

ASIA BEGUM SHAIK

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Location: Vijayawada, Andhra Pradesh, India



PROFESSIONAL SUMMARY

Dynamic Academician and Clinical Research Professional holding an M.Pharm with Distinction from Andhra University. Bridges high-level pharmaceutical academia with global clinical trial operations. Currently serving as an Assistant Professor at KVSr Siddhartha College of Pharmaceutical Sciences, educating postgraduates in Regulatory Affairs and undergraduates in Biochemistry, while acting as a postgraduate project guide. Complemented by 1 year of corporate experience at IQVIA specializing in eTMF filing, CTMS document tracking, and audit readiness, supported by a 6-month specialized certification spanning 5 clinical trial domains.

WORK EXPERIENCE

Assistant Professor — KVSr Siddhartha College of Pharmaceutical Sciences

- Deliver advanced lectures and curriculum design for M.Pharm (Regulatory Affairs), covering global submission pathways (IND, NDA, ANDA), ICH guidelines, and regulatory frameworks.
- Serve as a Postgraduate Project Guide, mentoring M.Pharm students through experimental research design, thesis writing, regulatory documentation, and publications.
- Instruct undergraduate students in B.Pharm Biochemistry, integrating core metabolic pathways with clinical and pharmaceutical applications.
- Facilitate academic seminars, journal clubs, and technical workshops connecting academic regulatory concepts with industrial clinical trial workflows.

Clinical Process Coordinator — IQVIA, Bangalore

- Managed end-to-end electronic Trial Master File (eTMF) filing in strict compliance with the DIA TMF Reference Model and ICH-GCP guidelines.
- Tracked, updated, and monitored critical clinical trial documents across global trial sites using Clinical Trial Management Systems (CTMS).
- Executed Quality Control (QC) reviews on essential regulatory documents (Form FDA 1572, Financial Disclosure Forms, IRB/IEC approvals, ICFs, Protocol Amendments) to maintain audit readiness.
- Collaborated closely with Clinical Research Associates (CRAs) and Project Managers to resolve document queries and clear trial backlogs.

CERTIFICATIONS & SPECIALIZED TRAINING

Advanced Certification in Clinical Research

- Clinical Research: Trial phases, protocol design, ethics committee governance, informed consent process, and ICH-GCP principles.
- Clinical Data Management (CDM): Case Report Form (CRF) design, data entry, query resolution, data validation, and database locking.
- Regulatory Affairs: Global regulatory submissions (IND, NDA, ANDA), regulatory bodies (USFDA, EMA, CDSCO), and approval pathways.
- Pharmacovigilance (PV): Adverse event reporting, ICSR processing, safety narratives, signal detection, and MedDRA coding.
- Clinical Operations & Quality Control: Site selection, monitoring visits (SQV, SIV, IMV, COV), and trial archiving.

EDUCATION

DEGREE / QUALIFICATION	INSTITUTION / BOARD	SPECIALIZATION	PERFORMANCE
Master of Pharmacy (M.Pharm)	Andhra University	Pharmacy	80% (Distinction)
Bachelor of Pharmacy (B.Pharm)	Aditya College of Pharmaceutical Sciences	Pharmaceutical Sciences	75%
Intermediate (10+2)	SRVBSJB College	Bi.P.C (Biology, Physics, Chemistry)	73%
Secondary School (10th)	Trinity Public School	General Education	80%

CORE COMPETENCIES & ACADEMIC EXPERTISE

- Academic Instruction: M.Pharm Regulatory Affairs, B.Pharm Biochemistry, PG Project Guidance & Research Mentorship
- Clinical Systems: eTMF Software, CTMS, Veeva Vault, Clinical Data Repositories
- Regulatory & Standards: ICH-GCP, DIA TMF Reference Model, USFDA / CDSCO Guidelines, Global Submissions (IND/NDA/ANDA)
- Domain Knowledge: Clinical Research, CDM, Pharmacovigilance (PV), Essential Document Quality Control