

CORPORATE PRESENTATION



Symphony Pharma Life Sciences

An ISO 9001-2015 Certified Company

DSIR Recognized R&D Facility

D&B D-U-N-S Number 65-061-8049

July 2019

ABOUT US

- ❖ Established in 2008
- ❖ Technology driven organization founded by scientists with proven industrial track record
- ❖ Expertise in Pharmaceutical and Chemical Research & Development
- ❖ Research partner for Global Innovator, Generic, Biotech, Biopharma and Chemical companies



VISION & MISSION

“TO ENHANCE VALUE BY PARTNERING WITH THE GLOBAL PHARMACEUTICAL AND CHEMICAL INDUSTRIES ACROSS ITS VALUE CHAIN”

LEADERSHIP TEAM-KEY MANAGEMENT

Dr. Raju Sirisilla – COO

- ❖ 25+ years of Pharmaceutical Industry experience working with Dr. Reddys for 15 years and Symphony for 10 Years.
- ❖ Expertise in Med. Chem, Process Research & Development, and regulatory filings (NDA & DMFs).
- ❖ Co-inventor for several US patents and international publications.

Dr. Ramajeyam Selvaraj – Principal Scientist/Head Chemical Research

- ❖ 15+ Years of experience in Synthetic Organic Chemistry, discovery Research and NCE development.
- ❖ Experienced at AstraZeneca, Aurigene (DRL) and studied at IIT Madras, Univ. of Delaware (USA), Purdue Univ. (USA)

Dr. Sreedhar– Principal Scientist/Head Analytical Research

- ❖ 10+ years of experience in Analytical research and method development etc.

Mr. Mayukh Mukherjee– Senior Manager, Business Development

- ❖ 15+ years of experience in International business development, strategy, operations, sales and marketing
- ❖ Experienced at TCG Lifesciences (Formerly Chembiotek)

Mr. Narsimlu– Senior Manager, Supply chain management

- ❖ 15+ experience in Supply chain management, procurements and imports/export documentation.

TEAM

- ❖ More than 90% are technically qualified
- ❖ Team members with Qualification of Ph.D, M.Sc and Engineering
- ❖ Scientific collective experience of over 100 years
- ❖ Extensive Synthetic chemistry, Analytical & Manufacturing skills
- ❖ Expertise milligrams to commercial scale
- ❖ Scientific advisory board, members from well-known institutes (US & India)

BUSINESS FOCUS



Contract Research (Full-Time Equivalent - FTE)



Custom Synthesis (Fee For Services-FFS)



Product Development (Process & Analytical)

Contract Research (FTE services)

- ❖ Efficient/ Experienced Manpower
- ❖ Deliverables up to 1000g
 - this higher quantity or repeated quantity is also a part of FTE work with exclusive of key raw materials cost.
- ❖ Competitive pricing based on chemistry
- ❖ Integrated project management
 - support all documentation (record book and bi-weekly tech.reports)

Custom Synthesis (Fee For Services)

- ❖ Short turn around time for enquiry response
 - 3-5 days for quote submission.
- ❖ Lab to commercial scale
 - few milligrams to multi kilogram scale
- ❖ Adherence to strict timelines & Specifications
- ❖ Product characterization
 - COA and individual data will be provided with impurity profile etc..



PRODUCT DEVELOPMENT

- ❖ Rigorous Literature Search
- ❖ Regulatory implication study
- ❖ Cost effective and environment friendly process
- ❖ Robust scalable process
- ❖ IP generation for patent filings
- ❖ Complete tech-pack preparation
- ❖ Access to exclusive market opportunities
- ❖ CMC documentation support

INFRASTRUCTURE

- ❖ 25,000+ sq. ft research facility on a 2+ acre lot located in Research & Knowledge park (Biotech park) in Hyderabad
- ❖ Working space for 50 Scientists-scope for expansion of another 50 scientists
- ❖ Fit-for-purpose labs with 18 fume hoods-scope for expansion of another 18 fume hoods
- ❖ Pilot plant with 100Lt to 500 Lt GLR and SSR reactors for scale-up of 100 Kg quantities
- ❖ Analytical Lab with well equipped separation sciences instruments like HPLC, GC etc..
- ❖ Quality assurance division to support documentation

CHEMISTRY SERVICES

Early phase drug Discovery/Med.chem

- Synthesis of building blocks (100+), scaffolds (35+) & analogues/libraries (200+) of NCE's
- Developmental work for NCE compounds.

Custom Synthesis (pharma& chemical)

- Synthesis & supply of non-catalogue compounds at all scales
- Advanced Intermediates & key starting materials
- Fine & Specialty chemicals
- Working standards , Impurities & Metabolites

Process R&D

- Exploring all the synthetic routes/ selection
- Process Development, Optimization & Validations
- Non-infringing route development

Analytical R&D

- Analytical method development, Validations & Transfer
- Stability Study : Accelerated & Long term
- Impurity profiling

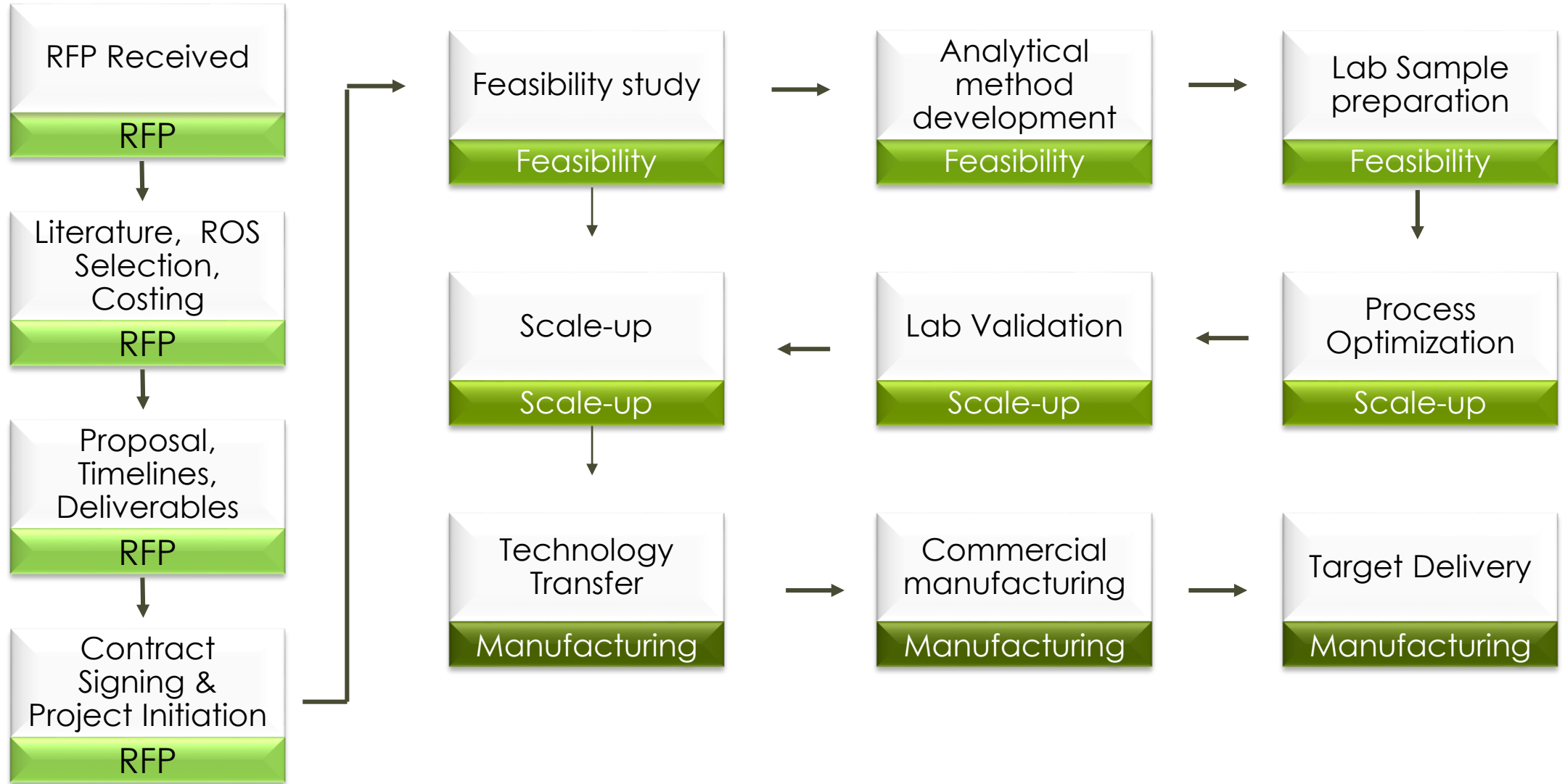
cGMP pilot plant (up to 100 Kg)

- Supply of pre-clinical and clinical drug substance including CMC documentation
- Supply of API Advanced intermediates & Fine & Specialty chemicals

R&D (PROCESS & CHEMICAL) STRENGTHS

- ❖ Route Scouting
- ❖ Quick process development to provide proof of concept
- ❖ Optimization for a robust and scalable process
- ❖ In-process controls
- ❖ Process validation and scale up studies
- ❖ Preparation of standards samples & impurities
- ❖ Technology transfer to manufacturing sites
- ❖ Stability testing and Degradation studies
- ❖ Solid state studies
- ❖ Multi-step chiral synthesis
- ❖ Chiral resolution
- ❖ Carbohydrate chemistry
- ❖ Amino acid chemistry
- ❖ Peptide synthesis (solution phase)
- ❖ Bio-transformations
- ❖ Suzuki Coupling, Heck Coupling and Sonogashira Coupling
- ❖ Grignard reaction
- ❖ Borane / Diborane chemistry
- ❖ Carbonylation
- ❖ Swern Oxidation

Our Approach for Process development & Scale-up



ANALYTICAL R&D STRENGTHS

- ❖ Method development
- ❖ Specification development
- ❖ Impurity profiling
- ❖ Stability testing and Degradation studies
- ❖ Release of products with COA
- ❖ Qualification of working standards/Reference standards
- ❖ Spectral characterization by NMR, IR, LCMS
- ❖ Solid state characterization by XRD, DSC, IR
- ❖ Support to regulatory filings



SCALE-UP : DOCUMENTATION SUPPORT

GMP:

- ❖ Approved certificate from local FDA
- ❖ Campaign report
- ❖ BMRs
- ❖ Operational SOPs
- ❖ COAs of KSMs, Intermediates & Final
- ❖ Specs & MOAs KSMs, Intermediates & Final
- ❖ Technology transfer report from R&D to plant
- ❖ Material Vendor qualification documents

Non-GMP:

- ❖ Campaign report
- ❖ COAs of KSMs, Intermediates & Final
- ❖ ROS & Brief manufacturing details

GMP PILOT PLANT INFRASTRUCTURE

- ❖ 500 Lt- SSR
- ❖ 250 Lt-SSR
- ❖ 100 Lt-SSR
- ❖ 250 Lt- GLR
- ❖ 100 LT-GLR
- ❖ Vacuum tray drier
- ❖ (25-50 Kg drying in single slot)
- ❖ Blender
- ❖ Miller
- ❖ Oil freed boiler
- ❖ Chiller upto-10 0C



PRODUCTS: BUILDING BLOCKS

Bicyclo compounds	Azaindoles	Thiophenes	Quinoxalines
Pyrazoles	Imidazoles	Pyridines	Pyrimidines
Furans	Benzaxozoles	Benziimidazol es	

PRODUCTS: APIs & INTERMEDIATEs

Lacosamide (US DMF Ref 26594)	Bazedoxifene acetate	Mirabigron	Cinacalcet hydrochloride
Dabigatran Etxilate	Dronerdarone hydrochloride	Flupiritine maleate	Vemurafenib
Plerixafor	Brivaracetam	Eliglustat	

PRODUCTS: API-IMPURITIES (Quantity: 50mg to 1000gm)

- ❖ Bazedoxifene
- ❖ Mirabigron
- ❖ Dronedarone Hydrochloride
- ❖ Cinacalcet Hydrochloride
- ❖ Lacosamide
- ❖ Dabigatran Etexilate Mesylate
- ❖ Asenapine
- ❖ Desloratadine
- ❖ Valsartan
- ❖ Atorvastatin
- ❖ Bazedoxifene
- ❖ Irbesartan
- ❖ Olmesartan
- ❖ Ranolazine
- ❖ Lurasidone
- ❖ Lamotrigine
- ❖ Sitagliptin
- ❖ Ezetimibe
- ❖ Linagliptin
- ❖ Voriconazole
- ❖ Saxagliptin
- ❖ Agomelatine
- ❖ Tolterodine
- ❖ Zafirlukast
- ❖ Pemetrexed
- ❖ Lenalidomide
- ❖ Nateglinide
- ❖ Pregabalin
- ❖ Enalapril
- ❖ Bicalutamide
- ❖ Montelukast
- ❖ Lansoprazole
- ❖ Fluconazole
- ❖ Ramipril
- ❖ Eslicarbazepine
- ❖ Carvedilol
- ❖ Rosuvastatin
- ❖ Eszopiclone
- ❖ Valganciclovir
- ❖ Oxaprozin
- ❖ Amlodipine
- ❖ Linezolid
- ❖ Escitalopram Oxalate
- ❖ Famotidine
- ❖ Solifenacin
- ❖ Vilazodone

Track Record

- ❖ Invented about 150 new pigments under FTE research program for US chemical major and some of these new pigments moving toward commercial launching globally.
- ❖ In-house development of >25 NCEs and supplied as clinical substances to discovery Pharmas
- ❖ Developed 6 APIs with 1 USDMF
- ❖ Started with synthesis at 250 mg scale and end delivery up to 250 Kg scale to single Pharma
- ❖ >250 in-house stock of impurities
- ❖ Experience in working with >150 building blocks
- ❖ Successfully executed several projects in record time from process development to multi-kilo scale for innovator and generic pharma companies across the globe
- ❖ Customized services to provide cost-effective and robust processes for API and NCE development
- ❖ Scientific advisory board members from well known institutes of US and India
- ❖ Strategic research partner for some of the top Indian pharma companies

Thank



USA

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