Dr Ripal Gharia, MD, PGDPHV, PMP®

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A sophisticated authority with comprehensive knowledge of clinicalresearch and global regulatory requirements.

About Me

I am a humble medical doctor trying to unravel nuances of drug development since last 20 years in my various roles. While pursuing my MD in Pharmacology, I was acting as a CRC in a Phase II clinical trial which fascinated me to pharma world. Leaving my established academic career behind, I decided to pursue pharma career in hope to contribute more to patient care and safety. My experience spans esteemed organizations, where I have tried to excel as a Safety Expert, Medical Monitor, and Medical Writer in therapeutic domains like Oncology, Cardiology, Dermatology, and more. I have spearheaded regulatory submissions for FDA, EMA, and DCGI, and conducted impactful training programs for global project teams. I believe in constantly updating my skill set through continuous learning. Apart from MD in Clinical Pharmacology I have also completed my Post graduate Diploma in Pharmacovigilance and Project Management Professional (PMP) certification from prestigious Project Management Institute (PMI).

Key Skills

Pharmacovigilance & medical safety	ICSR/PSUR/PADER/PBRER/RMP/aRMM/CE mark evaluation/PMCE/SMP/Signal Detection/ISS/Literature Management/PSMF/QPPV/PVA/Audits and Inspection
Clinical Trial (Phase I-IV) Management	Study Design/Feasibility/Regulatory Applications/Training/Site selection/Project Management/Medical Monitoring/Safety Monitoring/Site Development and Support PMS/IIS/PAP/CUS/Active Surveillance/Immunogenicity/Epidemiology Studies/Prescription Use Studies
Medical Writing	Protocol/Synopses/Clinical Study Report/Regulatory Scientific advise documents/Labels/Patient Information Leaflets RWE Data Collection/RWE Data Analysis/Publication
Drug Development	•NPD evaluation/Lifecycle Management Strategies/Program Development/Product USP creation
Business Development Support	•RFP/Proposals and Contracts/Client Communication/Lead Generation/Branding Strategies
Technology	•PV Intake and Literature Automation Support Tools/Case Processing Software/eCRF/ARGUS/Lifesphere(ARISG)/IRMS/Medidata
Quality and Compliance	•GCP/GVP/GDP/ALCOA+
Regulatory Expertise	•IND/NDA/BLA/505(b)(2)/351(k)/EU-MDR/USFDA/EMA/ANVISA/
Product Expertise	•Drug/Vaccines/Medical Devices/Combination Products/ATMP/Gene Therapy/Biologics/Biosimilars/Cosmetics
Therapeutic Areas Experience	•Oncology/Neurology/Psychiatry/Cardiology/Pain/Dermatology/Rheumatology/Gynecology

Core Competencies

Pharmacovigilance and Drug Safety	Clinical Trials	Clinical Development
•Establishment of PV Systems in the organization inclusive of SOP/QMS management, team building and new business development support •Managing large teams for end to end pharmacovigilance services across all regulated markets encompassing all therapeutic areas •Reviving failing projects and convert in success stories •Vast knowledge in regulatory requirements for drugs, medical devices, biologics, vaccines, combination products •Compliant system with 21.CFR.803 (USFDA), Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices and MVPI (Materiovigilance program of India •Medical devices associated adverse events (MDAEs) Reproting, incidence Reporting, Field Safety Corrective Action (FSCA) reporting, PQC and Malfunction report handling, Pre market clinical investigations, Post market clinical follow up investigations (PMCF), Periodic Safety Reports (PSRs), PRRC requirements, Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs)	•Concept Development • Feasibility synopsis •Medical Writing: Protocol (Phase I to IV), ICD/PDA/CRF etc, Clinical Study Reports •Training : GCP, GDP, Regulations (EMA - CTIS, 21 CFR, NDCT etc) •Site Selection, Development and Support •EC Communication and management •Regulatory Scientific Advise documents •Regulatory meetings for protocol and product approvals for DCGI/EMA/USFDA •Medical Monitoring: Medical oversight, patient elibility/on-site monitoring/Risk based monitoring/Central Data Review •Scientific writing : RWE analysis,Statistical modellings, Cost benefit/Cost effectiveness analysis/ publication support	•Identify unmet clinical and medical needs for new product development •Assess developmental and commercial viability of concepts •New concept generation by combining formulation technology platforms, clinical needs, patient preferences and commercial success potentials •Life cycle development plans including preclinical and clinical development strategies

Career Experience

APCER Life Sciences, Ahmedabad, India

Associate Vice President – PVG & Medical Safety (2020 – till date)

Leading large scale pharmacovigilance projects for end-to-end services as delivery lead. Mentoring and training teams, ensuring timely delivery with utmost quality and stringent timelines.Contribute toproject feasibilities, RFPs, bid defence meetings. Collaborating for regulatory inspections for various clients. Contributing to system and SOP development.

- Lead larger teams of more than 120 persons for MNC clients for end-to-end service delivery.
- Expert in ICSR Operations, Medical Review, Literature Monitoring and medical safety including PSURs/PBRERs/PADERs/RMPs/Signal detection
- Development and review of Intake Automation and Literature Automation software
- Audit and inspection support including MHRA, USFDA and bFarm
- Vast experience of pharmacovigilance concerning drugs, medical devices, combination products, vaccines, biologics, gene therapy, ATMPs etc
- Managing clients effectively and leading projects with agile methodology with utmost quality and effective cost

COD Research Pvt Ltd, Ahmedabad, India

Vice President / Principal Consultant - PVG, Medical & Regulatory Affairs (2020)

Provide effective services including, medical monitoring, medical, regulatory/scientific writing, training, auditing for system start-up, and strengthening. Contribute to project feasibilities, site development, site selection, and software development for clinical research. Participate in clinical development plans for ANDA, 505b2, 351k, 510k, and other NCE programs.Direct Client meetings, orientation and business intelligence, and business development activities.Coach and Train internal and external teams on various processes such as GCP, GVP, GDP GCLP concepts, MedDRA, and WHODD.Enable various Sponsors and CROs in the development of clinical trial and pharmacovigilance operations, project management, and quality management systems.

- Developed and maintainedpharmacovigilance, medical affairs, and regulatory departments from scratch with more than 70 SOPs.
- Business discussions and Client Management for Pharmacovigilance and Clinical Trials.
- Set up compliance monitoring and time-sheet monitoring system for all Pharmacovigilance and Medical Writing Activities.
- Organizedmore than 10 speaker engagements in various conferences.

Cliantha Research Ltd,Ahmedabad, India

Associate Director-Medical Services & Pharmacovigilance(2015-2020)

Delivered coaching and mentoring to practice staff to develop and retain talent within the organization.Facilitated strategic input to business development and brandingto pursue strategic opportunities for the organization.Contributed tomedical and project delivery procedures. Conducted regulatory and Client meetings to inform responsible individuals about how one or more practices, processes, or other activities are considered to violate the guidelines.

- Directed 15 successful regulatory meetings for drug approvals, 20 medical monitoring projects, and more than 50 protocol writing for late-phase clinical trials.
- Managed and mentored a team of 65 individuals including 5 medical reviewers and rest of other healthcare professionals for various processes like ICSR Processing, Aggregate Report Writing, Signal Detection, etc.
- Set up compliance monitoring and time-sheet monitoring system for all Pharmacovigilance and Medical Writing Activities.
- Handled more than 25 Global Clients for Pharmacovigilance and Clinical Trial Safety Monitoring for USFDA, EMEA, and ROW markets.
- Achieved project management professional certification from the prestigious Project Management Institute.

Lambda Therapeutic Research Ltd, Intas Group Company,Ahmedabad, India

Manager-Clinical Trials & Medical Services(2013-2015)

Provided medical expertise for trial oversight and safety concerns to ensure seamless operation. Acted as a medical writer and reviewer for the creation of scientific documents.Performed medical writing/review of clinical trial protocols, informed consent documents, and clinical study reports for drugs, biologicals, vaccines, and devices.Reviewed efficacy and safety data for ongoing clinical studies.

- Led medical monitoring of more than 30 projects inclusive of various biosimilar products like bevacizumab, rituximab, teriparatide, recombinant FSH, recombinant HCG, omalizumab, ranibizumab, adalimumab, etanercept, denosumab, pegaspargase, etc.
- Launched and introduced biosimilar ranibizumab first time in the world.
- Represented the organization in various regulatory meetings with DCGI, USFDA, and EMEA.

Intas Pharmaceuticals, Ahmedabad, India

Manager-Medical Affairs (2012-2013)

Developed and produced materials that deal specifically with medicine or health care to bring together industry and healthcare professionals with a focus on mutual goals and aspirations. Supervised the medical staff and provided Therapeutic training. Delivered quality support to the marketing team to improve productivity.

- Introduced three products in India.
- Developed and implemented clinical development plans for new drug delivery system products like nanosomal paclitaxel, nanosomal docetaxel, nanosomal topical gel of minoxidil and finasteride.

Additional Experience

Principal Investigator▪Auriga Research Ltd,New Delhi, India (2012)

Manager-Clinical Research & Pharmacovigilance▪Torrent Pharmaceuticals, Ahmedabad, India (2010-2012)

Class I Gazetted Officer, Professor and Clinical Research Coordinator▪Government Medical College, India (2008-2010)

Government Medical College▪Government Medical College, India

House Doctor - Internal Medicine▪Government Medical College, India

Lecturer▪Kesar-SAL Medical College, India

Education&Certification

M.B.B.S (Bachelor of Medicine, Bachelor of Surgery)

Maharaja Krishna kumarsinhji Bhavnagar University, Medicine, Surgery, India

M.D

Maharaja Krishna kumarsinhji Bhavnagar University, Clinical Pharmacology, India

Certification

POST GRADUATE DIPLOMA IN PHARMACOVIGILANCE CLINIMINDS l India

Project Management Professional Certificate Project Management Institute I USA

Affiliations

ISCR – Indian Society of Clinical Research | IPS – Indian Pharmacological Society | DIA – Drug Information Association | PMI- Project Management Institute