



Dr. Bhavana Bhagat

- A multidisciplinary experience of 25 years with a prominent footprint in pharmacovigilance & medical writing space, 5 years in academics (i.e. teaching in Forensic Medicine & Toxicology), brief stint in Hospital/Healthsystems Management including Medical & Health Insurance.
- Successfully expanded business in Mumbai by gaining stakeholder trust, led high scale end to end PV business transitions seamlessly as against planned project timelines till Business As Usual (BAU).

Profile: Medical physician (M.B.B.S.) with M.Phil. in Hospital Health Systems Management

- Enabled best in class transitions using six sigma/lean sigma principles
- Successfully led & implemented multiple outsourcings & delivery management
- Business Expansions: Built RFP/RFI solution designs customised to global Pharma MNCs' needs including Japanese Markets
- Integrated Quality By Design (QBD) in processes to ensure GxP compliance & assist in audits/inspections

Current Designation: Associate Vice President: Lead Clinical Safety, Safety Surveillance and Risk Management

Career Objectives: Be a thought leader who creates optimization opportunities, drive seamless transitions, and partake in pivotal transformations in an agile organization.

Key Achievements: (chronology by recency)

1. **YOY incremental performance:** Leveraged industry-based growth models i.e. capability maturity model, process optimizations, automations and enable BAU
2. **Value creation:** Seamlessly transitioned safety/medical writing project in house in a short span with significant cost savings; another business proposal under deliberation
3. **Strong collaborator:** Facilitated strategic organizational change by aligning stakeholder expectations, a 40% increase in customer satisfaction was noted within 1.5 year & now operating as equal partners
4. **Strengthened GxP compliance:** Used process flows to identify and mitigate compliance risks, consistently delivered zero critical or major corporate/global audits
5. **Developed talent:** Identified critical talent to maintain strong knowledge/proficiency pool who assist in continuous learning programs to enhance quality through team proficiency
6. **Stabilized attrition:** hired right team composition to offset competitive talent, defined career progression, enabled internal job transfers
7. **Championed Flagship programs to enhance employee engagement:** e.g. Women in Leadership (WIL) was launched leveraging personal connect with Lean In Mumbai circle, quarterly magazine, cultural & quality initiatives, role modeling winning behaviors, etc.
8. **Safety data migration project:** ARISg to Argus data transfer was successfully deployed in line with global regulations (including US FDA, EU, Canada and Japan), customization of B2B auto-submissions and signal module was implemented in a phased manner
9. **Ideated EMA's new EV web database change (E2B R2-R3):** in line with EMA regulatory specifications in close collaboration with QPPV & 3rd party database vendor as part of Argus upgrade
10. **Partook as a knowledge influencer:** Assisted in drafting "Indian Pharmacovigilance guidance document" under Indian Pharmacopoeia Commission (IPC), Pharmacovigilance Programme of India (PvPI), Ghaziabad

Key Attributes:

- Spearheaded offshoring from transitions using 6D model to project and delivery management
- Scaled projects (>225 team size for top 5 global MNC project in 2007)
- Develop & deploy robust process framework by mapping As-Is process design to To-Be to enable lean systems & cost value




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 <p>LinkedIn: https://www.linkedin.com/in/dr-bhavana-bhagat-890ba613/</p>	
<p>Education</p> <ul style="list-style-type: none"> ✓ M.Phil. in Hospital & Health Systems Management :2001 B.I.T.S.-Pilani, Rajasthan in collaboration with CMC Vellore, Bombay Hospital; & Tulane University, New Orleans. ✓ MBBS (Bachelor of Medicine & Surgery):1999 MGIMS College, Sewagram, Wardha, Nagpur University, Maharashtra <p>Hobbies and/or personal accolades:</p> <ol style="list-style-type: none"> 1) Counseling and Psychotherapy: <ul style="list-style-type: none"> ▪ Personal counseling certification in Robert Carkhuff psychotherapy model ▪ Rational Emotive Behavior Therapy (REBT) model of counseling ▪ Basic certification in Neuro-Linguistic Programming (NLP) 2) Affiliated to Lean-In Mumbai Circle Member, championing gender parity causes for social equity (Lean-In org) 3) Coach on leadership skills and personality development (soft skills) 4) Avid reader: Poetry, classic literature, philosophy and psychology and love for words and language 	<p>which was later released in India in 2017.</p> <ol style="list-style-type: none"> 11. Third party vendor due diligence: conducted vendor audits, assessed & negotiated vendor quotations to outsource case processing services, eventually decided to develop strategic set up as an extended infrastructure/HR in Pune to conduct medical writing & case processing services 12. Competitive intelligence of global PV outsourcing Market was assessed and organization-based strength/sales pitch to expand business value chain was proposed 13. Collaborated with sister owned database company to successfully create Vaccine vigilance safety database module: Assessed vaccine guidelines for a largest Vaccine developer in India & later ramped up Vaccine vigilance & reporting proficiency to enable seamless transition to BAU on 100% vaccine reporting delivery 14. Transitioned multiple projects using Integrated Quality Management Systems including On-site knowledge transfers or proficiency development, project kick off to seamless delivery since 2009 onwards. 15. Business portfolio expansion: Partook into large scaled bid defenses since 2009, with focused customer centricity as an SME, innovative solution designs were catered to varied business needs across global Pharma clients as part of their RFPs/RFIs; as an industry SME, partook as a business influencer to promote brand & gain business leads 16. Developed a business proposal to set an offshoring unit in Mumbai for a Japanese CRO: consulted and guided Japanese CRO executive management by creating off shoring business proposal in India, as an SME partook in sales pitch and clinched business deals with top Japanese Pharma customers; set up PV and scientific writing projects in 2013 in Mumbai 17. Managed multiple Change Of Ownership (COO/site) transfers, legacy data transfers, tripartite and Quadripartite SDEA or other business proposals by providing insights to legal or PV teams to ensure GxP compliance as an SME 18. Panelist speaker in PV Conferences like Virtue Insight Mumbai, Pharmalytica Hyderabad: topics revolved around <ul style="list-style-type: none"> • Challenges and best practices in Risk Management Plan; mitigation strategies in safety reporting • Outsourcing – a shift from antagonists to partnerships between Sponsor and CRO: critical success evaluating parameters • GPV: 'Role of Technology and Health Outcomes: A Peek into the Future' 19. Refuted fraudulent claims as a medical investigator on pre-existent ailments or disability/accidental or homicide/suicide cases enabling significant cost savings in overseas travel medical insurance and disability/death claims respectively. 20. Led 2nd year medical academics in Forensic Medicine and toxicology (FMT) department in a medical college singlehandedly; developed keen interest in the subject as a lecturer, used innovative teaching strategies, newer teaching aides & delivered academic excellence by preparing students for final examinations within a year to 90% success results in university as against 55% averages of the past. <p>Experience</p> <ul style="list-style-type: none"> • Viatri: Mylan Pharmaceuticals Private Limited: 03 Jan 2023 – Present: Associate

Vice President - Lead Clinical Safety, Safety Surveillance and Risk Management, Hyderabad India.

- **Apotex Research private Limited: 23-April-2018 till end Dec. 22:** General Manager – GBS Operations (Service Leader GPV and GRA: DI-RM & Labeling)
- **Lupin limited: 07 Mar 2016 till 20 Apr 2018:** Deputy General manager – Drug Information and Risk management (PV)
- **Lambda Therapeutic Research Limited: 06 Oct 2014 till 15 Feb 2016:** General Manager – HOD Pharmacovigilance
- **CAC India Private Limited: 03 Oct 2011 to 30 Sep 2014:** Project Manager (Consultant) – Pharmacovigilance and Medical writing
- **Accenture Services Pvt Limited: 17 Aug 2011 – 30 Sep 2011:** Global PV capability Lead
- **Tata Consultancy Services: 25 Jun 2007 – 12 Aug 2011:** Drug Safety Consultant; Subject Matter expert (SME) - Business Development)
- **Novartis Healthcare Pvt. Ltd: 24 Oct 2005 – 22 Jun 2007:** Narrative writer II– DOC India – Clinical Development Centre India, (NICCI)
- **TATA AIG General Insurance Pvt. Ltd: 08 Jan 2004 – 17 Oct 2005:** Medical Claims Executive – Accident & Health Claims, Mumbai
- **Raksha TPA Private Limited & Apollo Family Health Plan TPA: 23 Dec 2002 – 17 Jan 2004:** Health Insurance and Medical claims; Medical officer Advisor
- **Mahatma Gandhi Mission's Medical College, Kamothe, Navi Mumbai: 5th Aug 1999 to 19th Dec 2002:** Academics in Medical College & hospital: Assistant Lecturer in Forensic Medicine & Toxicology (FMT)