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SHARAN SURESH

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Senior Clinical Research Management Professional | Ph.D. in Life Sciences | Post Graduate Diploma in Clinical Research

India 📍

Core Competencies

- Clinical Research
- Clinical Data Management
- Planning and Implementation
- Technical Operations
- Technical
- Content Development
- Project Management
- Risk Assessment
- Revenue Recognition
- Business Development
- Clinical Operations
- Process Improvement
- Documentation
- Claims Substantiation
- Training and Compliance
- Liaison/ Coordination
- Data Management
- Quality Control and Audits
- Operations Management
- Relationship Management
- People Management
- Team Management

Academic Credentials

- Post Graduate Diploma in Clinical Research
JJ University, 2011
- Ph. D. in Life Sciences ,University of XYZ,
Mumbai, 2008
- Selection of dissertation topic for research
2001
- MSc in Life Sciences
University of XYZ, 2001
- BSc Life Sciences
University of XYZ, Mumbai, 1999

Executive Summary

Highly focused, results driven and accomplished clinical research management professional with credible experience in clinical data management, research, planning, implementation, quality control, new product development, training, compliance and clinical practice and teaching, equipped with extensive background in conducting initial research , data analysis, evaluation and develop viable solutions for integration into the market.

Hands-on experience in shaping effective quality control measures to improve overall quality of the data processing activities with demonstrated success in executing technical content for claims support and beauty activation campaigns/ programs by designing protocols/ hand-outs and consumer technical insights. Progressive and technically competent professional with capabilities to synergize technical and social aspects with health improvement methods with comprehensive knowledge of various pharmaceutical, nutraceutical and cosmeceutical products.

A motivated leader with strong organizational and prioritization abilities coupled with ingrained confidence, adaptability and tact emanating from versatile experience in the industry.

Important clinical studies include:

Oxidative stress and management of diabetes with the help of anti-diabetic plants- the plants were grown using micro propagation techniques. Quantification of active constituents of the anti-diabetic plants using HPLC technique. In depth study on various antioxidant markers such as Superoxide dismutase (SOD), Catalase (CAT), Glutathione peroxidase (GPx), Vitamin C, and Vitamin E.

Work Experience

XX YY CONTROL, Mumbai, India

April 2019 – Present

(XYZ Control Group France and Partner Laboratories BIO-TEC)

Senior Manager – Clinical Operations

Key Deliverables:

- Manage overall project progress while closely working with the team to execute the study at the same time develop and build the team
- Evaluate the safety and efficacy of cosmetic products on consumer
- Curate technical content/protocols for the Business Development teams, generate focused content for digital marketing initiatives and presentations needed for customer engagement meetings
- Responsible for CRO, stakeholder management and R&D Operations in the areas of Pharmaceutical, Life Sciences and Healthcare verticals
- Develop and execute clinical R&D and trial protocol studies and integrate specific considerations into strategic as well as operational decisions
- Conduct safety studies on cosmetic's active ingredients through HRIPT and PIPT tests and lead them to completion
- Efficacy studies for skin care products using various instruments like Sebumeter, Chroma meter, Corneometer, Tewameter
- Approach educational institutions to add volunteers to the team
- Plan and organize counselling scripts as well as mentor counsellors to address any apprehensions and anxiety of first-time volunteers
- Contribute towards improving trials and volunteer participation by introducing schemes such as lottery, lucky draws, rewards and remuneration for participation
- Manage the site start-up activities including evaluation of site feasibility, processing regulatory approvals, performing site training and site document management
- Evaluate the safety and efficacy of cosmetic products on consumer

Key Achievements:

- Reduced the turnaround time, improved efficiency and increased savings by >40% with a thorough assessment of the 'as is' Clinical trials lifecycle followed by teams and suggested re-engineering measures
- Saved 30% per project and reduced overall personnel costs by leading processes in the pre-study planning phase, administration/coordination of critical tasks, data maintenance and closeout documentation/archiving
- Enhanced procedures by developing benchmarks in the protocols by introducing new concepts derived through industry study and research papers
- Augmented the volunteer database by 80% through introducing methods of acquiring new sources, active participation and better categorization of the volunteers for a faster selection and onboarding
- Boosted in-house capabilities and executed SOP's to ensure the reduction of efforts in mundane tasks and leverage time of the 'Research / Technician' time for quality-centric critical tasks
- Developed a macro excel application to store and generate required information
- Identified suppliers and agencies for rare and imported ingredients/materials for studies, contracting for efficient pricing and supply guarantee
- Successfully completed project on intimate hygiene product study which involved recruitment of human participants. Completed clinical trials within 60 days (estimated timeline was 90 days) and presented projects report to the sponsor company.
- Executed big budget project on Gynaec Safety product within 30 days (estimated timeline given by Sponsor company 45 days)
- Appreciated by the business operations head of Mascot Spin control after presenting the work undertaken on topical derma product for Alembic Pharmaceuticals - September 2019

ABC (CRO), Mumbai, India

Jan 2014 – Mar 2019 | Project Manager

Key Deliverables:

- Prepared protocol level budget by liaising with teams, negotiated as well as executed all site level budgets
- Managed the delivery of the protocol concerning subjects recruitment, data quality and turnaround time
- Supervised the project team to ensure execution of study is compliant
- Supported company to position competitive rate by setting up budgeting practice to get a consistent margin over similar type of clinical trials across industry type and cosmetic product type
- Conveyed the occurrence of any adverse event during the trial to Ethics Committee and the sponsor company after getting inputs from the dermatologist
- Reviewed processes to form efficacy and claim substantiation on the topical application for facial pimples
- Accomplished the claim substantiation for reducing hyperpigmentation and acne cream for all skin types
- Directed in claim substantiation for hair color products, with Henna based and Ammonia free
- Sensory analysis - Methodology - Initiation and training of assessors for skin care product

Key Achievements:

- Improved efficiency by participating in the literature survey for newer formats/ products
- Increased study revenue by more than 60% in the first 6 months by re-calibrating protocols through introducing latest internationally acclaimed equipment and materials
- Facilitated the organization leveraging in technology to differentiate itself from competitors
- Premeditated a protocol for anti-pollution product and efficaciously implemented the study design
- Improved efficiency by training and mentoring junior CRA's/study team members and retaining them
- Reduced cost by 30% per the outsourced study by associating with various laboratories for outsourcing needed specialized studies
- Improved the product performance in MNC/FMCG company by developing a sensory panel for estimating the cosmetic products
- Appreciated by the reporting manager for outstanding contribution in conducting clinical trials, completing the clinical trials within the stipulated time frame
- Received appreciation email from Sponsor Company for delivering exceptional results

ABC, Mumbai – India

May 2012 – Dec 2013 | Technical Management Associate

Key Deliverables:

- Maintained seamless coordination with brand building and business development teams to generate case and technical dossier in defense of the companies claims as well as defending complaints filed by competitors
- Offered support for emotive used in all hair care products by creating an extensive database on hair, hair care products and hair related concerns
- Assessing efficacy of hair care products & claim substantiation using instruments like ex-Diastron, Texture analyzer, HLCR & Shinometer
- Developed inter-term communication protocol by coordinating with formulation team, QA team and Brand Building (BB) team
- Established process and flashcards containing quick key pointers prepared for lever care executives to capture complaints on hair care products
- Maintained categorization criteria to bifurcate the complaints into high, medium and low categories
- Presented product overview through short demos