SHITAL A. NARUTE

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OBJECTIVE

To work in a challenging environment and bringing out the best of me by working hard, striving towards the growth and development of organization which makes me grow professional as well as personal level thereby directing my future endeavours as an asset to the organization.

EXPERIENCE

Siddhi College of Pharmacy, Pune — May 2023 - Till date
Assistant professor

Synergen Bio,Pune — Jun 2022 - Dec 2022
Research associate in Clinical Trial Dept

- Communication with potential sites for collection of CDA and FQ
- Preparation of TMF (Trial Master File) along with eTMF folders and updating it regularly
- Collect and review Essential documents from sites for regulatory submission and approval
- Track and supervise ongoing study data & ensure adequate tracking is in place for all activities and reports
- Assist manager in conducting feasibility assessment of sites
- Registration of new trials on CTRI and updation of previous trials
- Conduct project co-monitoring visits
- Assist the project team with day to day activities
- Preparation of EC dossiers
- Preparation of synopsis, feasibility questionnaire & draft appendices according to protocol
- Attended and presented study protocol in SEC (Subject expert committee) meetings with CDSCO
- Preparation of draft CTA according to site
- Preparation of site payment invoices as per CTA budget sheet

Dr. D. Y. Patil Hospital and research centre, Pune — Jun 2021 - Jun 2022
Clinical research coordinator

- Facilitates and coordinate the daily clinical trial activities.
- Handling of Investigational Product.
- Maintaining IP accountability log, daily temperature logs, receipt of IP.
- During conduct of trial, follow the ICH-GCP guidelines.
- Entering Data & Resolving queries in EDC as per the source documents (MedidataRave)
- Responsible for documenting & reporting serious adverse event reports of clinical studies to Ethics Committee & in EDC
- Capturing all AE and SAE
- Filling individual case safety report form (ICSR).
- Maintaining subject safety report.
- Maintaining all documents in Site Master File (SMF).
- Coordinate and facilitate monitoring visits.

Agio pharmaceutical, Pune — Apr 2018 - Oct 2018
Trainee IPQA

- To perform IPQA activities at shop floor in each and every stage of manufacturing and packing process.
- QA overview for clean room behavior and aseptic activity.
- Review of batch processing records.
- Review of all documents relating to the manufacturing, Packaging & analysis report prior to batch release.
- Review of documents of respective areas and logbooks for adequacy and completeness.
- QA overview for receipt of material from warehouse to production

EDUCATION

Dr. D. Y. Patil institute of pharmaceutical sciences and research Pimpri,Pune. — 2021
Master in Pharmacology (M.pharmacy)
8.23

Modern College of pharmacy, Nigdi, Pune 2017
B.pharmacy
61%

Shri. Bhairavnath College, Bhosari, Pune 2012
HSC
58%

Shri. Bhairavnath Highschool, Bhosari, Pune 2010
SSC
75%

M.PHARM THESIS PROJECT

Evaluation of in vivo antifungal efficacy and prebiotic potential of developed formulation in Swiss Albino mice

PERSONAL DETAILS

Date of Birth : 12 Sep 1994

PRESENTATION

Oral presentation at International symposium on medication therapy and management
by CliMed Research Solutions in collaboration with
Indian Pharmaceutical Association, World Youth Heart Federation-India in Jan 2021

CERTIFICATES

Good Clinical Practices certification by NIDA(2021)
National Drug Abuse Treatment Clinical Trial Network(NIDA)

Professional course in Clinical Research and Data Management
6 months certificate course

State Level Workshop on "Clinical Research Ethical and Regulatory Requirements an Indian and Global Scenario"
by Dr. D. Y. Patil Institute of Pharmaceutical Science and Research, Pimpri, Pune in 2020

National Conference "ABMH PharmaCon-VII, 2019"
by Aditya Birla Memorial Hospital, Chinchwad, Pune in 2019

Workshop on DNA Analysis
By BVG life Sciences,Pune in 2019

Executive diploma in Pharmacovigilance
Certificate course

National Service Scheme(NSS)
NSS camp organised by Govt. Of India in 2016

PROJECT HANDLED

Handled COVID 19 Covovax Vaccine trial of ICMR/ Serum Institute of India as well as Gennova mRNA Vaccine trial during worked with D Y Patil Hospital and Research Centre in the year 2021-2022

KEY PERSONNEL ATTRIBUTES/SKILLS

Negotiation and conflict resolution

Deceiveness and Good team worker

Manage time effectively in order to produce quality deliverables in expected time frame.

Flexibility and adaptable to change

Good knowledge of ISF, TMF, CRF web

Good command on Microsoft office skills (Word, PowerPoint, Excel)

Good communication, interpersonal, analytical, problem solving ability and motivational skills.

DECLARATION

I hereby solemnly affirm that all the information furnished by me is true to the best of my knowledge
-Shital Narute