



Dinesh Gunjal
dineshgunjal691@gmail.com
8108571425
Mumbai, Maharashtra
<https://www.linkedin.com/in/dinesh-gunjal-9567a7a7>



CAREER OBJECTIVE

To secure a responsible career opportunity to fully utilize my training and skills, while making a significant contribution to the success of the company.

ACADEMIC QUALIFICATIONS

Masters of Management Studies (2020-2022)	Bharati Vidyapeeth's Institute of Management Studies and Research Second Year (Last Semester In Progress) First Year cGPA- 9.81/10 Specialization – Marketing
Bachelor of Pharmacy (2012-2016)	Bombay College of Pharmacy cGPA – 6.67
Higher Secondary School Certificate (2010)	Sanatan dharam Vidyalaya and junior college, Chembur, Mumbai Percentage -59.19% Stream - Science
Secondary School Certificate (2008)	SKP School-Kurla, Mumbai Percentage -68.92%

WORK EXPERIENCE

Forbes Marshall Intern (Marketing) 25 th May- 15 th July 2021	<ul style="list-style-type: none">○ Built Excel Dashboards to present company and transporters monthly performance.○ Involved in Data Purification, Data analysis and Data Visualization to different stakeholders○ Communicated with external and internal stakeholders with regards to alignment of processes.
IQVIA Senior Clinical Process Associate (Aug 2016 –March 2021) 4.7 YEARS	<ul style="list-style-type: none">○ Involved in digitization of clinical trial informed consent forms for the sites globally.○ Enhance documents with web capabilities using HTML.○ Involved in mentoring and guiding the new joiners and project managers of US team, India team and The Philippines team with respect to the process knowledge.○ Experience in content management system platform (CTMS).○ Distribute processed document to internal project team members.○ Responding to queries asked by the sponsor and/or sites through the system.○ Preparation and review of essential document pack for clinical study initiation as per the country's regulatory guidelines (EDP review).○ To review and track documents required for submission to the regulatory authorities and ethics committee for initiation as well as during the study.○ Point of contact for study binder services.○ Prepare clinical study binders customized as per clinical study sites.○ Perform regulatory start up and maintenance activities according to applicable regulations, SOPs and work instructions.○ To maintain the database with reports and soft copy of the documents that is required for the site initiation.○ Ensure accurate completion and maintenance of internal systems, databases and tracking tool with project specific information○ QC reviewer and SME for electronic informed consent digitization document and study binder services.

	<ul style="list-style-type: none"> ○ Reviewing documents to ensure that the same are compliant with government regulations and protocols and that highest quality products are delivered. ○ Manage the activities of regulatory affairs within the field of responsibility ensuring the implementation of appropriate and effective regulatory strategies. ○ Actively participating in multiple work groups and dissemination information across all levels of departments. ○ Distribution of workload among the team and ensure timely delivery within SLA. ○ Ensuring the quality of the outcome meets the established standards. ○ Assist the team in the preparation, handling, distribution, filing and archiving of documentation according to the scope of work and standard operation procedures. ○ Prepare client deliverable documents using appropriate tools to present to patients visiting clinical trial sites. ○ Assist with completion of relevant clinical trial management system (CTMS) fields, databases, tracking tools, timelines, and project plans with project specific information. ○ Interaction and presentation to internal and external clients as required. ○ Proof documents to company standards using multiple levels of quality control. ○ Provide product support to a growing list of global clients. ○ Work to meet team goals as well as individual goals.
Certifications and Licenses	<ul style="list-style-type: none"> ○ Pharmacist, Maharashtra State Pharmacy Council. ○ Current regulatory requirements for conducting clinical trials in india for investigational new drugs/new drug (TOPPER), CDSA. ○ Advance Microsoft Excel, Tata Steel. ○ MS Office, Tata Steel.



Elite

NPTEL Online Certification

(Funded by the Ministry of HRD, Govt. of India)

This certificate is awarded to

DINESH KAMLAKAR GUNJAL

for successfully completing the course

Current regulatory requirements for conducting clinical trials in India for investigational new drugs/new drug (Version 3.0)

with a consolidated score of **90** %

Online Assignments	24.58/25	Proctored Exam	65.5/75
--------------------	----------	----------------	---------

Total number of candidates certified in this course: **418**



Prof. Sucheta Banerjee Kurundkar
Director Training,
CDSA

Aug-Oct 2021
(8 week course)



Andrew Thangaraj
Professor,
Department of Electrical Engineering, IIT Madras
Coordinator, NPTEL



CDSA Clinical Development Services Agency



Roll No: NPTEL21GE25S14020354
To validate and check scores: <https://npTEL.ac.in/noc>

CERTIFICATE

is presented to

Dinesh Kamlakar Gunjal

for successfully completing the Elearning program on

Advance Microsoft Excel

08-07-2021

DATE



Jaya Singh Panda

JAYA SINGH PANDA
Chief Learning & Development

CERTIFICATE

is presented to

Dinesh Kamlakar Gunjal

for successfully completing the Elearning program on

MS Office

01-06-2021

DATE



Prakash Singh

PRAKASH SINGH
Chief Capability Development