

TEHMINA ADNAN

Professional Resume

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Marital Status: Married.

OBJECTIVE:

I have a passion for clinical research that has led motivating me to continue my current position as Manager Quality Assurance for one of the best research organization in Pakistan. I would bring an extensive breadth of knowledge in clinical research with multiple areas of expertise. I would like to lead the organization being strategic partner of technical team of organization and obtain challenging position in a dynamic organization that's provide ample opportunity for development of knowledge, skills & attribute also to acquire useful experience thus contributing towards the prosperity of that organization, country & my own professional growth. Achieving organization goal is first priority within competitive environment, where using skill to meet the challenges and interact with the internal as well as external environment.

EDUCATION:

Master of Pharmacy in Pharmaceutics (University of Karachi)

Pharmacy (University of Karachi)

PROFESSIONAL CAREER SUMMARY:

October 2013 to now as a Manager Quality Assurance and QMR in CBSCR, University of Karachi

April 2013-October 2013 as Manager Regulatory and Data management and QMR in CBSCR

April 2009-March 2013 as a Assistant Manager Clinical Services in CBSCR

Nov 2008-April 2009 as a Trainee in Bioanalytical Laboratory in CBSCR

March 2008-May 2008 as Pharmacist in Guardian Pharmacy

March 2000- Holy family Hospital as a Intern Pharmacist

ADDITIONAL SKILL:

- Regulatory Binders in research (Investigator files)
- IRB/IEC application/Submission
- Developing Research Protocol and its compliance with the ICH, TGA ,WHO,EMEA and US-FDA, bioequivalence Guidelines
- Understanding of Good Laboratory Practice,
- Fundamental Regulatory Requirement for Clinical Trial
- Data management in Research
- Drug accountability and Storage
- Achieving of Study Documents and Investigational Drugs
- Completion of CRF and Source Data
- Standard Operating Procedure Writing
- Training and Certification on ISO 9001:2015 and ISO 17025:2005
- Toxicological studies on animal

- Microsoft office application(MS word, Excel, Power Point)

Work Experience:

Designation: Manager Quality Assurance and Quality Management Representative

Organization: CBSCR, International Centre for Chemical & Biological Sciences (ICCBS),
University of Karachi

Area(s) of Experience:

To provide necessary training to concern staff. To ensure that in process and other internal audit are well planned and organized timely. Confirm the compliance with the applicable regulatory requirement, Protocol QSPs, SOPs and work instructions. Review of procedures and compliance and updated in timely manner. Verify study report accurately and completely reflects the data of the study. Participate in inspection procedures conducted by regulatory bodies. Participate in MRC and present report on CPA and internal audit.

Work Experience:

Designation: Manager Regulatory and Data management

Organization: CBSCR, International Centre for Chemical & Biological Sciences (ICCBS)

Area(s) of Experience: Responsible to deal with regulatory affairs and Technical matters in connection with the all applicable guideline of Bioequivalence Study with potential clients as appropriate. To liaise with sponsor, IEC/IRB, Drug regulatory authority in study initiation as well as Correspondence, communication, and schedule appointments and visit of regulatory inspectors and monitors/sponsors. Maintain pharmacy, control investigational drugs for studies. Designing Protocol by the literature survey, investigational brochure development, informed consent form, subject information sheets, investigational file, randomization scheme and study report compilation, reporting of protocol deviation/violation and to plan the CA/PA for the deviation or violation. Decoding of analytical results, archiving of study drugs and documents.

Work Experience:

Designation: Manager Clinical Services

Organization: CBSCR, International Centre for Chemical & Biological Sciences (ICCBS)

Area(s) of Experience: Responsible to conduct of clinical part of study in GCP compliance, Collection of drug Serum/plasma, Preparation of study related documents as per ICH GCP Guideline. Informed Consent Form of research study. Case Report Form of research study Volunteers Screening, Recruitment and Selection Procedure. Blood sampling Processing, Storage and Transport.

Academic Certificates/Awards

Sr.	Certificates	Year
1	Got scholarship from PIA Employees Children Scholarship.	1993
2	Excellent Performance Certificate from “The Caring Club” Pharmacy	1998

Professional Development achievement

Sr.	Workshops / Seminars	Year
1.	On job Training on Bioanalytical method development & Validation	Nov. 2008- April 2009
2.	On job training on protocol writing and Report writing investigational drugs.	May 2009-10
3.	Attended a lecture on “QA/QC Statistics for Non Statisticians” organized by	July 28, 2010

Cando Consultancy and Training Services at Hotel Pearl Continental, Karachi

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| 4. | Attended the Technical Course on “Introduction to the HPLC, its troubleshooting and maintenance” conducted by Technology Links Pvt. Ltd. | Nov.
8-13 2010 |
| 5. | “Good Laboratory Practice” organized by CBSBR, ICCBS, University of Karachi | Dec. 10, 2010 |
| 6. | Training on Bioequivalence studies from PRU Jordan Amman | Aug.16- 23,
2011 |
| 7. | Attended a course on “ISO 9001:2008 Quality Management System” by 3D Educators-Trainers and Consultants. | 31 July-30 Sep.,
2011 |
| 8. | Attended a lecture on “Awareness to ISO 9001:2008(Quality Management Systems) at CBSBR, ICCBS, University of Karachi | May 23, 2011 |
| 9. | ISO 9001:2008 and QMS | June 2011 |
| 10. | Basic Fire Fighting Training at ICCBS, University of Karachi | May 19, 2012 |
| 11. | Training on ICH Harmonized Tripartite Guidelines for Good Clinical Practices E6(R1) | June 26-
28, 2012 |
| 12. | Basic Understanding of ISO 17025:2005 by Cypress at University of Karachi | Oct.13, 2012 |
| 13. | Awareness of ISO 17025:2005 by Saeeda Fatima (ISO Consultant) | Nov. 12, 2012 |
| 14. | 1 st Symposium on “Bioequivalence and Bioavailability Studies” organized by CBSCR, ICCBS, University of Karachi in Lahore. | 15-16 April,
2014 |
| 15. | Participated in a two day in house Training Course on “Awareness and Internal Audit Training on ISO 9001:2008” by Bureau Veritas | Sept. 10 and
11 2014 |
| 16. | 2 nd Symposium on “Bioequivalence and Bioavailability Studies” organized by CBSCR, ICCBS University of Karachi | 18-19 Nov.,
2014 |
| 17. | 5th International Symposium Cum Training Course on Molecular Medicine and Drug Research organized by PCMD, ICCBS, University of Karachi | 12-15 Jan.,
2015 |
| 18. | First Workshop “culture of Quality” by Dr.Obaid, Sultan Ghani and Iftikhar A.Jafri. | Oct.10, 2015 |
| 19. | Participated in webinar entitled “Chemical Risk Management” jointly organized by ICCBS and GRDF global USA. | Mar. 19-Apr.
27, 2017 |
| 20. | Attended a workshop entitled, “How to give an Effective Lecture”, held at ICCBS, University of Karachi | May 27, 2015 |

21. 3rd Symposium on “Bioequivalence and Bioavailability Studies” at ICCBS, University of Karachi. Aug. 18th-19th 2015
22. Attended a workshop entitled, “Intellectual Property Rights and Entrepreneurship in Pakistan” in collaboration with the Federation of Pakistan Chambers of Commerce and Industry (FPCCI), and Intellectual Property Organization (IPO) at LEJ, ICCBS. October 5, 2015
23. 4th Pak-France Bi-national Workshop on Drug Discovery and Molecular Medicine jointly organized by PCMD, ICCBS and Embassy of France, Islamabad, Pakistan. 12-14 Oct., 2015
24. Scientific Writing Organized by Virtual Education Project Pakistan (VEPP) and LEJ, ICCBS, University of Karachi Oct. 20-21, 2015
25. Training on Clinical Trial Protocol writing as per ICH-GCP E6 (R1) by Dr. Iven Heiko 16-27 Nov., 2015
26. Participated in “National Training Course on chemical Industry Standards” Jointly organized by ICCBS, Pakistan, Federation of Pakistan Chamber of Commerce and Industry (FPCCI, Pakistan), Sandia National Laboratories (SNL, USA) and CRDF (USA) 7, 18 Mar, 2016
27. Attend one-day workshop on “sample sized calculation through NCSS pass”. Feb. 24, 2016
28. The human care and use of laboratory animals “Species Specific Animal Use and Care Course” from ICCBS. May 06, 2016
29. Second Annual Forum “culture of Quality” by Dr. Obaid, Sultan Ghani and Iftikhar A. Jafri at Habib University. Nov. 26, 2016
30. Participated in the series of webinar entitled, “Implementation and Assessment of Chemical Safety and Security Risks in Academic Institutions of Pakistan” Jointly organized by the CWC National Authority and Disarmament Cell, (Ministry of Foreign Affairs, Pakistan), (ICCBS, Pakistan), (VEPP, ICCBS), Sandia National Laboratories (SNL, USA), and CRDF Global (USA). Jan. 19, 26 and Feb. 2, 2017
31. Attended a lecture on “Awareness of ISO 9001:2015” from Sardar Yasin Malik Jan. 28, 2017
32. Attended discussion Forum on “Bioequivalence studies, Comparative dissolution profile and contemporary quality affairs” delivered by Dr. Obaid Ali, Roohi Obaid and Iftikhar A. Jafri. Feb. 25, 2017
33. Attended a One day Discussion Forum on ICH, Q1-Q1F (Stability Studies) at HEJ, ICCBS, University of Karachi March 26, 2017
34. Attended a one day “Bioequivalence and Pharmacovigilance Awareness April 08, 2017

Session” at CBSCR, ICCBS, University of Karachi

35. Attended a one day Discussion Forum on “Q7-Good Manufacturing Practices for Active Pharmaceutical/Biological Entities) & Q11 Development of Drug Substances” at HEJ, ICCBS, University of Karachi April 23, 2017
36. one day Training session on Unfolding Complexities in GMP to Develop Progressive Strategy of Control” by Dr.Obaid Ali May 13, 2017

Project Accomplished at CBSCR:

1. Pharmacokinetic of Poston CS Pfizer Pakistan 2009
2. Drug Free Plasma for CTLS London 2009
3. Pharmacokinetic study of Atenolol for Platinum Pakistan (Pvt.) Ltd 2010
4. Pharmacokinetic study of Peg Interferon for Getz Pharma (Pvt.) Ltd 2010
5. Bioequivalence study of Ethionamide Schazoo Zaka (Pvt.) Ltd 2011
6. Bioequivalence study of Clarithromycin Suspension for Merck (Pvt.) Ltd 2012
7. Bioequivalence study of Levofloxacin for Merck (Pvt.) Ltd 2012
8. Bioequivalence study of Amlodipine for Merck (Pvt.) Ltd 2012
9. Bioequivalence study of Clarithromycin Tablet for Merck (Pvt.) Ltd 2012
10. Bioequivalence study of Atovastatin Tablet for Merck (Pvt.) Ltd 2012
11. Bioequivalence study of Candesartan Cilexetil for Merck (Pvt.) Ltd 2012
12. Pharmacokinetic study of Naloxone HCL 2012
13. Bioequivalence study of Gabapentine for Merck (Pvt.) Ltd 2012
14. Bioequivalence study of Losartan Potassium +Hydrochlorthiazide for GSK(Pvt.) Ltd 2014
15. Bioequivalence study of Candesartan Cilexetil + Hydrochlorthiazide for Merck (Pvt.) Ltd 2014
16. Bioequivalence study of Azithromycin for GSK (Pvt.) Ltd(Protocol approval) 2014
17. Bioequivalence study of Diclofenac Sodium for Abbott (Pvt.)Ltd. 2016
18. Toxicological studies of pesticide 2016-17
19. Bioequivalence study of Omeprazole for Pharmatec (Pvt.)Ltd. 2017

Co-curricular / Leisure Activities

Sr. Description of Activities

- 1 Reading Books
- 2 Web Browsing/Net Surfing
- 3 Cooking

Personal Information

Father's Name : Maqbool Ahmed
 Marital Status : Married
 CNIC No. : 42201-0426308-4
 Religion : Islam
 Language Competency : English & Urdu

Field Of Interest

Sr. Skills & Abilities

- 1 Trial coordinator in CRO (Contract Research Organization)
- 2 Internal Quality auditor

References

- 1 Dr.Raza Shah General Manager CBSCR
- 2 Dr.Abid (Medical Doctor at University of Karachi)
- 3 Dr.Ali Azmat Abidi (Ex.Director LNH)