# Personal DETAILS



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# Career Objective

Seeking new challenges across Business/ Research Program Management, Auditing, Medical Writing, Clinical Operations, Site Management, Medical Affairs, Medical Imaging, and Data Management in Academics, Biopharmaceutical industry, CRO, Government and Healthcare organisations that can effectively utilize my passion, education and work experience in pharmaceutical research.

# SUMMARY

* Extensive work experience of 25 years in health-care (Hospitals and Medical Schools), global and local Clinical/ Contract Research Organisations, Academic Research Organisation, Site Management Organisation, Medical Imaging, Clinical Bioavailability and Bioequivalence (BA-BE), global Pharmaceutical Company and Public Health.
* A multifaceted dynamic healthcare and clinical research professional combined with prompt and astute decision-making capabilities and organisational skills.
* Demonstrated and proven track record for *managing businesses, administration and coordination of several hundred complex global programs (clinical studies) in various capacities*.
* Held top managerial positions as COO, Country Manager, Vice-President, Director, Project Manager and Professor in national and international organisations and institutions.
* “Roll up the sleeves" and "on the floor” attitude with strong quantitative/ qualitative reasoning abilities.
* Expert in delivering full scope BA-BE, Phase 2 to 4 Clinical Trials, Medical Imaging, and Academic Studies.
* Strong leadership, communication & problem-solving skills, and capability to enthuse, motivate and involve individuals and teams; passionate, forward thinking and growth-oriented individual with an analytical bent of mind who likes to take up new challenges and believes in thinking out-of-the-box.

## Overall Experience in Project Management at Academics, Healthcare, CRO, SMO, Pharmaceutical Company and Government Service

* **Project Leadership and Administration:**
* Overseen project and program delivery for all assigned customer contracted work ensuring metrics and customer goals are achieved, consolidating resources, sharing best practices, and achieving customer loyalty
* Served as a senior operations customer-facing linkage between the company and client, developing relationships within customer development group and liaising with other customer functional groups to enhance the value of the partnership
* Established and lead activities related to the Executive and Operational Governance bodies and be directly responsible for resolution of issue escalation, both internally and externally
* Interactions with key officials at Ministries of Science & Technology, Ministry of Health and premier Academic Institutions for translation of innovation for improving public health
* Managed staff in accordance with organization's policies and applicable regulations. Responsibilities include planning, assigning, and directing work; appraising performance and guiding professional development; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Approved actions on human resources matters. Worked with Program Directors, Program Managers and Line Managers to determine and meet the needs of specific programs
* Facilitated team building and communication
* Worked with other internal departments to ensure project related tasks and/or issues are resolved
* Promoted and championed process development and implementation efforts within department for improved operational efficiencies. Identified and implemented strategic opportunities (risk management, contingency planning, and enrolment strategies) to enhance and improve the project deliverables. Monitor performance metrics
* Ensured study launch, conduct, and closeout according to the Sponsor’s and Company's contractual agreement and study progresses according to quality standards, SOPs, GCPs, local and federal regulations
* Managed study budgets and expenses. Review and approve timesheets/expense reports (billable and non-billable)
* Overseen and tracked site payment issues in coordination with Finance departments
* Ensured clients are invoiced in a timely manner and follows up on receipt of payment
* Reviewed protocol, CRF, ICFs and other documents for consistency and local requirements
* Overseen the regulatory document collection and submission process
* Ensured project documentation, including TMFs are complete and audit-ready
* Negotiation and contracting process with outside vendors (labs, printers, etc)
* Vendor Management - Regulatory Consultants, Auditors, Central Lab, Trainers, etc.
* Author/reviewer for SOPs/ process guidance for projects
* **Costing and Budgeting:**
* Provided information for costing or budgeting (number of hours for writing or reviewing the medical content in the protocol, ICF and SAE forms, capture of appropriate medical information as per protocol in the paper CRF/eCRF, site visits for SAE assessment, assessment of enrolment criteria, review of medical information that goes to Site and Regulatory Authorities, etc.)
* **Reporting:**
* Maintained and evaluated project progress by maintaining timelines and other tracking/ analysis tools
* Ensured that staff are meeting defined workload and quality metrics through regular review
* **Communication:**
* Guided effective communication with the Client and project team
* Reviewed and approved information from PMs for internal review meetings
* Lead project team meetings
* **Business Development:**
* Built relationships with all current and prospective clients
* Support Business Development Teams in the creation, development, and nurturing of key strategic client relationships
* Built networks to acquire new and/or repeat business
* Develop proposals, budgets and scope of work for Customer requested opportunities
* **Knowledge Sharing/Training**:
* Facilitated team training in accordance with protocol and/or project requirements, including therapeutic area and process training
* Implemented appropriate Project Management practices with associated staff training to support improved efficiency, development, and management
* As Project/Medical Director, trained project teams on current therapeutic environment, drug development trends, facilitate knowledge sharing and ‘Lessons Learned’ sessions for junior staff
* Facilitated training for building young researchers in the country (14 trainings in 12 months)
* **General Skills**:
* Ability to work across multiple functions and cultures
* Ability to travel domestically and internationally as required
* Excellent English communication skills: written and verbal
* Strong organizational skills and ability to deal with competing priorities
* Strong reasoning and creative solving skills
* Excellent presentation skills

# EDUCATION

**The University of Hong Kong, Hong Kong**

* *MMedSc in Clinical Trials Methodology,* July 2001

**Kasturba Medical College, Mangalore**

* *MD Pharmacology,* December 1998

**Kempegowda Institute of Medical Sciences, Bangalore**

* *MBBS,* January 1991

# WORK EXPERIENCE – Clinical Research

**Clinical Research Consultant, Hyderabad**

* **1 Jul 2016 to Present**
* Advising for global and local bio-pharmaceutical companies, CRO, Medical Device and related clients onSOP, study protocol, business start-ups, review of drug development process, regulatory approvals, etc.

**Clinical Development Services Agency, Faridabad** (an Autonomous Organisation of Department of Biotechnology, Ministry of Science & technology, Government of India)

* ***Chief Operating Officer & Program Director***
* **1 Apr 2013 to 31 May 2016**
* **Achievements:**
	+ Interactions with key officials at Ministries of Science & Technology (DBT, DST and CSIR), Ministry of Health (DoH&FW, DHR and ICMR), Academic Institutions (AIIMS, JIPMER, PGIMER, KGMU, and hundreds of other government and private institutions), Centres of Excellence (JSS University, CMC Vellore, KEM Pune, CCDC & SAS, New Delhi), and Small and Medium Enterprises (Innovators)
	+ As a Faculty and Facilitator for training programs across the country for building young researchers in the country on GCP, awareness of regulatory requirements on drugs, biologics, phytopharmaceuticals, medical devices and for Ethics Committee members, coordinated 60 training programs in 38 months touching 4800+ participants from 1380 institutions with 749 faculties in 40 cities
	+ Provided quality CRO-type support services to the investigators and institutions
	+ Coordinated large investigator-initiated academic studies and clinical trials (Malnutrition, Pre-term Birth, Respiratory Distress Syndrome, Pulmonary Tuberculosis, etc.)
	+ Technical advisor to Government agencies before or after funding of clinical program
	+ Auditing of Clinical Studies, including stem cell research
	+ Involved in high-level committee meetings to draft accreditation plans for Investigators, Sites and Ethics Committee.

**Asia Pacific Clinical Research Auditing (APCRA) Ltd., Hyderabad**

* ***Clinical Research Consultant***
* **11 Feb 2012 to 31 March 2013**
* **Advising/**Consultingfor global and local bio-pharmaceutical companies, CRO and related clients onSOP, Administrative and study protocol review, business start-ups, review of drug development process, etc.

**Daiichi Sankyo India Pharma, Gurgaon**

* ***Sr. Vice President (Executive Director) & Head, India Clinical Development***
* **2 May 2011 to 20 January 2012**
* **Achievements:**
	+ **Managed and maintained better working relationship with local CRO partners** to whom studies were outsourced. The local team consisting of **75 CRAs and PMs** **managing 200+ sites** indirectly reported in to me through the Clinical Study Managers
	+ **Was responsible for regional piece of largest global programs (40,000+** patients**) in cardiovascular and oncology**
	+ **Authorized financial transactions,** resource **planning, and budgeting. Responsible for annual US$2 Million India P&L**
	+ Monthly medical meeting (telephonic) with TIMI Group and India KOL on the India medical issues and trouble shooting
	+ **Assessed a NCE** (for Diabetes Mellitus) for in-sourcing

**AXIS Clinicals (Formerly Known as Trident Life Sciences), Hyderabad**

* ***Vice President – Clinical Research***
* **16 February 2009 to 30 April 2011**
* **Achievements:**
	+ Created a new business vertical – Clinical Bioavailability and Bioequivalence (pharmacokinetic) studies and Clinical Trials for top 10 global generic and innovator companies for conduct in India.
	+ **Coordinated 30+ clinical studies across 90+ sites in India across oncology, neurology, nephrology, and ophthalmology.** Some of the sites inspected by US FDA with no critical or major findings.
	+ Initiated data management (build, validate, capture, data lock and export) for large Pharma major’s several studies in Oracle Clinical

**PAREXEL International, Hyderabad**

* ***Director, Operations – Medical Imaging & General Manager, PI India***
* **3 October 2006 to 30 January 2009**
* **Achievements:**
	+ Built Perceptive Informatics’ business in India from ground zero (as **first FTE**) to become one of profitable hubs.
	+ **Supervised 60+ Imaging Research global studies** (image digitization, processing, and make it available for radiologist review). Responsible for Europe and Asia-Pacific region

**Manipal AcuNova (Now Called as Ecron Acunova), Bangalore**

* ***Vice President – Site Management Services***
* **1 June 2006 to 30 September 2006** (support up to December 2006)
* **Achievements:**
	+ Created a separate vertical for Site Management Services (SMO) services. Though a short stint, I was able to build processes and procedures and able to add a commercial flavour to the academic and clinical trial work.
	+ **Coordinated study site related activities for 100+ phase 2 and 3 clinical trials** (multinational and national pharmaceutical, biotech, and CROs)

**Asian Clinical Trials (A Suven Life Sciences Company), Hyderabad**

* ***Project Manager, Heads – Clinical Research and Medical Affairs***
* **1 August 2001** **to 31 May 2006**
* **Achievements:**
	+ Having being the **first FTE**, I built the organisation from scratch and **Lead several phase 2 to 4 clinical trials in oncology, orthopaedics, cardiology, diabetes mellitus, cosmetology and dermatology for US, EU and India based biopharmaceutical companies**.
	+ Business Development & Contract Management (RFPs, bid defences, proposal writing, initiation of contracts, attending exhibitions, etc.). Developed content for website.
	+ Project managed all studies, with responsibilities of line management
	+ Written several protocols, SOPs, designed several CRFs, ICFs and other study related documents, logs and forms, etc.
	+ Trained on Oracle Clinical® Version 4.5.0.3
	+ As Medical Monitor, provided oversight and support to project team and site. SAE Management (triage, causality assessment, and narrative writing). Reviewed Safety Lab Data for inclusion/exclusion criteria. Trained on medDRA
	+ Assisted in initiation of India’s first Not for Profit Institution for clinical research education

# WORK EXPERIENCE – Academics

**A. J. Shetty Institute of Medical Sciences, Mangalore**

* *Associate Prof. in Pharmacology (Visiting Faculty)*
* 10 October 2002 to 21 August 2010

**Yenepoya Medical, Dental & Nursing College, Mangalore**

* *Asst. Prof. in Pharmacology*
* 28 December 1998 to August 2000

# WORK EXPERIENCE – HealthCare

**Self-Owned Clinic, Mangalore**

* *General Practitioner (Family Physician)*
* 15 October 1996 to 15 August 2000

**CSI Hospital, Chikballapur, Kolar District, Karnataka**

* *Resident Medical Officer*
* July 1991 to December 1994

## STRENGTHS

* **Wide experience in CRO, SMO, Medical Imaging, Clinical BA-BE Center, Pharmaceutical company and Government**
* **Excellent networking capabilities** within regional biopharma companies, CROs, academic institutions, hospitals, and governmental agencies
* **Expert in delivering full scope Bioavailability & Bioequivalence, Phase 2 to 4 Clinical and Medical Imaging** **studies from bidding, winning, writing study protocols, designing study-related documents, preparing regulatory dossier for Regulatory and Ethics Committee submission, site and investigator feasibility, setting up investigator meetings, site initiation, medical & clinical monitoring, close out, auditing, data queries and resolution, assist in interpretation of results, and writing study reports**
* **Established efficient operating practices for organization (policies), departments (SOPs), and regulations (CDSCO)**
* **Successfully managed and staffed** not only business start-ups, but also periods of rapid, sustained corporate growth. Lead a team of 40 to 140 people with global and local reporting
* Global awareness of cultures having traveled to many countries worldwide
* Represented company at several exhibitions and conferences along with other BD colleagues in the US and EU.
* Strong skills in **Microsoft Office suite** (Word, Excel, PowerPoint), **Adobe** **Professional**, **Oracle Clinical** (basic), and **Internet**
* **Speaker** at several (100+) global and local scientific forums, including ACRP 2010
* **Reviewer** for Perspectives in Clinical Research, official publication of the Indian Society for Clinical Research