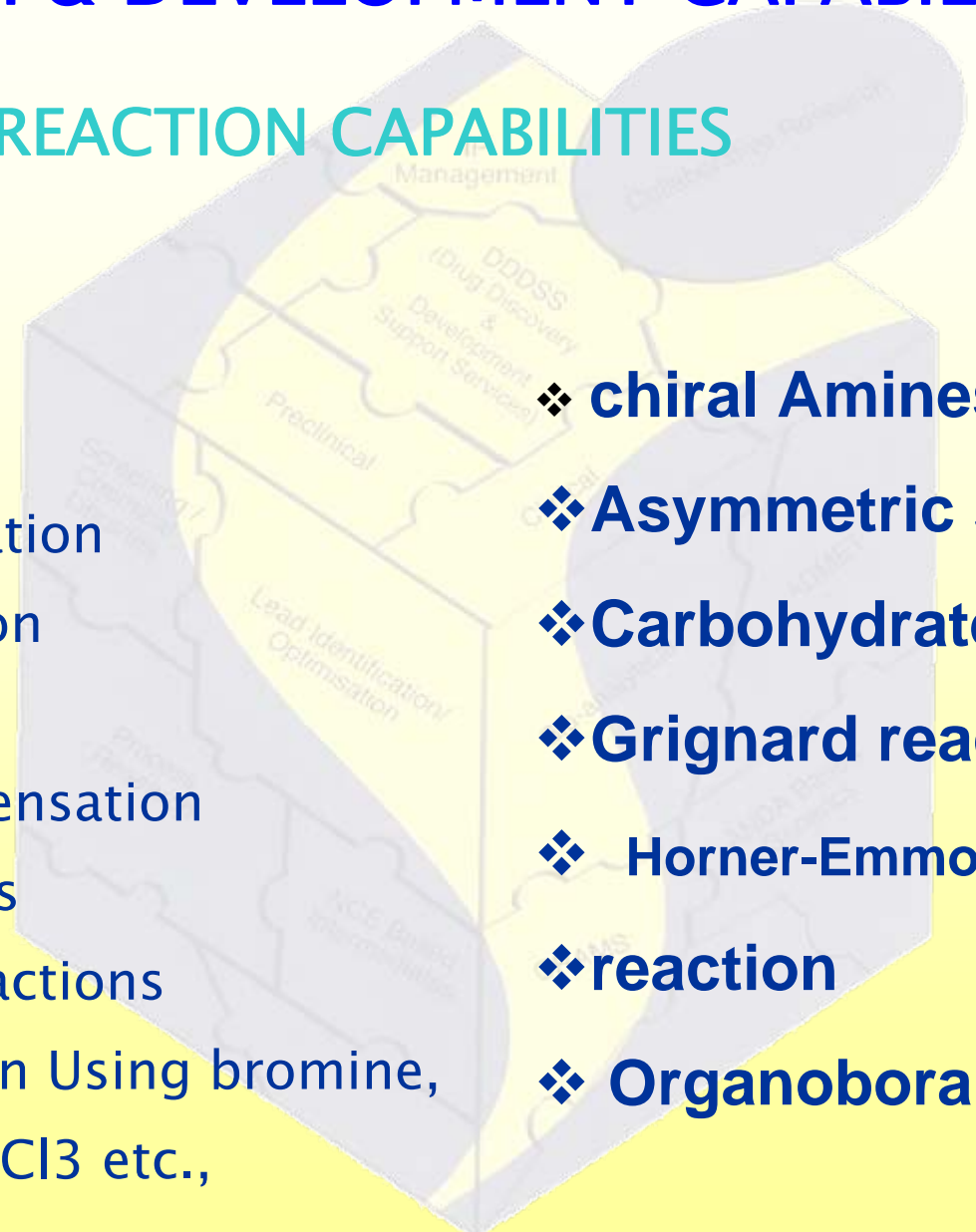
- ❖ A Project Team is led by a Project Manager and a team of scientists to guarantee the quality and the timelines of each project.
- ❖ The Project Manager is the single point of contact with the Client. The entire communication process is through Secured E-mails, regular teleconferences, videoconferences and periodic Report.
- ❖ The Project manager will report the progress on a weekly basis, detailing the progress and future direction of the project.
- ❖ Finally a detailed project report will be provided upon the completion of the Project and all the materials and information deemed necessary will be transferred to the client based on the initial terms and conditions of the agreement.

SECURITY / CONFIDENTIALITY

Intellectual Property

- ❖ Suven Life sciences Limited will strictly adhere and implement the recently approved international patent law.
- ❖ To ensure the security and confidentiality of client data, we use data only for the purpose intended. Access to client data is restricted to the Team leaders working on the respective project and observe strict standards of confidentiality.
- ❖ All Confidential Information and any other information in whatever form or medium supplied by the Client to us shall be delivered immediately upon demand at any time until the partnership remains in force or thereafter.
- ❖ All confidential information shall remain the property of the Client.

REACTION CAPABILITIES

- 
- ❖ Alkylations
 - ❖ Acylation
 - ❖ Amidation
 - ❖ Chiral alkylation
 - ❖ Condensation
 - ❖ Cyanation
 - ❖ Cyclo-condensation
 - ❖ Formylations
 - ❖ Grignard reactions
 - ❖ Halogenation Using bromine, chlorine, POCl₃ etc.,
 - ❖ Heck Arylation
 - ❖ chiral Amines syntheis
 - ❖ Asymmetric synthesis
 - ❖ Carbohydrates
 - ❖ Grignard reaction
 - ❖ Horner-Emmons Wadsworth
 - ❖ reaction
 - ❖ Organoborane

- ❖ Hydrogenation using Pd/C, Pt/C, Rh/C and Raney-Ni
 - ❖ Metallation – MeLi / n-BuLi / LDA/HMDS
 - ❖ Mitsunobu Reaction
- ❖ Oxidation – Jones, Swern, KMnO₄, NaIO₄, Nitric acid
- ❖ Reductions – Catalytic, Metal hydrides, High pressure, Metal catalysed, Birch reductions, Diborane, LAH, DIBAL-H, Catalytic, NaCNBH₃
 - ❖ Suzuki Coupling
 - ❖ Asymmetric synthesis
 - ❖ Enzymatic resolution

Target molecule without chemistry information

❖ Chemistry route selection phase (1-2 weeks)

based on

- Retro-synthetic analysis
- Literature search
- Raw material availability
- Capabilities of chemistry and facilities
- Raw material cost
- Paper costing

❖ Proof of concept phase

- pilot experiments (2-4 weeks)
- Molecule identification and characterization

❖ Optimization phase (2-3 weeks)

- Process optimization
- process variation
- critical parameters
- In-process control

parameters

- specification settings
- safety evaluation.

Scale-up phase (4-6 weeks)

- Raw material procurement
- Facility identification
- Batch record writing
- Scale-up implementation
- Dispatch of products
- Campaign report writing

Note: This timeline is considering 4-6 steps synthetic process. The timeline may vary if the special raw material is required with respect to scale-up.

For Target molecule with small scale process given

❖ Raw material availability (one week)

- Capabilities of chemistry and facilities
- Raw material cost
- Paper costing

❖ Optimization phase (2–4 weeks)

- Process optimization
- process variation
- critical parameters
- In–process control parameters
- specification settings
- safety evaluation.

❖ Scale–up phase (4–6 weeks)

- Raw material procurement
- Facility identification
- Batch record writing
- Scale–up implementation
- Dispatch of products
- Campaign report writing

Note: This timeline is considering 4-6 steps synthetic process.
The timeline may vary if the special raw material is required.

CHIRAL TECHNOLOGY PRODUCTS

SUFINAMIDE CHIRAL TECHNOLOGY VIZ.,	t-Butylsufinamide (R &S) p-Toluenesufinamide (R&S) P-Toluenemethane sulfoxide (R&S) 2.4.6-trimethylphenylsufinamide (R&S)
PYRROLIDINE RELATED TECHNOLOGY	3-Hydroxytetrahydrofuran (R&S) 3-hydroxypyrrolidine (R&S) 3-Aminopyrrolidine (R&S) 3-Cyanopyrrolidine (R&S) 3-Carboxypyrrolidine (R&S) 3-Hydroxy-N-benzylpyrroline (R&D) 3-Aminotetrahydrofuran (R&S) Pyrrolidine-3-carboxylic acid (R&S)
SUGAR DERVATIVES	4-Hydroxy-2-pyrrolidone (R&S) 2-Hydroxy-1,4-diol (R&S)

PROJECT REPORTING

- ❖ Gantt Chart provided at start of project
- ❖ Weekly reports provided every week of specified days on status
- ❖ Teleconferences on periodic basis as per the customer.
- ❖ Project coordinator accessible round the clock
- ❖ Detailed report submitted within 3–5 weeks on completion of project covering
 - ❖ Project summary
 - ❖ Experimental details
 - ❖ Synthetic Scheme, Raw Materials, Critical Issues, Stepwise Process
 - ❖ Description, Modifications carried out to documented processes,
 - ❖ Development history of process on parameters and conditions.
 - ❖ process safety information.
 - ❖ Suggestion for further improvement if any
 - ❖ Literature References,
 - ❖ Analytical methods and data

ENVIRONMENT AND HEALTH AND SAFETY

Safety

- ❖ PPE is a culture
 - Apron
 - safety glasses
 - Safety gloves
 - Face shield
 - Dust respirator
 - Splash Goggle
 - Vapor Respirator
 -
- ❖ Safety Manager
- ❖ Safety Audits
- ❖ HAZOP studies

Health

- ❖ Pre-employment medical clearance
- ❖ Periodic Health Check

Environment

- ❖ Waste segregation
- ❖ Waste minimization
- ❖ Compliance to local laws

2005 Case Study – 1

Project – Production scale up

Deliverable: 900 Kg of a Pyrimidine based molecule by December 2005

- **Initiated: September 2005**
- **Technology received: September 2005**
- **Sample qualified: September 2005**
- **Scaled up from 10 kg to 200 kg/batch**
- **Delivered: December 2005**

2005 Case Study – 2

Project – Commercial Production

Deliverable: 5 MT of a poly-substituted, benzyllaniline (chiral) based molecule by December 2006 (6 step process)

- **Initiated: May 2006**
- **PO received: July 2006**
- **Scaled up from 150 kg to 500 kg/batch**
- **Delivered 2 MT: October 2006**
- **Delivered 3 MT: November 2006**

2008 Case Study – 3

Project – Commercial Production

Deliverable: 30kg of Sugar derivatives by January 2008 (5 step process)

- **Initiated: December 5th 2007**
- **PO received: December 19th , 2007**
- **Scaled up from 50g to 30kg**
- **Delivered 30kg: January 19, 2008**

2008 Case Study – 4

Project – Commercial Production

Deliverable: 30kg of Sugar derivatives down stream by June 2008 (9 steps process)

- **Initiated: April 2008**
- **PO received: 5th April, 2008**
- **Scaled up from 30g to 60kg sugar derivatives**
- **Step-6 to 9 Scaled up from 50 g to 50kg**
- **Delivered 50kg: June 30th , 2008**

Coming together is a beginning
Keeping together is progress
Working together is success.

–HENRY FORD

THANK YOU