

Dr. RAJESH V GUPTA. M.Sc. Ph.D (Director-Biology, Sai Life Sciences Ltd)



📍 A410, DELIGHT FORTUNE,
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Education: Ph.D (Biochemistry), Dec 2012, University of Pune, Pune, India, through Lupin's Ascent scheme.

PROFESSIONAL SUMMARY

An experienced professional with expertise in Discovery research and Biologics. Experienced (24+ yr) in small-molecule drug discovery (integrated discovery projects) from lab to clinical development as well as Biologics (Biosimilars- recombinant therapeutic proteins and monoclonal antibodies), managing and leading projects. Rich experience in working CRO industry and handling FTE collaborations (integrated) and FFS based client projects. Multiple peer reviewed publications and PCT/ patents. Demonstrated expertise in Molecular biology, assay development, *in vitro* screening, HTS, host cell line engineering for expression of mAbs or discovery targets, protein expression (bacterial, mammalian and insect cell systems), Molecular pharmacology, biochemistry, neurobiology, immuno-oncology, new target ideation and validation, PK/ PD for advancement of molecules. Managing and leading MCB and assay development labs, managing projects. Worked in highly reputed and innovation driven pharmaceutical companies.

PROFESSIONAL EXPERIENCE

- SAI LIFE SCIENCES LTD, HYDERABAD, TELANGANA [FEB, 2021-CURRENT]**
Current: Director- Biology Services. Sai Life Sciences Ltd, IKP Knowledge Park, Genome valley, Hyd-500100, Telangana.
- LUPIN LTD, LUPIN RESEARCH PARK, PUNE [DEC-2008- NOV 2020]**
Position: Assistant Director- In vitro (MCB and Assay Development), in Novel Drug Discovery & Development (NDDD), LRP, Lupin Ltd, Pune-411021, India.
- New Drug Discovery Research, Matrix-Mylan Ltd, Hyderabad, India. [Feb' 2008 – Nov' 2008]**
Sr. Manager/Head-In Vitro Biology, NDDR Matrix-Mylan R&D Bollaram, Medak Dist, Jinnaram (Mandal), Hyderabad, Plot No.34A&B, ANRICH Industrial Estate, Pin: 502325.
- Lupin Ltd, Lupin Research Park, Pune, India. [Apr' 2005 – Jan' 2008]**
Research Scientist (Group Lead), Molecular Biology, Pharmacology Department, NCE Research.
- Zydus Cadila Ltd, Ahmedabad, , Gujarat, India. [Mar' 2003 – Apr' 2005], Biotechnology Dept.**
Associate Scientist [Biotechnology, Genomics Lab], Zydus Research Center, Zydus Cadila Research centre, Moraiya, Nr.Nova petrochemicals, Sarkhej-bavla N.HNo-8A, Ahmedabad –382210. India

6. **Sun Pharmaceuticals Ind Ltd, SPARC, Akota Road, Gujarat, India. [July' 1999 – Mar' 2003]**
Executive, Sun Pharma Advanced Research Center, Biotechnology, Akota, Baroda 390019. Gujarat, India.
7. **Torrent Pharmaceuticals Ltd, (TRC), Ahmedabad, Gujarat, India. [Jan' 1998 – June' 1999]**
Scientist-II: Cell and Molecular Biology lab, Torrent Research Centre (TRC), Torrent Pharmaceuticals Ltd. P.O. Bhatt, Gandhinagar - 382428
8. **Sun Pharmaceutical Ind Ltd, SPARC, Akota Road, Gujarat, India. [Sep' 1996 – Dec' 1997]**
Sun Pharma Advanced Research Center, Biotechnology, Akota, Baroda 390019. Gujarat, India.

Academics

Dec'2007 to Dec' 2012: Ph.D (Biochemistry) from University of Pune (UoP), Pune. Ph.D Degree awarded in Nov

Degree	Year	Specialization	University
Ph.D	2007-2012	Biochemistry	University of Pune, Pune
M.Sc.	1993-1995	Biochemistry	M.S.University, Baroda
B.Sc. (ZBC)	1990-1993	Zoology	M.S.University, Baroda
H.Sc	1990	Science	CBSE Board.

2013. Completed under ASCENT scheme.

Thesis Title: "Study of mechanisms for anti-diabetic effect of *Cinnamomum zeylanicum* with reference to glucose homeostasis and nuclear receptor"

KEY INDUSTRIAL ACHIEVEMENTS (24 + year Industry Experience)

- Having worked in Discovery research for > 15 years have vast experience in multiple therapeutic areas (Metabolic disorders, Pain/ Inflammation, CNS and oncology/Immuno-Oncology). Core skills in Molecular biology, assay development, cell biology, in vitro pharmacology, leading and development of various cell-free and cellular assays for screening in discovery projects. Leading and managing projects with skilled scientific teams. New target ideation and validation for POC till in vivo efficacy.
- **CRO experience:** Experience in working with multiple clients (20+) and multiple FTE and FFS collaborations with global clients for small-molecule and integrated discovery projects and also on cellular, protein and enzyme assay development for evaluation of compounds, screening/novel assay development based projects. Responsible for revenue targets for biology, budgeting, Capex, managing teams and team leads, lab management, client communications, presentations etc.
- Project leadership experience: As biology co-lead, lead key projects in metabolic disorders and pain. Contributed in lead and candidate identification for advanced/clinical development of few programs in the NDDD of Lupin Ltd (Lupin Research Park, Pune, Maharashtra). **Two immuno-oncology** projects culminated into pre-clinical stage deal with Abbvie, USA and BI, Germany.
- Expertise in Biologics (vaccines, recombinant therapeutic proteins and biosimilars like GCF, GM-CSF, IFN- 2a, EPO and mAbs for human therapeutic use. Reagent creation (multiple targets, protein expression, stable engineered cell lines) for discovery research (bacterial, mammalian and insect cell expression), upstream process, purification of tagged proteins for BC assays, novel assay development.
- Demonstrated expertise in (host cell engineering, clone development, stable cell lines expressing target, validation and tech-transfer). Development of multiple cell based assays for GPCRs, difficult to express ion-channels, cancer targets, thermal shift, polarization assays, cell based FRET, FLIPR, calcium flux, HCS, BRET and Nano-BRET assays for compound evaluation). More than 8 yr hands on experience in **CRISPR/Cas9 technology** for host cell engineering expressing mAbs for research use and target KO /KI cell lines for studies (metabolic, oncology project) in Lupin Ltd as well as for target validation projects for clients in CRO.
- Stake holder and key contributor for identification and development of drug (Metabolic program-LIPAGLYN/ Saroglitazar) in Zydus Cadila, Ahmedabad. Contributed significantly towards development

of recombinant therapeutic proteins (Biosimilars) in ZRC, Zydus Cadila and in Sun Pharmaceuticals ltd. **Two products were advanced and launched in domestic market by Zydus.**

- One of the Inventors in the Patent filed by Lupin Ltd, Pune bearing Title “ANTIDIABETIC AZABICYCLO [3.1.0] HEXAN COMPOUNDS”, (WO/2008/010238) (Link: www.wipo.int/pctdb/en/wo.jsp?WO=2008010238).
- One of the Inventors in the Patent (WO/2009/115874, dated 24 Sep 2009) with title: “Novel heterocyclic compounds, pharmaceutical compositions containing them and processes for their preparation” filed by Matrix-Mylan Laboratories Ltd, Hyderabad, for discovery molecules in disease class- Asthama/COPD. Multiple publications in peer reviewed journals.
- Certificate course from IIM, Ahmedabad for training on “Leadership Intervention Programme for High Performing Managers” jointly organized by Lupin Ltd and IIM Ahmedabad in 2007.
- Awarded with ESOP (stock options) twice in Lupin in **2011** and **2016** as part of high recognition for demonstrating higher performance and significant contribution for consecutive years.

PROFESSIONAL COMPETENCIES AND TECHNICAL SKILLS

EXPERIENCE IN DISCOVERY RESEARCH

- Technically competent and held leadership roles, supervisory roles in advancing discovery projects: Biology Co-lead for few metabolic disorder projects for candidate identification and pre-clinical development. Lead HTS campaigns for screening (corporate library for Hit identification) in Lupin Ltd.
- Obtained hands on-training in Tecan system from Tecan, Switzerland in 2010 for high throughput compound screen (Cell-free and cell based). Handled two HTS campaigns (Cell based and one BC assay in Lupin Ltd. Handled multiple client based discovery projects (IDD) in CRO (Sai life sciences Ltd).
- Leading MCB and Assay development team of highly skilled scientists to support discovery projects in Novel drug discovery team. Expertise in leading team of discovery reagents generation for screening (target over-expressing stable cell lines, expression and purification of tagged target proteins for biochemical assays, secondary assays, Biacore based binding assays etc.), development, validation of cellular assays including **FRET**, **BRET** (for PPI), HCS platform, FLIPR, Calcium flux, and Nano-BRET. Strategizing methods for novel cutting edge technologies (**CRISPR/Cas9**) for target KO cell lines for target engagement studies for lead compounds.
- Screening of NCEs (multiple therapeutic areas- pain, inflammation, immuno-oncology, CNS & metabolic disorder) for identifying hits and leads. Development of various cellular, functional cAMP/CREB, and calcium flux assays, multiple reporter assays (Firefly luciferase and secretory G luciferase) for screening of compounds for various targets, reporter assays (PPARs, other targets), and enzyme based screening assays for NCEs in (MD, inflammation) in Matrix- Mylan. Gene expression studies, Quantigene multiplex assays using Luminex platform and profiling studies in Lupin.
- Interaction with Cross functional teams for lead advancement for pre-clinical studies (DMPK and Toxicology/Drug safety assessment) and CROs for related studies.
- Computer based and electronic data management trainings for documentation like CromasLite, ChemBio-office (CBOE), BioSAR from PE. Hands on experience in effective implementation using CBOE, SpotFire (data visualization, analysis), BioSAR for electronic data record in Lupin Ltd.
- Designing strategies for host cell engineering and in-house development of target Knock-out cell line (in HCT-116, MCF7, Jurkat, B16F10, 4T1, HEK293, CHO) and co-ordinating with CROs (US and China) for development of KO/KI animal models, lead evaluation, profiling (off-target).

- Experience in designing labs and resource management, budgeting, Capex and mentoring team for achieving project goals, client communication and management of project, maximizing effectiveness.
- Sensitive enzyme based inhibition assays, FRET, Alpha screen assays. Cloning, expression and affinity purification of target proteins using e.coli or insect cell expression system to support screening. Strategies for in vivo biotinylation of proteins for SA based binding studies in Biacore.
- Skilled in IND enabling study report preparation, IB brochure, STPs/SOPs, Due-diligence etc.
- Novel target evaluation: Literature search and evaluation with POC for suitability as drug target. Animal handling skills: Conducting animal efficacy studies in C57 mice for OGTT, TG estimation.

EXPERIENCE IN BIOSIMILAR PROJECTS

- Extensive experience in host cell engineering for development of in-house GS knock out and FUT8 KO CHO cells using CRISPR/ Cas9 Gene editing- technology for improving the quality and efficacy of mAbs for both research and human therapeutic use. Strategizing for gene cloning and expression of proteins from e.coli and mammalian cells (CHO), clone development/selection/optimizations.
- Experienced in designing strategies for engineering of CHO cells (**CHO- dhfr** as well as **GS KO CHO** cell system) for expression of HC and LC of mAb for optimal expression and minimizing aggregation issues. Clone identification and development.
- Development of cellular potency assays for evaluation of protein batches, HCGD method development for therapeutic proteins. Experience in setting up lab scale process 2.2 L Bioreactor (New Brunswick, U.S.A) for expression of CHO cell based therapeutic proteins.

Scientific Publications and Patents:

Karche N, R.K.Kamboj, **Rajesh Gupta**, Venkata .P.Palle, et.al.: Discovery of isoquinolinone and naphthyridinone based PARP inhibitors as anti- cancer agents. **Biorg. Med chemistry**, 2020 (28), 115819.

Nilesh Raghunath Khedkar , **Rajesh Gupta** , Anil Kalia, Rajender Kumar Kamboj , Venkata P Palle. Discovery of a Novel Potent and Selective Calcium Release-Activated Calcium Channel Inhibitor: 2,6-Difluoro- N-(2'-methyl-3'-(4-methyl-5-oxo-4,5-dihydro-1,3,4-oxadiazol-2-yl)-[1,1'-biphenyl]-4yl)benzamide. Structure-Activity Relationship and Preclinical Characterization.J Med Chem. 2021Dec9; 64(23):17004-17030.do10.1021/acs.jmedchem.

Neelima Sinha, Navnath Karche, (multiple author's), **Rajesh Gupta**, Rajender. M. Kamboj, Venkata. P. Palle, et.al.,. Discovery of novel, potent, brain permeable, and orally efficacious PAMs of alpha 7 NAChR: Structure activity relationship and preclinical characterization. J. Med. Chem. 2019,63,3, 944-960.

Ramdas V, Talwar R, Kanoje V, Loria R,(multiple authors), **Gupta R.V**, Kamboj R.K, Palle V.P et.al., Discovery of potent, selective and state- dependent Nav1.7 inhibitors with robust oral efficacy in pain models: SAR and optimization of chroman and indane aryl sulfonamides. J.Med.Chem., 2020, 63, 11, 6107-6133.

Gupta. R, Walunj. S, Awate. S, Kulkarni. R, Joshi. S, Sabharwal. S and Joshi. K. Ethanolic Extract of Cinnamon Potentiates in vitro PPAR γ Reporter activity in presence of PGC1 α and SRC1 and Improves Glucose Tolerance in Mice. International Research Journal of Biotechnology, 2011. Vol. 2 (2), pp. 047-057.

Joshi. K, Awte. S., Bhatnagar. P, Walunj. S, **Gupta. R**, Joshi. S, Sabharwal. S. Cinnamomum zeylanicum extract inhibits proinflammatory cytokine TNF α : in vitro and in vivo studies. Research in Pharmaceutical Biotechnology. 2010. Vol. 2 (2), pp.14-21.

Kodimuthali A, **Gupta R**, Parsa K, Venkata L, Padala LP, Pal M. Evaluation of Novel 7-(hetero) aryl-substituted Pyrazolo [1, 5-a] pyrimidines as PDE4 Inhibitors. Frontiers in Drug Design and Discovery 2010. 7, 402-408.

Gupta R, Walunj. S.S, Tokala. R. K, et al.: Emerging Drug Candidates of Dipeptidyl Peptidase IV (DPP-IV) Inhibitor Class for the Treatment of T2DM. Current Drug targets 2009: 10 (1), 71-87.

Patent: "ANTIDIABETIC AZABICYCLO [3.1.0] HEXAN COMPOUNDS", (WO/2008/010238) (Link: www.wipo.int/pctdb/en/wo.jsp?WO=2008010238). Lupin Ltd., 2008

Patent (WO/2009/115874, 24 Sep 2009): "Novel heterocyclic compounds, pharmaceutical compositions containing them and processes for their preparation" filed by Matrix-Mylan Laboratories Ltd.

Symposium/ Seminars/Training:

- DAE symposium by Department of Biochemistry, Faculty of Science, MSU, Baroda in 1994.
- Participated in International; Symposium on Molecular medicine organized by Sun Pharmaceutical. Ind. Ltd. in 2001 and 2002. Was also volunteer in reception committee.
- Participated in Drug Discovery symposium organized by Astra-CHI in Bangalore, 1999.
- Ramanbhai Foundation 2nd International Symposium on Current Trends in Pharmaceutical Sciences: "Role of Genomics and Proteomics", Jan 23-25, 2005, Ahmedabad, India.
- International symposium on "Advances in Diabetes Therapy-Basic Science and Clinical Aspects", feb1-4, 2007, Zydus research centre, ZRC, Ahmedabad, India.
- Society of Biological Chemists (India), 78th Annual Meeting, 30th Oct -1st Nov' 2009, NCCS, Pune, India.
- Training program (10 Day) on HTS (Freedom Evoware) in Tecan, Switzerland in 2010.
- Manager Plus-I and Manager Plus-II leadership de't program Lupin Ltd, 2015 and Jan, 2017.
- Basic computer skills (MS office, excel, Oracle course), Sun Pharmaceutical Ind Ltd, Baroda, Gujarat, India.

Awards and Certifications

- Cleared Graduate Aptitude test of Engineering (GATE), 95 in Life science with **90.83%** tile.
- Cleared NET/ASRB exam 1995 conducted by All India Agricultural University, ICAR, Delhi.
- Computer certificate from ACT computer education centre for MS office, power point, Windows, Foxpro.
- Awarded ESOPS (Stock options) as recognition of Higher performance in 2011 and 2016.
- College level: Holder of Air wing Senior NCC "C" certificate from Airwing NCC HQ, Baroda, Gujarat, India.
- PG Diploma (PGDOM) in Operations management as distance learning course, IGNOU, Delhi in 2002.
- Certificate in Leadership skill development programme "Leadership Intervention for High performing Managers" from IIM, Ahmedabad, jointly conducted by IIM Ahmedabad & Lupin Ltd, Mumbai.

References:

1. Dr. Kalpana. Joshi, Professor & Head-Biotechnology, Sinhgad College of Engineering (SCOE), Vadgaon (Budruk), Pune, India, e.mail. joshikalpana@gmail.com
2. Dr. Sreedhara Swamy (+919892410547), retired -VP Pharmacology. Ex-Lupin. (Reporting M)
3. Dr. Sreekanth Rouduri (+919011045920), Ex- Sai Life sciences (Reporting M)