Dr. Ahmad Kamal (Ph.D.)

Personal: ✉ ahmadkhrl@gmail.com
WORK : ✉ ahmad.kamal@orcitrials.com

OBJECTIVE

As a seasoned healthcare professional in clinical research with over 14 years' experience, I have proven record in clinical research infrastructure development, monitoring trials, training teams, ensuring pharmacovigilance activities and performing quality assurance audits. As a study accountable responsible person, I have led projects that resulted in improved trial efficiency and high-quality data while working in both sponsor and CRO setups. With an extensive experience in quality assurance, project management and training (local & across border), I am committed to contribute to shaping the clinical research industry to its highest standards and ensuring patient safety utmost.

PROFESSIONAL QUALIFICATION & SKILLS

- Served as local study accountable person and led 09 projects
- Developed infrastructure for Biological's Trial in Pakistan that was not present previously
- Adequacy in development of budget, contracts with sites & vendors and development of essential documents for project delivery
- Acted as regulatory contact person, prepared and submitted regulatory dossiers for projects and organizational licenses in Pakistan
- Monitored trial from start-up till close-out with all queries and issues resolution within stipulated budget and timelines
- Proven knowledge of ICH-GCP and associated guidelines - Received satisfactory score in evaluation by QC team of GSK EMAP
- Formulated SOPs, directive documents, processes and mechanisms, CAPAs and ensured its implementation
- Remained Quality & Risk and Training Manager at CROs and multinational pharma/biotech organizations.
    - Developed, enhanced, and maintained a business risk and continuity plan at the project and departmental levels for smooth business functions
    - Developed training roadmap and training material as per ICH-GCP & local guidelines under the guidance of organization management
    - Identified training needs and imparted training via face-to-face or virtual methods as local trainer both for CROs and GSK international level
    - Collectively trained a team of 20 individuals as CRA/Sr. CRA/CTAs and Team leaders
- Performed Quality Assurance activities for more than 11 sites of different countries and generated reports for audit findings with their categorization
- Experience of working in diverse therapeutics such as biologicals, cardiovascular, oncology, infectious diseases in both adult and paediatric population
- Have proven record of trusted relationships with stakeholders/KOLs and earned recognition as an effective team player by the GSK management with known matrix environment principles
- Recognized as Global Trainer and Quality Assurance person by international CROs global alliance
- Available to travel locally and internationally

WORK HISTORY

Clinical Project Manager & Training Manager, 2023 to present
OrciTrials Pvt. Limited - Lahore

- Creating and implementing individual plans for assigned projects, to include an assessment of potential risks to the project delivery.
- Driving study forecasting and budget management on assigned studies.
- Monitor and report on the progress of delegated clinical trials, which includes budgets and timelines.
- Preparing and reviewing documents that are related to assigned clinical study.
- Ensuring the availability of necessary resources for the execution of clinical projects.
- Review and approve invoices being presented by study vendors and external consultants.

- Attaining clinical study's goals by working with other members of the study team to outline their priorities, and to also resolve conflicts that may come up in the project process.
- Developing new training curriculum for new joiners with role specific assessments
- Identifying training gaps, developing training modules, giving hands-on training and developing team on project and organization level
- Developing/Upgrading the training material as per developing need and upraising the standards of working at OrciTrials
- Conducting workshops for internal & external stakeholders on ICH-GCP basics and advanced concepts
    - Training conducted at Cancer Care Hospital for Investigators (from diverse disciplines) received highly satisfactory score
- Always searching for contemporaneous practices in clinical research and developing team accordingly.
- Recognized and selected by Across Global for training global teams as Global Trainer

As Quality Assurance (Auditor)

- Performed audit and quality assurance activities for 03 projects including vendor quality audits with report generation
- Tracking audit findings and shaping departmental strategies to achieve service excellence
- Developing strategy for capacity building based on CAPA findings and learning for OrciTrials Team
- Developing internal quality management system based on risks at OrciTrials
- Reviewing, and improving SOPs, processes and directive documents of OrciTrials as per current market practices and ICH-GCP standards
- Implementing quality strategy of department with team
- Training, coaching and leading Quality and Clin-Ops Team at OrciTrials, Pakistan
- Selected in Across Global Alliance auditor's and training's panel

Clinical Project/Research Manager, 2018 – till 2023
Promedix CRO Pvt. Ltd. Lahore, Pakistan

- Developed, enhanced, and formulated organisational infrastructure for clinical research operations in collaboration with the team management
    - Developed working SOPs and guidelines essential for clinical research of the organization as per international and local guidelines
    - Developed training roadmap and coaching of team members under QA guidance
    - Did task oriented training, task assignment and evaluation of team members as per company SOPs & Policies
    - Developed and implemented internal quality control framework and competency evaluation plan within clinical research operations team
    - Developed and implemented departmental Risk Management & Contingency Plan
    - Established a network with vendors for execution of smooth clinical research activities
    - Liaised with state and academic institutes and vendors as per organization strategic plan for building trusted relationship

Supervised PPC-2000 Phase-I/II clinical study

- Developed a cross-functional liaison with study experts and participated as major contributor in development of project's documents including protocol, ICF, procedural manual, logistical plan, budget with milestones, project's vendors and institutes agreement, study risk plan and other documents as per ICH-GCP essential documents list
- Prepared dossiers, replies and timely reports for Ethical Committees and Drug Regulatory Authority of Pakistan (DRAP) and got approvals in due time
- Held investigator's meeting and trained staff on protocol, study procedural manual and ICH-GCP guidelines
- Developed safety communication and issue escalation plans and ensured study delivery according to these guidelines

- Sponsors were kept abreast over the KPIs, study metrics, challenges, financial & budgetary updates and it was ensured that study milestones are achieved within stipulated timeframes
- Worked with cross-unit teams to provide alternate solution where issues aroused
    - Developed referral system to enhance COVID-19 patient recruitment by collaborating with different institutes/doctors
    - Provided alternative solution for COVID-19 testing when it was a limiting step for the study progress by coordinating with another testing lab and standardizing it
- Supervised site qualification and selection, monitoring reports including close-out reports, data analysis, CAPA development and implementation, and study progress reports.
- Ensured that source documents and the Trial Master File were kept up to date in accordance with ALCOA + CCEA rules
- Completed the study's recruitment, data base, and final report within the study timelines and allotted budget

As Quality Assurance Auditor/consultant

- Performed audits for 09 projects of different countries and regions both remotely and on-site (USA, Spain, India, Mexico, Nepal, Kenya and Pakistan). The activities included reviewing;
    - Trial Master File (TMF)
    - Source Documents and eCRFs (SDR and SDV)
    - IRB/EC & Regulatory documentation and approvals
    - Monitoring visit reports
    - IP management
    - Sponsors/CROs SOPs
    - Other essential documents as per ICH-GCP
- Managed CAPAs and its effectiveness for audit conducted
- Tracked and ensured CAPAs are completed on time and any overdue CAPAs are escalated to management
- Reviewed evidence of completion to verify CAPAs are complete, and effectiveness checks for its quality assurance
- Generated reports and metrics to identify CAPA completion trends and challenges for the performed audits

Senior Clinical Research Associate ǀ **Backup Local Trainer & Regulatory Contact** ǀ **Risk Coordinator,** 2014 to 2018
GlaxoSmithKline Pakistan Limited – Lahore

- Herpes Zoster Trial in oncological patients
  Successfully monitored Pakistan's first biological study of the organization
    - Established a robust infrastructure of cold chain management under guidance of team – a key step for all upcoming vaccine trials in Pakistan.
    - Formulated a realistic & achievable budget as per Fair Market Value (FMV)
    - Performed feasibility and site selection – One site exceeded recruitment by 200%
    - Pioneered to implement successfully the first "quality gate activity" in the organization
    - Monitored sites by assuring high quality data delivery as per ALCOA + CCEA rule and TMF/eTMF kept up-to-date all the times
- Proficiently mediated Audits and Assessments on
    - Cold chain process for Biological trial by GSK auditors
    - Independent third-party audit of Zoster project selected site
    - GSK Audit on Zoster study
    - Quality Assessment by Regional Manager
    - Various quality assurance activities conducted by EMAP team members
- Performed several independent "Quality Assurance" assessments on external studies in the region with the report identifying gaps and proposing possible CAPA (if required)
    - Template created for the reporting was adopted at regional level as guiding document
- Got certification in competency as Senior CRA after achieving "Satisfactory Score" in competency evaluation conducted by the EMAP Manager
- Won 1st prize in debate competition amongst team in India and Pakistan over assigned topic

- As a Backup Local Trainer
    - Organized and hosted regional training meeting in Pakistan in which three countries participated to cover training gaps pending from three years.
    - Catalogue gap in the guidance over "LAR during ICF process" and co-function with different GSK departments to develop directive document on the needful issue
    - Mediated LOC team to create a SOP for local ICF for Pakistan which was not present previously
- As a Backup Local Regulatory Contact
    - Prepared clinical trial dossiers as per local regulatory requirements and received approvals
    - Furnished the authority's requirements by preparing periodic updates and reply of the queries
    - Facilitated expedited regulatory submissions of different CROs on behalf of GSK
    - Played a pivotal role in exchange of communication and holding meeting between GSK and the Authority
- Risk Register Coordinator
    - Identified potential risks and issues which could impact business conduct and proposed mitigation plan during meetings which ensured business continuity in unforeseen situations
    - Remained responsible to organize and update risk register of the department and projects

Clinical Research Associate, 2011 to 2014
GlaxoSmithKline Pakistan Limited – Lahore

- Acute Otitis Media Project
  Superintended successfully Pakistan largest recruiting multicentre multicounty study
    - Crafted budget yielded completion of project within stipulated estimation
    - Precise feasibility and site selection guaranteed target recruitment by all the sties
    - When assigned to the project, Pakistan was lagging from global milestones, did a successful combine Local Investigator Meeting and prepared the site with extensive trainings which enabled Pakistan to achieve 1000 subjects target within timelines
- Meningococcal Project
    - Study budget and feasibilities were meticulously done, and IRB approvals were granted for the study on appropriate rationales
    - Exertive efforts and contributions with Investigators, GSK Legal, Medical and Central team resulted in resolution of the concern raised by IRB over OPV Vs IPV vaccine use in Pakistan
- Provided support for Metabolic (Cardiovascular) and Oncology Trials
    - In Pakistan, my assigned site completed query resolution at the earliest basis and Pakistan was praised for query completion activity in the region
- Won "Bingo Bonanza Prize in myLearning" in GloxoSmithKline Pakistan Limited organization by completing highest number of learning modules

TRAININGS

(Attendance at several training meetings conducted by diverse group of trainers within and outside the country and also presented topics at different forums)

- ICH GCP Guidelines with R3 changes expected workshop by Steven Bukvic, Lahore (Feb-2024)
- Conducted ICH-GCP training at Cancer Care Hospital, Pakistan (Dec-2024)
- Essential for Audit Report Writing by Promedixcro, 2019
- Remote Audit and GCP compliance by Promedixcro, 2019
- Quality Assurance Essence by Promedixcro, 2018
- Conducted Investigator's Meeting of PPC-200 Phase I/II clinical study at Lahore General Hospital, Lahore (June-2018)
- "Quality and Training meeting"- GSK Lahore Sales Office, Pakistan (Feb-2016)
    - Hosted the meeting and conducted session on ICH-GCP updates, MVR writing best practices, Risk Base Monitoring, updates on Local Regulatory requirements etc.
- "EME Clinical Operations Training" – GSK Bryanston Office, South Africa (July 2015)
    - Presented topic "Study finding sharing and its CAPA plan."

- "Cross Boundaries, Joint Progress" - EM Clin-Ops Training Istanbul, Turkey (May-2014)
    - Conducted training session on “PACE Process” of Inform
- 2013 Refresher Training Course for Clin-Ops Team in MENA and GSK GCP workshop Istanbul, Turkey (May-2013)
    - Presented topic “Monitoring best practices”
- Zoster-039 (116428) Monitors and Investigators Meeting at Seoul, South Korea (Mar-2013)
- Monitor’s meeting of EPI-STREP-060 BOD EM, 115672 at Istanbul, Turkey (Oct-2012)
- “Communicate to Connect” communication skills workshop Karachi, Pakistan (Jun-2012)
- CRP Meeting Islamabad 2012 “Focus on Quality” and “Monitoring Essential Skills Workshop-Pakistan by TQRM” (Jun-2012)
    - Presented topic “ICF process and its documentation”
- “Conducting Quality Monitoring Activities” Regional Monitors Training Meeting at Beirut, Lebanon (May-2012)
- Investigator and Monitors Meeting of MenACWY-TT-087 (114858) at Ankara, Turkey (Apr-2012)
- Co-Monitoring at AUB (American University of Beirut) Beirut, Lebanon (Feb-2012)
- Adaptive Site Monitoring Virtual Training (Dec-2011)
- Monitoring@GSK Part I Newcomers Training Johannesburg, South Africa (Sep-2011)
- LPL100601 protocol virtual training Lahore, Pakistan (July-2011)
- ALTTO 106708 protocol virtual training Lahore, Pakistan (May-2011)
- CRP Meeting at Lahore, Pakistan (Feb-2011)

EXPERIENCE IN DIFFERENT THERAPEUTICS

Therapeutic categories	Specialized area(s)	Population	Phase(s)
Infectious Disease	Streptococcal (EPI Study)	Pediatrics	IV
Infectious Disease	Herpez Zoster	Adult	III
Infectious Disease	Meningococcal	Pediatrics	III
Infectious Disease	SARS-CoV-2 (COVID-19)	Adult	II
Cardiovascular	Heart Disease	Adult	III
Oncology	Breast Cancer	Adult	III
Healthy Volunteers	Safety	Adult	I

EDUCATION

Doctor of Philosophy (Ph.D.): Pharmaceutics, 2024
Publication*: Evaluation of Renessans (Iodine Complex Molecule) Safety in Human Beings: An Open-Labeled Clinical Study*

Master of Philosophy (M. Phil.): Pharmaceutics, 2016
Thesis: *An observational and retrospective study to evaluate the incidence of Acute Otitis Media (AOM) in children at Lahore, Pakistan*

Doctor of Pharmacy (Pharm-D): Pharmacy, 2010

INTEREST

- Sports – Table Tennis and Cricket in particular – Remained Captain and Champion of both games during graduation studies. Soccer, Baseball, Long Tennis and Darts are also very much liked.
- Travelling and tasting different cuisines and learning about different cultures
- Internet surfing with keen interest in new technology & development especially in medicines

REFERENCE

References will be furnished on request.