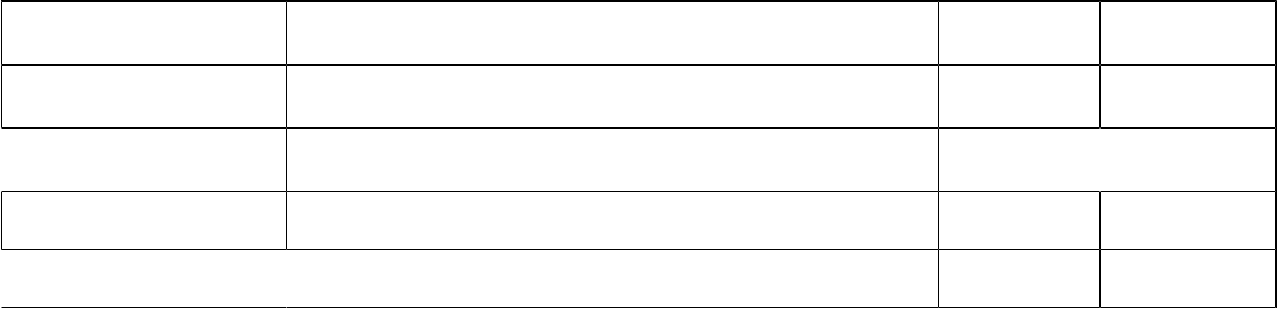
|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Curriculum Vitae** | | | |  |
| **Ms.Krutika Pol** | |  |  |  | **Mob: - 9370323400** |  |
|  |  |  |  |  | **krutikapol1994@gmail.com** |  |
|  |  |  |  |  |  |  |

**CAREER OBJECTIVE**

To grow with a leading organization that utilizes my abilities to the fullest extent possible, helping me realize and develop my potential and be a part of a team that scales great heights through continuous learning process and utmost dedication.

**EDUCATIONAL QUALIFICATION**



**Education** **School / College**

**Passing Percenta**

**Year** **ge**

Clinical Research &

Data Management

 B Pharm

HSC

Ruby Hall Clinical services. Pune

Institute of pharmaceutical education and Research Wardha

New English Junior College Wardha

2017 A+

2016  61%

2012 61.70%

 SSC  Lok-vidyalaya School Wardha

**INDUSTRIAL TRAINING**

-Industrial Training in Unijules Life Science Ltd, Nagpur, Injectable Division.

2010 86.55%

**Post Graduation Diploma in Clinical Research And Data Managment:**

“**Post Graduation Diploma in Clinical Research And Data Managment From Ruby** **Hall Clinical Services in 2017.**

**CLINICAL TRIAL MANAGMENT:** ICH- GCP , Site Selection, , Phase I,II,III & IV Trials,Responsibilities of Monitor, CTA, CRA, CRC, Investigator, Sponsor, Protocol, Investigator Brochure, CRF, eCRF.

**CLINICAL DATA MANAGEMENT:** Electronic Data Capture, CRF designing, Validation ,Coding, Clinical Data Management (Process Flow) Data Collection, Data Loading/Transfer, Data Storage, Data Validation, Data Export, Query Management, Data Archiving, Quality System, SOPs and Audits, Query resolution, Clinical Database Management System, Oracle Clinical overview, Data entry and data collection including Data transfer.

**PHARMACOVIGILANCE:** ADR, Serious Adverse Reaction, SAE, Med DRA, Risk Management,Pharmacovigilance role, SUSAR, ICH guidelines, Adverse event reporting (Med Watch Form).

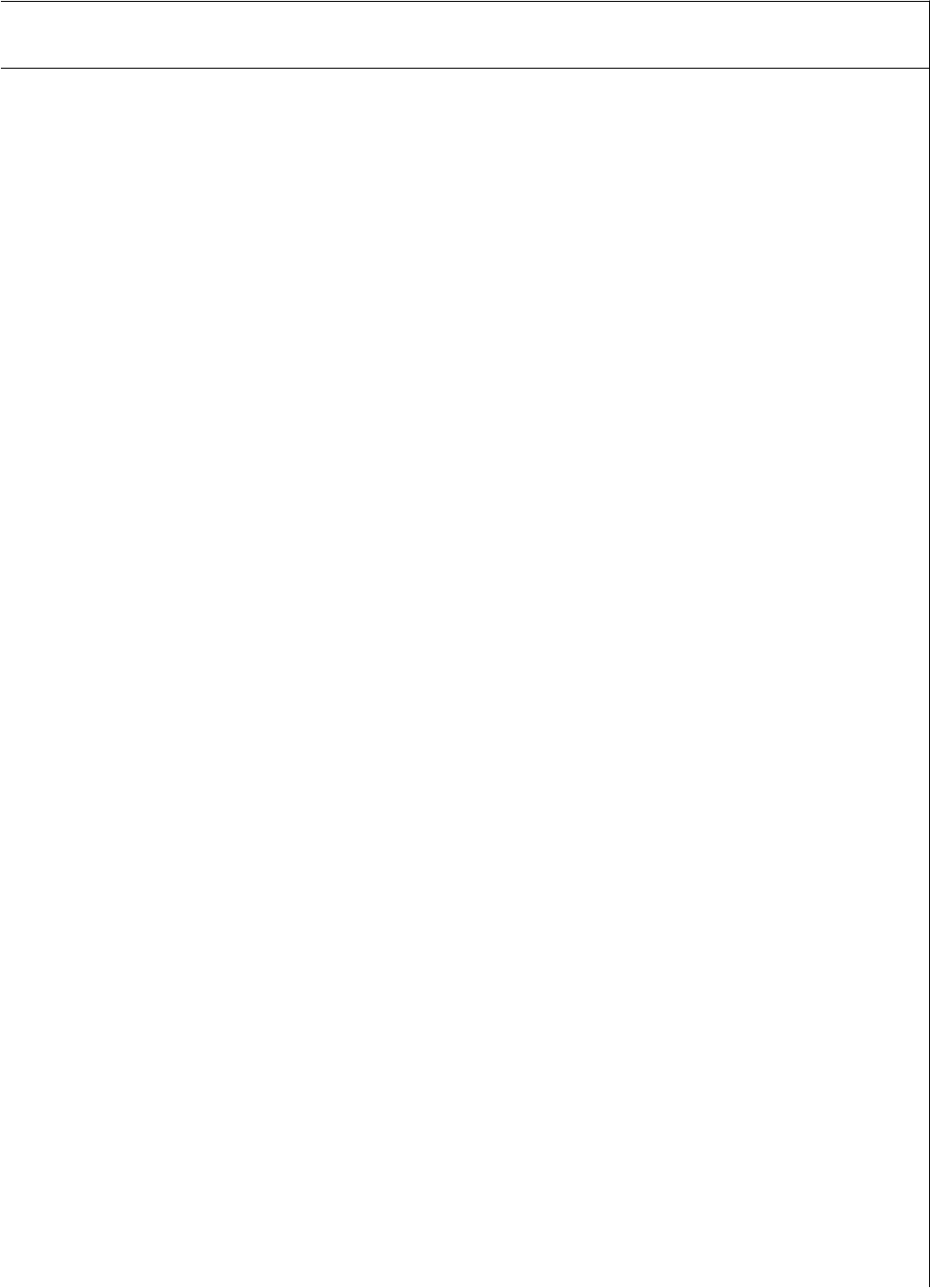
**Strength:**

* Leadership qualities, Good communication skills, Self confidence, Dedication, Hard working, Strong will power, Zeal to excel.
* Worked as Clinical Research Co-ordinator in various Phase II to IV, Observational & PMS clinical trials in Diabetes Mellitus, Obesity,Cardiovascular outcome trial,etc
* Have experience in handling clinical, regulatory aspects of Clinical Trial .& submission aspects efficiently.
* Have 1 years of experience in handling data entry ,query resolving Electronic Case Record Form (e-CRF) like Inform, Clinion, etc
* Very well accustomed with the technical aspects regarding data entry field & have completed various web based online trial specific trainings.
* Have the urge to learn new things & ability to grasp them fast.

**Other Courses completed :**



|  |  |  |  |
| --- | --- | --- | --- |
|  | **Training** |  | **Year** |
|  | | |  |
| InForm 6.0 training for CRCs\_v2 | | | 2017 |
|  |  |  |  |
| Technical | Complaint | Reporting | 2017 |
| ( InForm 4.6 & 6.0) | |  |  |
|  | | |  |
| IV/WRS – For Site Users c3 v2 | | | 2017 |
|  | | |  |
| IWRS – for site users c3.1 v1 | | | 2017 |
|  | | |  |
| IV/WRS Site staff training c2 | | | 2017 |
|  |  | |  |
| FIRECREST | Temperature | | 2017 |
| Deviation | and Drug | Handling |  |
| version 1.0 | |  |  |
|  |  |  |  |
| FIRECREST | Adverse | Event | 2017 |
| Reporting Amendment 3 | | |  |
|  | | |  |
| FIRECREST NN 9924-4221 Trail | | | 2017 |
| Overview | (including | |  |

 Amendment 3 )

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Brookwood | | Essential | | Good | | 23rd MARCH 2017 |
| Clinical Practice (ICH GCP E6 R2 | | | | | |  |
| V16.1) | |  |  |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| Critical Data Overview | | | |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| compound overview | | | |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| product complaint | | |  |  |  |  |
|  | | | | | |  |
| Investigatorspace by trifecta | | | | | | 2017 |
| e-diaries, Tablet (slate) & trial | | | | | |  |
| manager demo training | | | |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| Central lab overview | | | |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| Mixed | Meal | Tolerance | | | Test |  |
| Training | |  |  |  |  |  |
|  | | | | | |  |
| Investigatorspace by trifecta tral | | | | | | 2017 |
| manager overview | | | |  |  |  |
|  | | |  |  | |  |
| Investigatorspace | | | by | trifecta | | 2017 |
| SAE Reporting | |  |  |  |  |  |
|  | | |  | |  |  |
| Investigator Site | | | Personnel | | ICH | 16/11/17 |
| GCP | Training | Certificate | | | v1.3 |  |

June 2017

**Work Experience** : - Working as Clinical Research Co- ordinator At DeenanthMangeshkar Hospital & Research Centre,Pune From 3rd March 2017 to till date.

**Faced the GCP audit was performed on 24 & 25 Aug 2017 by Novo Nordisk auditor Dr. Vanya Dagat**

**Job Responsibilities:**

* Ensure timely submissions & management of study from start-up to database lock.
* Data Collection, data entry, Query resolving & data cleaning activities.
* Drug receipt, handling & dispensing to subjects.
* Reporting of Adverse Events & Serious Adverse Events.
* Manage clinical trials for industry, in-house research trials dealing with Diabetes to include patient screening, eligibility, informed consent, study specific drug orders, symptom management, toxicity assessment, SAE reporting, compliance and data management.
* Supervise regulatory documentation of annual renewals, consent form changes; comprehension of regulatory guidelines and GCP.
* Develop study specific tools to assist in the collection of all required data.
* Update and revise patient screening log sheets.
* Investigator product dosaging , compliance ,accountibility maintainance
* Completion of Case Report Forms(CRFs) Electronic Data management (Oracle, Inform version 6.0)
* Completion of IVRS and IWRS process.
* Maintenance of Investigator site File and other study related files

**Specific Key Responsibilities:**

* Preparation of documents for Ethics Committee submissions and notifications for all studies at site, submission of Follow reports, study progress reports
* Providing support for new team members including assisiting in training activities of new members.
* Training site personnel for ICH-GCP requirements and conduct of the study
* Completion of Site Feasibility questionnaires for diabetes and other indications.

* Conduction of patient visits.
* Investigator product dosaging , compliance ,accountibility maintainance
* Adverse event reporting, SAE reporting.
* Manage , guide & lead team of trial staff members.

**Over all Clinical Research Experience for following indications:**

|  |  |  |
| --- | --- | --- |
| **Endocrinology (Diabetes)** | | **:** Phases 3b |
| **Cardiovascular** |  | **:** Phase 3b |
| **Obesity** |  | **:** Phase III |
| **PERSONAL PROFILE** |  |  |
| Name | : - | Krutika Sudhir Pol |
| Home Address | :- | Savali Homes, Flat No. 507 'A” Wing , near Samata Vidyalaya, Uruli |
| Devachi, Pune |  |  |
| Date of Birth | : - | 21-May-1994 |
| Language Knowledge | : - | Marathi, Hindi, English. |
| Hobbies | : - | Reading Books, Traveling,Shopping. |