

## **Curriculum Vitae**

**Name** : BIRADER MOHAMMED AMEENUDDIN S/o Younusuddin  
**Address** : Room no. 1 Khilji housing society tilak nagar 90 feet road Sakinaka  
Andheri east Mumbai Pin-400072  
**E mail** : ✉ ameen.birader@gmail.com  
**Mobile No.:** 📞 +91-7620767454, +91-9139660788.

### **Objectives**

To pursue a career in a reputed organization such provides opportunities for professional growth and where I can utilize my potential, skills and experience for the growth of both organization and mine.

### **Professional Experience**

Present association with **Tata Consultancy Services Ltd**, as a Regulatory Document Specialist /Publisher from June-2016 till date. Designation is Senior Process associate and Reviewer.

#### **○ Regulatory Document Publishing Activities**

- Handling of various Clinical Study Documents like PSUR, PSUR Addendums, PADER, ACO, CSR & Clinical Overviews, Protocol, Investigator Brochure, Health Authority document etc, Publishing of these documents in Publishing tools like Lorenz DocuBridge, Insight Publisher & ISI Publisher etc.
- Having experience of working on List of literature references.
- Checking of Electronic Submission readiness/Formatting of documents (Advanced knowledge of MS Word).
- Checking of Electronic Submission readiness PDF documents using ISI toolbox. - Use of software's like ERIS and CONNECT as document repository and use of Publishing tools like ISI Publisher (V3.2), ADLIB and Lorenz DocuBridge (V5.6) for Document Publishing activity.
- Responsible for the construction and submission readiness of different types of eCRFs (Subject CRF, aCRF, Sample CRF and Clinical Study Data Reviewers Guide (cSDRG). - Well versed with CTD modules.
- Performing Document publishing activities of the regulatory documents in scope and other clinical documents to ensure that they are submission ready.

- Perform the required activities within the established timelines that are of high quality with adherence to regulatory guidelines and applicable standards, styles, guidelines and processes.
- Perform peer review and Quality Control review of documents within established timelines with adherence to applicable guidelines using appropriate checklists.
- Maintain metrics, tracking sheets and training records as per the process requirements.
- Facilitate effective interaction and information exchange/communication among coauthors and reviewers as appropriate (including problem solving and resolution of issues)

### Educational Qualification

Year	University	Percentage	Year of passing	Class
Final year M. Pharm (Pharmaceutics)	BAMU	71.00%	2015	Distinction
Final year B. Pharm	BAMU	65.00%	2013	1 <sup>st</sup> Class
H.S.C.	Maharashtra Board	65.15%	2009	1 <sup>st</sup> Class
S.S.C.	Maharashtra Board	57.21%	2007	2 <sup>nd</sup> Class

### Achievement

- Appreciation for Teamwork in TCS
- Was chosen among the new recruits to be part of eCRF publishing team
- Apart from document publishing activity and eCRF publishing activity also been chosen as the POC (Point of Contact) for the project plan management.

### Other Skills

- Proficient in Windows based application MS Office. Presentation & Report Writing Skills.
- Proficient in Windows based application MS Office.
- Hands-on proficiency in Software like
  - ISI Toolbox
  - Adobe Acrobat
  - Docubridge

### Personal Details

**DATE OF BIRTH:** 18/01/1992.

**MARITAL STATUS:** Married

**NATIONALITY:** Indian

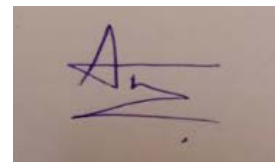
**RELIGION:** Muslim

**SEX:** Male

**LANGUAGES KNOWN:** English, Hindi, Marathi, Urdu(R.W.S)

### Declaration

I hereby declare that the above written are true to the best of my knowledge and belief.



**Place:** MUMBAI

**(Mr. Ameen Birader)**