AMREEN AIJAZ

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CAREER OBJECTIVE

I am a very dynamic personality open to indulge and interact to work in a firm with professional work driven environment where I can utilize and apply my knowledge and skills as an ambitious person towards continuous growth and advancement. Consistently achieved top rankings throughout my academic journey, including first place in the university during my Master's program. I attained a highest CGPA of 8.2 during my Ph.D. coursework and demonstrated exceptional performance in my professional career. Over 13 years of experience in the healthcare industry with a focus on Clinical Research and Pharmacovigilance, proficient in managing quality documentation and analysing medical records related to clinical trials. Successfully led teams and collaborated with medical professionals to ensure compliance with scientific guidelines. Demonstrated strong analytical skills and expertise in Phase-IV studies. Published multiple research papers and presented at national and international conferences.

Career insight: Pharmacovigilance/Clinical Operations/PhD Research Analyst.

ACADEMIC DETAILS

Ph.D. (Clinical Research), DIT-ICRI India, Dehradun (2020-Ongoing, Last Sem, 8.2 CGPA, Top Rank)
M.Pharm (Pharmacognosy), SCOPE, Indore, RGPV Bhopal (2008-2010, 80.3%, University Top Rank in 1st & 2nd Sem)
B.Pharm, IPS Academy, Indore, RGPV Bhopal (2003-2007, 72.33%)
Class XII, St. Theresa's School, Burhanpur, M.P. Board (2003, 80.8%)
Class X, St. Theresa's School, Burhanpur, M.P. Board (2001, 76.8%)

CURRENT JOB DETAILS

1. Organization: Cognizant Technology Solution (Healthcare-IOA), Hyderabad (T.S.)
    - Designation: Senior Process Associate
    - Tenure: 23-June-2023 to Present.

Operational Responsibilities:

a) Clinical Safety Studies-Phase-IV-Aggregate reporting:

- Drafting and review End to End Aggregate report including Periodic Safety Update Reports (PSURs), Periodic Benefit-Risk Evaluation Reports (PBRERs), and Periodic Adverse Drug Experience Report (PADER).
- Exposure in Annual Safety Reports (ASRs), DSURs, and RMP review.
- Medical Writing in CTD dossier, modules 2.5 and 2.7.
- Signal Management End to End Process.

- Analyse and interpret safety data from various sources to prepare concise and accurate summaries.
- Collaborate with cross-functional teams, including pharmacovigilance, regulatory affairs, and medical writing.
- Ensure compliance with applicable regulatory guidelines.
- Meet strict timelines and quality standards for report submission.

b) Medical Summarization (Quality documentation specialist-QA)

- Review and summarize medical records, including diagnoses, treatments, and procedures.
- Review documentation coverage for a set of healthcare providers, which involves analysing patient's clinic visits reports and leveraging technology to summarize medical facts in professional clinical reports.
- Achieve proficiency in navigating EHRs and clinical reports into customer EHRs, adhering to specific clinical guidelines and workflows.
- Assess the risk associated with each case and determine the insurability of applicants.
- Maintain a high-quality standard and adhere to account-specific documentation which delineates documentation requirements for our customers.
- Collaborate with medical professionals and underwriting team members to gather necessary information.
- Collaborate with managers as Senior process expert on team feedback from providers and clients and successfully resolving issues.
- Ensure compliance with established scientific guidelines and regulatory requirements.
- Provide support and guidance to other team members.
- Proficient in working with medical records and terminology.
- Strong analytical skills and the ability to interpret complex medical information.
- Excellent scientific writing skills including advanced proficiency in communicating with international clients.
- Excellent listening skills and ability to understand diverse accents and dialects of physicians, their staff, and patients.
- Expertise with the Advanced AI tools, IOE healthcare database, Microsoft Office 365, or other cloud-based productivity tools.
- Ability to lead the team and work independently.
- Worked as back-up team lead

PREVIOUS JOB DETAILS

2. Organization: Vigilare Biopharma Pvt. Ltd. Hyderabad (T.S.)
    - Designation: Sr. Drug Safety Associate (Signal Management)
    - Tenure: 22-Jan-2022 to 01-Jan-2023

Operational Responsibilities:

- Signal Management End to End Process.
- Experience in drafting SVR, SMR, SDR Aggregate reports.

- Expertise in MedDRA coding (25.1) and safety database (Argus 8.1)
- Knowledge in Line listing generation, literature assessments, and quality checks.
- Worked as Medical Reviewer (Experience of writing MR assessment in Signal reports).
- Expertise in Management of Signal activities.
- In Depth Knowledge about PV Safety Databases.
- Handling of Audit or regulatory Inspections
- Proactively assess and prevent the process or operation gaps.
  Other Key Areas:
- Periodic Retrospective review of Quality on Signal Management reports.
- Performing Signal Management training activities
- Plan and organize day-to-day PV operations including compliance, quality, and productivity.
- Finishing the allocation for multiple projects based on priorities and deadlines.

3. Higher Education involvement:
Organization: MGM regional hospital, Warangal (Telangana).
Designation: Clinical Research Analyst.
Tenure: 01-JUN-2022 to 30-JUN-2023
***Simultaneous with job**: Undergone research project from Cardiac emergency department of MGM regional hospital, Warangal (Telangana). Key area: Cardiology dept- Pre-hospital care and Outcomes of OHCA (Out of Hospital Cardiac Arrest).*

Organization: Dehradun Institute of Technology (DIT) affiliated to ICRI (Institution of Clinical Research India).
Designation: Research Scholar
Tenure: 07-JUN-2020 to 31-Dec-2021
Enrolled in PhD Clinical Research Program (Part-time-Ongoing).

- Carried out course work (6-months) and examination.
- Continued literature review and other studies (1-year) to get Institutional ethical committee board and local ethical committee board approval (granted) for carrying out clinical observation studies in clinical research centres.

4. Organization: Freelancing.
Designation: Scientific Writer
Tenure: 02-Aug-2018 to 01-May-2020
Worked as independent Scientific Writer, publications, promotional editor of IJPL, IJPR, journals related to Clinical research/Clinical trials/Pharmacovigilance/Pharmacy Research.

5. Maternal and Child-care gap: 1.5 years (Jan-2017 to Jul-2018).

6. Organization: Tata Consultancy Services (Pharmacovigilance), Pune (M.S.)

- Designation: Drug Safety Quality Associate (Grade3-Business Process Lead).
- Tenure: 05-Jul-2012 To 22-Apr-2016.

- 22-Apr-2016 to 31-Dec-2016 –in PDP pool (Released from current project) due to relocation from Pune to Hyderabad post marriage and non-availability of Clinical project in TCS-Hyderabad.

Operational Responsibilities:

- Handled on-shore team as PV operational lead. (Business Process Lead).
- Providing feedback to the case processors and QA team regarding specific errors and guiding for accurate case processing.
- Handling regular updates of case processing convention and sharing and updating the team on regular basis.
- Prioritizing daily cases as per regulatory guidelines based on the seriousness criteria, which help the process team for submitting the cases to the client, regulatory authorities, FDA as per the timelines.
- Generating queries pertaining to the cases and performing the reply received for the respective cases in priority and ensuring the reports are sent to the customers within the assigned deadlines.
- Initially was involved in case processing and reviewing of Spontaneous, Solicited, Clinical trial, Post-marketing, Literature, and legal cases.
- Coding of drugs suspect products and concomitants.
- Narrative writing according to current reference.
- Company comment and Case comment writing.
- Performing validity assessment for all cases, determining the seriousness of the events, and causality assessment.
- All Adverse event cases and Product Quality complaint using ARGUS database.

7. Worked as “Training Manager”; Clinical Research, in Marigold Pharma’s Training Centre (A unit of Marigold Pharmaceuticals Pvt. Ltd.), Pune (M.S.) - (Nov-2011 to May-2012).

8. Worked as Assistant Professor in Central India Institute of Technology (RKDF Group), Indore (M.P.) - (Feb-2011 to Sep-2011).

RESEARCH WORK EXPERIENCE

- Ph.D. (Clinical Research): An Observational Cohort Study on Pre-hospital care and Outcomes of OHCA (Out of Hospital Cardiac Arrest) in Telangana, India”. Also, we did PRISM meta-analysis (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) in the review publication to analyse all the studies published during Covid-19 on OHCA.
- M. Pharmacy: Effect of Precursors and Elicitors on Production of Berberine from Tissue Cultures of Tinospora cordifolia Willd.
  In-Vitro and In-Vivo Evaluation of Nardostachys jatamansi Rhizomes in Experimentally Induced Urolithiasis.
- B. Pharmacy: Process Analytical Technology (P.A.T.), Ocular Inserts.

SEMINAR PRESENTED/ATTENDED IN NATIONAL/INTERNATIONAL CONFRENCE/PROGRAMS

- Presented poster on “Investigation of Hepatoprotective Potential of Bombax ceiba Linn.”, 61th Indian Pharmaceutical Congress, 2009 at Nirma University, Ahmedabad.
- Presented poster on “Regulatory aspects of Herbal Drugs”, National Seminar on Technological & Regulatory Aspectsof Herbal Drug Analysis, at BRNCOP Campus, Mandsaur (M.P.)”.
- Presented poster on “Animal Models of Nociception - Current Status and Future Challenges”, Pharmacokinetic & Pharmacodynamic Modeling- Concepts and Applications, at SCOPE, Indore (M.P)
- Presented poster on “Antitussive activity of one indegenous plant and polyherbal formulation”, 61th Indian Pharmaceutical Association, 2010 at D.A.V.V. Indore.
- Attended Telemedicine conference, organized by MSME at NIT Warangal, Telangana.
- Attended “Leveraging and Exploring Business Opportunities in Health Care Industries”, organized by MSME at NIT Warangal, Telangana.
- Certified in High-quality CPR and use of Automated-External-Defibrillator (AED) in situation of sudden cardiac arrest organized by Srinivasa Heart Centre in collaboration with National Institute of Technology, Warangal as part of advanced management development program.

RESEARCH PUBLICATIONS

- Ph.D. (Clinical Research):

- Husain, Amreen Aijaz, Uddipak Rai, Amlan Kanti Sarkar, V. Chandrasekhar, and Mohammad Farukh Hashmi. "Out-of-hospital cardiac arrest during the COVID-19 pandemic: a systematic review." In **Healthcare (MDPI)**, vol. 11, no. 2, p. 189. MDPI, 2023 (**SCI Indexed**).
- Husain, Amreen Aijaz, Uddipak Rai, Amlan Kanti Sarkar, V. and Chandrasekhar. "Pre-Hospital Care and Effect of Cardiopulmonary Resuscitation (CPR) On Survival Rate of Out-Of-Hospital Cardiac Arrest (OHCA) Victims, Telangana (India)." National Journal of Clinical Medicine (NJCM) (**Scopus Indexed**).
- Husain, Amreen Aijaz, Uddipak Rai, Amlan Kanti Sarkar, V. and Chandrasekhar. "A Prospective Observational Cohort Study on Outcomes of OHCA (Out of Hospital Cardiac Arrest) in Telangana, India." (JRCM).
- A Retrospective Cohort Study on Impact of Covid-19 Outbreak on Out-of-Hospital Cardiac Arrest (OHCA) in Telangana, India (BMC Public Health).

- M.Pharma:

- Effect of elicitation on the production of phyto-constituents through plant tissue culture technique – A review, in “International Journal of Drug Discovery and Herbal Research (IJDDHR)”.
- Protective Effect of ethanolic extract of Nardostachys jatamansi rhizomes in ethylene glycol induced urolithiasis in rats, in “Phytotherapy Research”.
- Effect of plant growth regulators on the production of berberine from tissue cultures of Tinospora cordifolia Willd, in “Indian Journal of Biotechnology”.

ACHIEVEMENTS

- Achieved top rank in University (R.G.P.V.) in M. Pharm 1st and 2nd Sem.
- Achieved top rank in University (DIT, Dehradun) in Ph.D. Course work 2021.
- Attended and presented (as speaker) various Learning and Development (L&D) programs in different organizations.
- Organized social and learning development programs of healthcare in different sectors including National Institute of Technology (Warangal, Telangana).
- Achieved top rank multiple times within previous organizations and rewarded with Performance linked rewards (PLRs.)
- Promotional Editor of International Journal of Pharmacy and Life science
- Promotional Editor of International Journal of Pharmacy Research
- Appeared in National Level Pharmacy Talent Search Examination, Pharma helpline society, Jaipur.
- Achieved various ranks and certificates on the presentations in National and International seminars.
- Extra-curricular activities: Won several prizes in anchoring, speech, debate competitions, singing, and dancing during college and school's curriculum. Active participation in cultural activities and sports.

KEY STRENGTHS

Proficient in verbal and written communication skills, Comprehensive problem-solving abilities, team leading capability, also in organizing socio-skill development programs in the field of clinical research.

PERSONAL DETAILS

Name: Amreen Aijaz Hashmi
Date of Birth: 08th July, 1987
Gender: Female

PROFESSIONAL REFERENCES

1. Dr. Mandar Deshmukh, Delivery Manager at Tata Consultancy Services, Mob: 8888122221.
2. Joel Sandri, former Asst. Manager at Vigilare Biopharma Pvt. Ltd., Head of operations at JA Ministries, Mob: 8121811461

DECLARATION

I hereby declare that the above-furnished information is true and correct to the best of my knowledge and belief.

Date:
Place: Warangal Amreen Aijaz