

Nitesh Makade

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OBJECTIVE:-To obtain a respectable position in your organization which will enable me to use my talents, creativity and ability to the maximum, and contribute to the growth of organization as well as myself.

SUBJECT KNOWLEDGE:-Undergoing the training of “Advance Post Graduate in Pharmaceutical Statistics” from PHARMA-STATS, a Corporate Training Center& Consultancy services for BA/BE Studies- on application of various statistical tests in clinical research; basic concepts of bioequivalence, Clinical Trials, DOE & SAS programming.

BIO-STATISTICAL SKILLS:-

- Sample size calculation using SAS.
- Randomization schedule using SAS programming.
- Statistical Analysis Plan (SAP) for clinical trials.
- Various parametric & non-parametric bio-statistical tests: t-test, ANOVA, ANCOVA, Chi-square, F-test, Sign test.
- Conclusion & interpretation of statistical results.
- Knowledge of various statistical methods useful in BE & Clinical trials.
- Projects: 1) Calculation of Pharmacokinetic parameters & Bioequivalence analysis (2x2 crossover design) & 2) Phase-III clinical trial statistical analysis.
- Basic knowledge of SOP & Guideline terminology.
- Applications of Statistics in Designs of Experiments (DOE) according to ICH Q8 Guidelines.
- Insights of QbD aspects using Minitab Statistical Software.

Knowledge of basic SAS programming:

- Data management: Concatenating, Merging, Handling missing values, Reading raw data files, creating data structures, Handling data and programming errors, Accessing data, Appending data and managing data.
- Expertise in SAS/BASE with basic knowledge of PROC SQL and MACRO.
- Import-Export data using various techniques like PROC IMPORT, PROC EXPORT, LIBNAME, INFILE, PROC PRINT statements.
- SAS/ODS process to create useful outputs in different formats.
- Statistical analysis: PROC GLM, PROC MIXED, PROC MEANS, PROC FREQ, PROC UNIVARIATE, PROC REG, PROC t-test, PROC npar1way for various Statistical analyses.
- Clinical trial Report: PROC REPORT, Tables, Listings and Figures (TLF).
- Basic Knowledge of CDISC Standard- SDTM &ADaM and Regulatory Requirements.

Other Software skills:-

- SAS
- R-Software
- SPSS
- MS-Excel
- TOAD(ORACLE)
- Microsoft office

EDUCATION:-

QUALIFICATION	YEAR OF PASSING	PERCENTAGE (%)	UNIVERSITY
M.Sc. INDUSTRIAL-STATISTICS	2015	50%	North Maharashtra University, Jalgaon.
B.Sc. STATISTICS	2013	70.05%	North Maharashtra University, Jalgaon.

CERTIFICATION:

Course Name	Duration	Training Area	Institute
Advance Post Graduate in Pharmaceutical Statistics	3-Months (Jun,2016- Aug 2016)	Biostatistics, Bioequivalence, Clinical Trials, MINITAB, SAS programming	PHARMA-STATS (www.pharma-stats.in)

EXPERIENCE:**Position Trainee Data Scientist.**

Rainbow InfoTech, Pune	Responsibilities: Designed and developed metric reports using Graphs, Different types of Pivot table and Filters using Ms-excel.	Feb,16 – May,17
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M.Sc. PROJECT WORK:-**Title:-“Process Capability Analysis for Some Quality Parameter of Brake System”****Duration:** -December 2015 to February 2015.**Role:-** Collect data , analyse this data using some software like Minitab MX-Excel etc. and give some useful interpretation on this.**Purpose:-**Create and export-worthy business by adopting lean manufacturing principles, continuous up-gradation of design and manufacturing technology, continual improvement in quality and environmental management system.

- Lead the team on various front and presentations.
- Used MINITAB and MS-EXCEL for Analysis.

OTHER ACTIVITIES/ACHIEVEMENTS/WORK EXPERIENCE:-

- Active participation in poster competition event of **Avishkar-2012**.
- **Third Prize** in Statistical Posters Competition Z. B. Patil College, Dhule.
- Work as Volunteer in several State Level as well as National Level Events.
- Active participation in events of Department of Statistics.

PERSONAL DETAILS:-**Father's Name:-** Rajendra Harichandra Makade**Address** : -At-Post: Bahadarpur, Tal: - Parola, Dist: - Jalgaon, 425113.**Languages Known:** -English, Hindi, Marathi.**Hobbies:** - Reading Books, Chess, Cricket.*The details given above are corrected to best of my knowledge.*