Name	**:** Jaspreet Kaur
Designation	**:** Assistant Professor and Director Clinical Research
Qualification	**:** M. Pharm
Specialization	**:** Pharmaceutics
E mail id	**:** jaspreetkaur2002@gmail.com
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CAREER HIGHLIGHTS

- Over the years have successfully handled projects/assignments from concept to completion
- Experienced quality management and sales professional with proven track record in managing CRO set up, stakeholder management, business development and pharmaceutical quality functions.
- Instrumental in setting up of QA function of GLP facility and core team member for implementation of GLP accreditation for drug safety evaluation unit.
- Core team member in evaluating and setting up internal CRO at Mankind, running BA/BE business operations at Fortis
- Have hands on experience in pharmaceutical research and development processes, GCP/GLP and appropriate regulations and guidelines
- Coordination with local and international regulatory bodies for regulatory applications and approval, hosting audits, query responses and resolutions
- Oversee quality management processes and provide guidance & support to project teams to meet quality standards
- Actively led Internal Quality improvements and CAPA processes for clinical trials and BA/BE studies. Maintain GCP compliant processes which control the quality of work at the study site. Overseeing and/or performing quality functions and executing quality programs (clinical/bioanalytical operations, clinical laboratory, data management, Pharmacovigilance, GCP, GLP and general Quality Management
- Have abundant experience in identifying non-conformances with requirements, provide suitable recommendations and facilitate ongoing quality improvements using risk-based methodology. Proactively identify the project risks and assist in providing training to study staff in good clinical and documentation practices.

- A hands-on professional to review vendors, systems, data according to internationally accepted standards (e.g., in-life study audits, facility-based audits and report/raw data audit, system audits, protocol/report/e-CTD study dossier audits, CSV validation audits GAMP5, vendor audits)
- Conducted workshops and delivered training seminars on GCP, GCLP, GLP, GPvP, Quality Management, Clinical Operations, Inspection and Auditing at several forums.
- Hosted and facilitated sponsor, vendor and site inspections with extensive experience of handling inspections from USFDA, EMA, ANVISA, WHO, BfArM, afssaps, ANSM, MHRA, MCC, AGES, MOH Turkey, MOH Denmark, NABL, NABH, DCGI, JCI, CAP, AAALAC and National Good Laboratory Practice Compliance Monitoring Authority
- Handled queries from regulated and emerging market countries
- Performed audits of IT systems with respect to CFR part 11/Annex 11requirements and GAMP5 guidelines.

CURRENT EMPLOYMENT DETAILS

Employer	Designation	Function	Duration
Mankind Pharma Ltd, Manesar	Deputy General Manager – Clinical Research and Biopharmaceutics	Head Quality Management	Oct'16 till date
Confederation of Indian Industry(CII), Northern India	Co-Chairman CII, North Region Committee on Lifesciences and Biotech	Honorary position as Co-Chair, NR Committee on Life Sciences and Biotech	April 2022 till Date

PAST EMPLOYMENT HISTORY

Employer	Function	Duration
PharmAssociates Consulting Services, New Delhi	Founder Director – Clinical Research Services	Dec'15 to Oct '16
SRL Diagnostics Ltd, New Delhi	Head Business Development – Clinical Research, Comarketing tie-ups and Wellness (internal transfer from Fortis being group subsidiary company)	Apr'15 to Dec'15
Fortis Clinical Research Limited, Faridabad	Head Business Development and Project Management – BA/BE studies and Clinical Trials	Oct'13 to Apr'15
Fortis Clinical Research Limited, Faridabad	Head Quality Assurance and Training – BA/BE studies and Clinical Trials	Sep'10 to Oct'13
Vimta Labs Ltd, Hyderabad	In charge Quality Assurance – Preclinical and Clinical studies	Feb'10 to Sep'10
Ranbaxy Labs Ltd, Gurgaon	Sr. QA Auditor (Corporate Quality Assurance) – Clinical and Preclinical studies	May'03 to Jan'10

SKILLS

- Ability to build effective project teams, motivate, delegation, drive and make timely decisions
- Influencing skills including negotiation and teamwork to maintain effective working relationships with coworkers, managers, and clients.
- Effective communication skills to provide timely and accurate information to stakeholders. Ability to assess non-compliance situations and recognize potential or real wider strategic risk to project and escalate when needed.
- Ability to identify systematic causes of complex problems and recommend long-term solutions. Love to create a culture that fosters high standard of ethics
- Operational skills including focus and commitment to quality management and problem solving. Demonstrated ability to effectively interact with Competent Authorities

AWARDS & MENTIONABLES

- Appreciation for project PREVAIL (Pharmacovigilance risk management enhancement, value addition and increase learning), Global Pharmacovigilance application, Argus 4.2 SP1 Upgrade and electronic submission, Ranbaxy Labs Ltd, July 2007
- Junior Research Fellowship, Ministry of Human Resource Development during M. Pharmacy program, GATE-2000
- Represented Fortis Clinical Research Limited(FCRL) in several forums such as "Association of Clinical Research Organizations (ACRO)", Indian Society for Clinical Research (ISCR), ASSOCHAM, CPHI Germany, CPHI Spain, CPHI Mumbai, BIO International Convention (BIO) USA, AAPS National Biotechnology Conference, USA
- Liaison for FCRL with CDSCO office for BE studies/CT study approvals, 2011-2015
- Served as Media spokesperson for Fortis Clinical Research in association with Corporate Communications department of Fortis Group.
- Represented SRL Diagnostics in Ministry of Health, Medical education and Family Welfare, Ministry of Tribal affairs, Ministry of Food Processing Industries, meeting Principal Secretary/Joint Secretary/Deputy Secretary for PPP projects of the ministry in Delhi, Jharkhand, Tripura and Ahmedabad. SRL was awarded the project to set up 28 diagnostic labs in Jharkhand under PPP model and testing of Sickle Cell anemia in tribal children.

CONFERENCES, WORKSHOPS & CONTINUING EDUCATION

- Participated in GCP Workshop organized by ISCR for Investigator & Clinical Research Professionals on 8th July 2022
- Leadership Training Programme at Mankind
- Leadership Dinner Series-III "Max & Max-Unleashing potential in people" by Mankind Pharma in June 2020
- Strategies to Conduct Clinical Research Effectively in Covid-19 Era, by ISCR in June 2020
- COVID-19 User Guide Project Review, CDISC Interim User Guide, which the research community can utilize to represent data in studies pertaining to COVID-19 in May 2020
- Current operational and regulatory perspective for clinical studies in India and the various steps being taken to address the safety and wellbeing of volunteers and staff and ensure business continuity in these uncertain times, organized by Veeda Clinical Research Organization in May 2020

- Ethical Considerations for clinical research during Covid-19 Pandemic, by CDSA-THSTI in May 2020
- Issues related to Clinical Research during COVID-19A by Prof. Y K Gupta, Principal Advisor, CDSA-THSTI in May 2020
- Interactive meet on New Drugs and Clinical Trials Rules 2019; It's understanding and impact, organized by Development Service Agency (CDSA) an extramural unit of Translational Health Science & Technology Institute (THSTI), DBT, GoI jointly with Central Drugs Standard Control Organization (CDSCO), GoI in May 2019
- LEADERSHIP – Emotional Intelligence & Team Building organized by Corporate HR, Mankind Pharma in Mar 2018
- Seminar on 'Discovery & Litigation Hold', conducted at Mankind Research Centre by Mr. Jay P. Lessler, Blank Rome LLP, USA in March 2018
- CPHI, Madrid, Spain as Business Visitor, Oct 2016
- Represented Fortis Clinical Research as exhibitor at CPHI, Frankfurt, Germany, Oct 2013
- AAPS National Biotechnology Conference, San Francisco, California, USA, May 2011
- Workshop on "Study Management" by Training Resource and Information Nucleus at Training Council ISCR, Gurgaon, Feb 2011
- Conference on Pharmacovigilance and Risk Management (DIA) at Mumbai, Feb 2011

ADDITIONAL INFORMATION

- Speaker at the workshop "Continued Skill Enhancement for a Clinical Research Coordinator" organized by ISCR in collaboration with Medanta Institute of Education and Research on 22nd Dec 2022
- Speaker at International Conference on "Fostering High Quality Clinical Research for a Healthier World" held at NIMS University Jaipur on 26th Nov 2022
- Trainer for GCLP Training Program conducted by Shodh Clinicals on 17th Sep 2022
- As independent Consultant, Conducted 2 days' workshop on "Advanced GCP and Schedule Y" at Client site for employees of Jubilant generics Limited, Noida, UP, India, Sep 2016.
- Resource person in webinar on "Recent Advances in Clinical Trials" organized by NIMS Institute of Pharmacy, Jaipur, 27th march 2021.
- Speaker during webinar on "Quality Assurance: The most crucial Wing of Pharma Industry" conducted by Lloyd Institute of Management and Technology (Pharm.), 20th Sep 2020
- Delivered Expert Talk during webinar on "Clinical Research: Scope, Challenges and Opportunities, Lloyd Institute of management and Technology (Pharmaceutical Sciences), Jun 5, 2021.
- Delivered Curriculum lectures on Clinical Research and Quality Assurance to students in Pharmaceutical Medicine Doctoral Programme sponsored by Ranbaxy Research Labs, Jamia Hamdard University, 2006-2010
- Invited member, panel for external evaluation of M. Pharm dissertations, Department of Pharmaceutical Sciences, Birla Institute of Technology, Ranchi, India, 2016-17
- Delivered webinar on "Audits and Inspections in Clinical Trials" conducted by SGT University College of Pharmacy, June 2021, Haryana
- Resource Person during celebration of World Pharmacist Day, theme "Safe & Effective Medicines for all" sponsored by Pharma Innovation & Incubation Association (PIIA) & SGT University College of Pharmacy, Sep 2019, Haryana

- Delivered lecture on Opportunities in Clinical Research during 26th Annual Conference of IPGA, April 2011, New Delhi
- Speaker in International Conference organized by Pharmanext, “Pharmacovigilance and Clinical Research-Regulatory and ethical concerns around the globe” Feb 2011, Goa
- Delivered seminar on Advances in Clinical Research and Drug Discovery during National Pharmacy week Celebration sponsored by IPGA welfare trust in November 2010, New Delhi
- Delivered lecture on Ethics in Clinical Research during International Conference organized by PDM Educational Institutions, Bahadurgarh, June 2009, New Delhi
- Speaker during AICTE/ISTE Sponsored STTP “Recent Advances in Drug Discovery and Design” in March 2009, New Delhi. Title of presentation: “Audits & Inspections”
- Speaker during AICTE Sponsored National Seminar “Changing Scenario in Drugs Regulatory Affairs in March 2008, New Delhi. Title of presentation: “The FDA Process for Approving Generic Drugs”
- Demonstrated analytical techniques including UV Spectroscopy, ELISA, HPLC and Auto analyzer at various Quality Improvement Programs sponsored by AICTE at College of Pharmacy