Abul Kalam

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Preference: Teaching and Research

PROFILE SUMMARY AND EXPERIENCE

With extensive experience in regulatory medical writing and toxicology, I have worked on submissions for global markets and risk assessments for consumer products. I hold a Ph.D. in Pharmacology and have published research in various scientific journals. My expertise encompasses eCTD submissions, toxicological profiling, and technical reporting.

- Senior Toxicologist, **RMonitor India Pvt Ltd** from Dec 2024 to March 2025
- Regulatory Medical Writer, **Tata Consultancy Services** from Oct 2020 to Dec 2024
- Worked as **Toxicologist, Johnson & Johnson** Mumbai, from March 2019 to Sep 2020
- Worked as **Assistant Professor, College of Pharmacy** Agra, India from Jul 2017 to March 2019
- Worked as a **Guest Lecturer, Laxmi Bai Batra College of Nursing** 2015-2016
- Worked as a **Senior Research Fellow (SRF-ICMR)** Jamia Hamdard Oct 2012- 31 March 2014
- Worked as an **Associate Pharmacovigilance (Trainee)** with Kinapse India Limited (May 2012 to Sep 2012)

KEY COMPETENCIES

- Knowledge of comprehensive search of articles from PubMed/MEDLINE by using BOOLEAN OPERATORS, WILD CARD, TRUNCATION AND PROXIMITY SEARCH.
- Other databases like EMBASE, CENTRAL, ScienceDirect, etc.
- Data retrieval from PubMed to EndNote and then transportation in Excel sheet to perform review notes.
- Thorough understanding of national and international guidelines including Schedule Y, EMEA, ICH-GCP, CTD, OECD and SCCS.
- Analysis of preclinical data using GraphPad Prism Software. Arrangement of references using EndNote software.

ORGANISATIONAL EXPERIENCE

RMonitor India Pvt Ltd. **Dec 2024 – Apr-2025**

- Comprehensive QSAR-based structure activity.
- Conducted extensive literature research and to develop comprehensive toxicology profiles
- Managed toxicological risk assessments, Rigorous Margin of Safety (MoS) with SCCS and ECHA guidelines.

Tata Consultancy Services **Oct 2020 – Dec 2024**

- Create new eCTD applications with accurate ICH and regional metadata alignment.
- Ensure correct file naming as per ICH naming conventions for eCTD submissions.
- Compile sequences, generate published output, and perform final validation using Lorenz Validator.
- Archive eCTD sequences, core packages, and Health Authority (HA) communication emails.
- Develop dossiers for modules M1, M3, M5, including FDA forms and cover letters for eCTD submissions.
- Manage submissions of aggregate reports such as WW/EU/FDA PBRER, PADER, ACO, PSUR Addendum, DSUR, and SUSAR LL
- Coordinate with cross-functional teams (QA, QC, Packaging, CMC, Labelling, Clinical, etc.) to ensure document accuracy for regulatory submissions.
- Proficient in regulatory tools and systems including Insight for Registration, GRAIL, AWS, Reliant, EURS Validator, RIMdocs, RADR, VIPER, and Adobe Acrobat

Johnson and Johnson **Mar 2019 – Sep 2020**

- Conducted literature searches and collect safety data (preclinical and clinical) for toxicological evaluations.
- Perform literature reviews for hazard assessments and develop toxicology profiles of consumer product ingredients.
- Conduct toxicological risk assessments for raw materials and formulations, including Margin of Safety (MoS)

calculations for cosmetic applications.

- Assess safety of impurities, degradants, and final products in line with regulatory guidelines.
- Evaluate consumer product formulations using internal tools and platforms.
- Address compliance issues raised by regulatory authorities or QA, including impurity qualification.
- Liaise with business partners regarding safety assessment deliverables, prioritisation, and requirements.

College of Pharmacy, Agra **Jul 17 – Mar 2019**

- Delivered lectures and facilitated classroom discussions contributing to the academic development of students.
- Provided guidance and mentorship to students in pharmacy.

Laxmi Bai Batra College of Nursing, Delhi **2015 - 2016**

- Delivered lectures and facilitated classroom discussions as a guest lecturer at Lakshmi Bai Batra College of Nursing, contributing to the academic development of nursing students.
- Provided guidance and mentorship to students, fostering an interactive learning environment and supporting their understanding of key concepts in pharmacology.

ACADEMIC DETAILS

2012-2017	PhD **(Pharmacology)** from Jamia Hamdard (2013-2017)
2010-2012	M. Pharm **(Pharmacy Practice, Clinical Pharmacy)** from Jamia Hamdard
2006-2010	B.Pharm. from Jamia Hamdard (2010)

ACADEMIC PROJECTS

PhD Project: Research topic: "Comparative Evaluation of Anticancer Aromatase Inhibitors on Bone in Experimentally Induced Ovotoxic Mice and Possible Prevention by Raloxifene"
Senior Research Fellow-ICMR- entitled "Antiepileptic drugs and bone loss''
M. Pharm: "Therapeutic Effectiveness and Pharmaco-economics of two inhalational techniques in COPD patients"

ACADEMIC ACCOLADES

1. Best Poster Award in 6th International Conference on Recent Advances in Cardiovascular Sciences (RACS) 31st January & 1st February 2014 organized by DIPSAR, Delhi
2. ICMR Fellowship 2012-2014
3. AICTE-GPAT Post Graduate Scholarship (2010-2012).
4. Qualified GPAT in 2010.

Languages Known:

English, Hindi and Urdu