Akshay goley

Contact no. 7030535330

Mail Id- goleakshayy1996@gmail.com

#### Career objective:

Seeking a position to utilize my skills and abilities in the industry that offers security and professional growth while being resourceful, innovative, and flexible.

#### **Academic Details:**

B.pharmacy: Savitribai phule University pune. (2019)

D.pharmacy: Maharastra board (MSBTE mumbai)(2016)

Higher secondary college: Maharastra board (MSBTE mumbai) (2014)

### **Computer Skills:**

Microsoft Office (Microsoft Word, Microsoft Excel, Power Point, Internet) & other basics of Computer.

#### **INDUSTRIAL EXPERIENCE:**

**Employer:** Pharmazones Ahmedabad

Experience: October 2021 to till date

**Designation:** Sr. Exicutive (Clinical research associate)

### Roles and responsibilities:

- 1. Overall site management of clinical studies ensuring that project is progressing according to standards Protocol, SOP, GCP and other applicable guidelines.
- 2. Ensure the communication to site about the project Scope of work, time line and project goals, technical information and input from project Manager throughout the project.
- 3. Preparation of site visits report/monitoring report including, site qualification, Site Initiation, site monitoring, site closeout, etc.
- 4. To perform site initiation, visit which include ensuring each site has the trial materials and training of site staff to trial specific and industry standards with Project Manager and to prepare reports.
- 5. To prepare the site activation checklist.
- 6. Interim monitoring visit for trials conduct at site throughout its duration which will involve visiting the study site at predefined interval to assess that the study is being done in accordance with the protocol and monitoring plan and that the human right is not violated.
- 7. To perform site closeout to ensure that site has resolved all data queries, availability of updated site file, patient file and reconciliation of investigational product.
- 8. Ensure Communication with sites for ethics committee notification of serious adverse event, study progress, protocol deviation and safety reporting.

### On site experience:

### **Drug Category:**

- 1. Anticancer(Doxorubicin and Olaparib) end point.
- 2. Schizophrenia (Respiridone, Aripiprazole and paliparidone) end point studies.
- 3. Anemias(ferric carboxymaltose) end point studies.
- 4. Chronic obstructive pulmonary disease (Titropium bromide inhalation powder)

Site initiation visit: more than 15 studies

Site monitoring visit: More than 100 studies.

Site closed out visits: More than 30 studies.

## Previous organisations role and responsibilities:

**Employer:** Synergen Bio shivajinagar Pune

Experience: August 2020 to September 2021

**Employer**: Bioradius Hinjewadi Pune

Experience: October 2019 to June 2020.

**Designation:** Clinical research associate(Project coordinator)

### Role and responsibilities:

- 1. Supervision of Study Activities and Clinical Co-ordination.
- 2. Preparation of Trial master File.
- 3. Dispensing of IP.
- 4. IP's accountability.
- 5. IP's administration.
- 6. Response to QA audit (retrospective)
- 7. To ensure the quality and integrity of clinical data, oversee raw data compilation.
- 8. Review of Data and compliance.
- 9. Assisted in the reconciliation of Trial Master File.

# **Personal Information:**

Name: Akshay Goley Date of Birth: 05 Sep 1996 Marital Status: Unmarried

Languages Known: English, Hindi and Marathi

Permanent Address: At.post-Kenwad Ta-Risod Dist-Washim

### **Decleration:**

I do hereby declare that the above information is true to the best of my knowledge.

Akshay Goley