

# Name: Ashish Patil Biradar



## Education:

S.No	Time frame of course	Name of the course	Name of institution
1	2017-2019	Master of Pharmacy (Pharmaceutical Analysis)	Gokaraju Rangaraju College of Pharmacy
2	2013-2017	Bachelor of Pharmacy	Sri Venkateshwara College of Pharmacy
3	2011-2013	Intermediate	Sri Chaitanya Educational Institutions
4	2010-2011	Secondary School Certificate	Oxford High School

## Summary of Experience

S.No	Name of the organization	Years/Months of Experience	Designation
1	Freyr Software Solutions Pvt.Ltd	3 Years	Associate
2	HCL TECH	1 Year	Senior Associate
3	Aizant Drug Research Solutions Pvt.Ltd	9 Months	Project Trainee

## Key Skills

- Good Knowledge on Drafting Clinical Evaluation Report for Medical Devices
- Good Knowledge in reviewing and editing regulatory document's
- Hands on Experience for working on Clinical Safety Data Reports and Protocol (Documents for Preliminary Post market Surveillance stages)
- Good knowledge in drafting scientific validity report, clinical performance report of invitro diagnostic devices.
- Expertise in preparation of product summary document, literature search strings (for databases like- PubMed, M-Library).
- Expertise in conducting literature screening, and literature appraisal.
- Good knowledge, with utmost interest in clinical summary writing (organization, and examination of statistical data for establishing performance of an invitro device or medical device in diagnosis of a particular clinical condition)
- Good knowledge in collection and drafting of clinical information for State of the art of invitro diagnostics and medical devices.
- Special interest in Archival and Key learnings from any Performance evaluation report or clinical evaluation report completed.
- Involved in writing Clinical evaluation reports (Class IIa, and Class I devices).
- Ability to comply with regulatory guidelines in order to avoid errors and contribute to timely completion of documents
- As a Pharmacy postgraduate I possess the ability to draft and understand the intricacies of drafting regulatory documents for Drugs, Medical Devices, IVDrs
- Basic Knowledge on Document management and Document publishing too.
- Strong reliable and focused medical affairs specialist with good idea on medical devices and IVDRs and their clinical trials review and evaluation
- Good idea in clinical trial registries for example – EUCTR, UMIN, Ct.gov and CCMO
- Proficient in Microsoft office, and expertise in research methodology using PUBMED, NEJM and scholarly journals
- Proficient in navigating regulatory requirements of markets like USFDA, TGA, EMEA, PMDA.

**Past Experience 1 – HCL TECH**

**Current Position:** Senior Associate

**Duration:** 1 Yr

**Projects Handled :**

- Drafting Clinical Evaluation Report for Medical Devices
- Clinical Safety Data Reports and Protocol (Documents for Preliminary Post market Surveillance stages)

**Past Experience**

**Experience 1:** Aizant Drug Research Solutions Pvt.Ltd

**Duration:** 9 Months

**Projects Handled:**

- Handling of Dissolution Apparatus, Purging of HPLC systems (Waters), and Weighing Balance Calibration
- Development and Validation of Reverse phase- High performance liquid chromatography method for quantification of related substances in Dofetilide capsules.

**Past Experience**

**Experience 2:** Freyr Software Solutions Pvt. Ltd

**Aggregate Report Writer Duration:** 3Years

**Projects Handled:**

- IVDR Performance Evaluation Report Writing
- Identification of Predicate device, Analysis of test reports, labels, and multiple other requirements
- Preliminary understanding of requirements for registration of medical device in Australia, and Requirements of a sponsor.

**Personal Details:**

- Name: Ashish Patil Biradar
- Fathers Name: Late Anna Rao Patil Biradar
- Mothers Name: Shalini Patil Biradar
- Date of Birth: 22-Aug-1995
- Marital Status: Single
- Sex: Male
- Nationality: Indian
- Languages Known: Hindi, English, Kannada, and Telugu
- Hobbies: Watching Football, Reading Books (Especially Autobiographies), Watching Documentaries.
- Permanent Address: 14-9-121, Chudi Bazar, Near Begum Bazar Chatri, Hyderabad.