**MOHIT OHRI**

U‑9/47, U block, Sector 24, Phase 3, Gurgaon, Haryana

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**PROFESSIONAL SUMMARY**:

Have been working in clinical research industry since 2013 with experience in competitive intelligence of clinical trials and regulatory medical writing. Completed PG Diploma in Clinical research from Apheta Institute of Clinical Research. Qualified B.Tech in Biotechnology from Lovely Professional University.

**PROFESSIONAL SKILLS:**

* Knowledge of ICH guidelines, AMA Manual of styles for writing scientific and regulatory documents
* Experienced in preparing clinical study report (written 6 CSRs within team), patient safety narratives (worked in 6 programs and drafted 450-500 narratives including Death, SAEs, and NSAEs and QC reviewed more than 200 narratives)
* Acquired immense knowledge and working experience under the direct mentor ship of US/UK Principal & Senior Editorial Analysts on benchmarking clinical trial timings and with Senior Medical Writers for authoring regulatory documents
* Well versed in client tools such as GDMS, PREDICT, and AGN used for writing and maintain regulatory documents
* Upper hand in operating Drug database (Citeline- Trial Trove) and handled over 500 clinical trial analytics
* Data handling include scientific literature, and clinical trial data, data extraction, data entry, data analysis, interpretation and data presentation
* Understanding of drug development and clinical trial process through phase I-IV
* Knowledge of Bibliographic search on PubMed, Cochrane Library, EMBASE, Science direct and others
* Experience in independent task handling within team and allocation of assignments to team members
* Handled ClinicalTrials.gov and EudraCT tasks for clinical trial studies independently
* Knowledge of various clinical trial registries, Sec.gov, scientific meetings, and congress
* Experience of working in different therapeutic areas (CVS, Oncology, CNS, Autoimmune, Metabolic & Endocrinology)

**PROFESSIONAL EXPERIENCE:**

**Senior Associate Medical Writer** **June 2016 ‑ Present**

Kinapse India Scientific Services Pvt Ltd, Gurgaon

**Roles and Responsibilities:**

* Project lead for whole narrative writing program
* Authoring of Patient safety narratives in consideration of style, syntax, and grammar
* Quality check of Auto generated narratives and address QC findings in AGN tool
* Preparation of table of contents (TOC) for narrative and attachment of narratives in TOC
* Complete the status tracker and QC form for narratives of whole team.
* Undertakes project specific activities with minimal supervision from seniors within cost and time estimates; identify non-complex issues and provide proposals for issue resolution.
* Responsible for maintaining training records (Kinapse or client related) and completing global curriculum.

**Additional responsibilities:**

* Prepare sample document to meet client needs and specifications for a particular project.
* Mentoring new team members for authoring patient safety narratives and trained them in all writing aspects.
* Prepare guidance document for an ongoing project in narratives that included all recent updates received from client and Senior medical writers.
* Prepare meeting minutes of internal and external client meetings.

**Associate Medical Writer** **July 2015 – June 2016**

ADI Group, Mohali

**Roles and Responsibilities:**

* Preparation of Clinical study reports as per ICH E3 guidelines.
* Preparation of Patient safety narratives.
* Research, write, edit, and proofread to the highest standard (scientific and grammatical) for regulatory documents.
* Prepare training plans for team members based on developmental needs identified via feedback on an ongoing project.
* Peer review and quality check of document prepared by medical writers from team.

**Additional responsibilities:**

* Mentoring new team members for authoring regulatory documents and trained them in all writing aspects

**Medical Research Executive** **July 2013 – June 2015**

ADI Group, Mohali

**Roles and Responsibilities:**

* Take ownership for discrete pieces of work to support delivery of client projects, including:
	+ Provided worldwide clinical data research for the global pharmaceutical companies on the drug development under therapeutic area of Cardiovascular diseases
	+ Data collection of pharmaceutical clinical trials conducted worldwide (from web based searches, e.g. ClinicalTrials.gov, EudraCT, company product pipeline, press releases, scientific meetings, government websites)
	+ Structuring, cleansing, analyzing and interpreting data
	+ Preparation of a competitive landscape for drugs and clinical trials
	+ Execution of projects related to clinical trial analytics, indication overviews & prioritization
	+ Supporting client queries and follow up on the project deliverables
	+ Clinical Trial Timing Benchmarking
	+ Identify and add new information sources and establish methodologies for analytical enhancements within database
* Act as an informal coach to the more junior members of the team (progress to managing and mentoring to complete their trainings)
* Direct reporting to clients through web calls/Email

**Additional responsibilities:**

* Handle CT.gov macro daily and extract inscope studies for team and maintain status tracker
* Pubmed scan using search criteria for cardiovascular and division of inscope studies in team

**EDUCATIONAL QUALIFICATION**:

* PG Diploma in Clinical Research (2015) from Apheta Institute of Clinical Research, New Delhi
* Bachelor of Technology in Biotechnology (2012) from Lovely Professional University, Punjab
* Senior Secondary (2008) from Punjab School Education Board, Mohali
* Matriculation (2006) from Punjab School Education Board, Mohali

**PROJECTS AND TRAININGS**:

* Completed 6 months project entitled ‘Effect of L-Tyrosine Supplementation on Cognitive Performance under Simulated Multiple Stressors’ from **Defence Institute of Physiology and Allied Sciences, DRDO**, **Delhi**
* One-month hands-on-training in Microbial and Enzyme Technology from Lovely Professional University, Punjab

**CERTIFICATIONS AND PARTICIPATIONS**:

* Particpated in Hackathon 2017 at Kinapse India, Gurgaon
* Participated in Workshop on “Health Technology Assessment” (Apr 2016) at NIPER, Mohali
* Accomplishedonline course“Writing in the Sciences” with Distinction (Nov 2015) from Stanford University
* Participated in Tech-Fest Gyan Manthan 2011 held at Lovely Professional University
* First prize on district level in Science Fair 2006 for designing Non-Electric Refrigerator
* Participated in various social activities, cultural activities like annual functions at school and college level.

**COMPUTER SKILLS**:

* Proficient in Microsoft Windows, XP, 2007, and 8.1 Microsoft Office Suite (Word, Excel, PowerPoint and Access), Adobe Acrobat
* Databases and tools: JEdi v2.0, AGN v1.7, GDMS, and PREDICT v2.5.1

**PERSONAL DETAILS**:

Mother’s Name : Smt. Rajni Ohri

Father’s Name : Sh. Rakesh Ohri

Date of Birth : 15 Jan 1990

Gender : Male

Nationality : Indian

Languages Known : English, Hindi, and Punjabi

Permanent Address : Ohri Bhawan, Mohalla Ohrian, Near Katehra Chowk, Phagwara,

Punjab- 144401