RESUME

MANOJ D PATEL
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OVERALL CAREER SUMMARY:

- **M.Sc (Statistics) with 16 years' experience as a Statistician & Programmer**
- **SAS® Certified Programmer, SPSS Certified Programmer**
- **Motivational Speaker**
- **An Established author :** https://www.amazon.in/Jivan-Rango-Manoj-patel-Gujarati/dp/B079L9FKPZ

Designation	Department	Organization	Work. Experience
Director	Biostatistics & Programming	SaSTAT Organisation	Feb 2019 – Present
Sr. Statistician	Biostatistics & Programming	IQVIA	Mar 2015 – Feb 2019
Assistant Manager	Pharmacokinetics, Biostatistics & Programming	GVK Bioscience PVT Ltd	Jun 2013 – Mar 2015
Lead Statistician	Biostatistics & Programming	Lambda Therapeutic Ltd	Nov 2009 – Jun 2013
Biostatistician	Biostatistics	Cadila Healthcare Ltd	Aug 2007 – Nov 2009
Statistical Officer	Monitoring & Evaluation	FPA India	June 2006 – Aug 2007
Lecturer: Statistics	Statistics	National College of commerce	May 2006 – Aug 2007

- **Exposure with different type of trials as:**
  - **Pre-clinical trials:** Acute toxicity Studies, Subacute (Repeated dose) toxicity Studies, Chronic and Sub-chronic toxicity studies, Reproductive toxicity Studies, Genotoxicity/ Mutagenicity studies, Carcinogenicity Studies and Safety Pharmacology studies.
  - **BA/BE (Pharmacokinetic & Pharmacodynamics) trials:** Single dose, Crossover study, Parallel study, Multiple dose study (Steady State), Urine study, Replicated study, Reference Scaled study etc.
  - **Phase I, II, III & IV trials**: To assess the safety , efficacy, tolerability, pharmacokinetics and Dose ranging studies (SAD & MAD)
  - **Nutraceuticals Trials.**

- Sound knowledge of different regulatory guidelines like USFDA, MHRA, ANVISA, WHO, CANADA pertaining to GMP, GLP, GDP, BA /BE studies and faced USFDA, ANVIZA, EMEA Audits Successfully.

EDUCATIONAL QUALIFICATION:

- **Master's Degree in Statistics in year 2006** from Gujarat University, Ahmedabad, Gujarat, India
- **Bachelor's Degree in Statistics in year 2004** from Gujarat University, Ahmedabad, Gujarat, India
- **Certified in Base SAS Programming for SAS®** from SAS Institute Inc., USA,
- **SAS Certified Specialist : Base Programming for SAS®** 9.4 from SAS Institute Inc., USA, 2021
- **SPSS (Statistical Software) in year 2007** from SP University, Gujarat, India
- Certified in **MS OFFICE** automation from Alma Technology, India

PROFESSIONAL EXPERIENCE:

SaSTAT Organization

► https://www.sastat.com/

Director (Feb 2019 - Present)
Working as a Director at world class training Centre for Statistics & SAS at SaSTAT Organization

JOB PROFILE:

- Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives
- Leading and motivating subordinates to advance employee engagement develop a high performing managerial team
- Overseeing all operations and business activities to ensure they produce the desired results and are consistent with the overall strategy and mission
- Make high-quality investing decisions to advance the business and increase profits
- Enforce adherence to legal guidelines and in-house policies to maintain the company's legality and business ethics
- Review financial and non-financial reports to devise solutions or improvements
- Build trust relations with key partners and stakeholders and act as a point of contact for important shareholders
- Analyze problematic situations and occurrences and provide solutions to ensure company survival and growth
- Maintain a deep knowledge of the markets and industry of the company
- Developing new methods to develop business
- Leading all major all areas of company like Marketing, Business Development, Training and Operations.

IQVIA, formerly Quintiles IMS Holdings, Inc.

► https://www.iqvia.com/

Senior Statistician (19th March 2016– Feb 2019)
Working as a **Statistician** in Biostatistics & Programming Department for company: **Novartis**

Statistician 2 (5th March 2015– 18th Sep 2016)
Worked as a **Statistician** in Biostatistics & Programming Department for Company**: BMS (Bristol Myers Squibb)**

JOB PROFILE:

- Created SAS programs to generate derived datasets and required summary reports.
- Created and maintained production programs for tables and listings.
- Created and maintained various validation programs for tables and listings.
- Generated output files in HTML, RTF and PDF formats using SAS/ODS.
- Mapped raw data into the CDISC SDTM format.
- Customized reports using PROC TABULATE, REPORT, SUMMARY and also provided descriptive statistics using Proc Means, Frequency, and Univariate.
- Physical verification of results by comparing both production output and validation output
- Involved in validating and QC of the efficacy and safety tables, figures and listings
- Ensured proper and consistent implementation and maintenance of guidelines and standards within the department

GVK Biosciences Pvt. Limited.
India
► http://www.gvkbio.com/

Assistant Manager (28th June 2013 – 4th March 2015)

Lead the team as a Biostatistician in Pharmacokinetics, Biostatistics & Programming Department.

JOB PROFILE:

- Lead the Pharmacokinetics & Biostatistics department. First statistician in this newly created position and sole statistician for the department.
- Responsibilities included writing statistical analysis plans and write statistical methodology sections of protocols.
- Conducting analyses and programming specifications for clinical studies.
- Coordination with other departments for study conduction and give quality inputs.
- To make sure the compliance of the protocol, programs and study reports as per the respective regulatory requirement related to pharmacokinetic and Biostatistics.
- Perform statistical quality control review and program validation for assigned projects and review and verify the statistical integrity of clinical study reports.
- Interact with other departments, such as Clinical Operations and Project Management, to ensure a high level of client satisfaction through successful execution of projects.
- Respond to QA, Sponsor & Regulatory queries.

Lambda Therapeutic Research Ltd.
Ahmedabad, India
► Visit the website

Sr. Executive (13th November 2009 – 27th June 2013)

Worked as a **Lead Biostatistician** in Biostatistics and Programming Department of Lambda Therapeutic Research Ltd., Contract Research Organization dedicated to Clinical Research projects.

JOB PROFILE:

- Act as a representative of the Biostatistics department on project teams. Attend project team meetings as necessary.
- Write statistical methodology sections of protocols & Statistical Analysis Plans (SAP) to be carried out in the analysis of clinical studies.
- Perform statistical analyses of data and interpret results to ensure validity of conclusions.
- Meet with sponsor as requested throughout trial to discuss progress of clinical studies.
- Interact with data management personnel as necessary to ensure that datasets are in usable format; perform statistical diagnostics prior to database locking.
- Coordination with programmers and different departments to make sure the compliance of the protocol, programs and study reports as per the respective regulatory requirement related to pharmacokinetic and Biostatistics.
- Perform statistical quality control review and program validation for assigned projects.
- Interact with medical writers in production of statistical and integrated clinical/statistical reports and other documents containing statistical information. Review draft documents.
- Respond to QA, Sponsor & Regulatory queries.

Cadila Healthcare Ltd.
Ahmedabad, India
► Visit the website
Senior Scientific Assistant (13th August 2007 – 5th November 2009)

Worked as a **Biostatistician** for various departments like clinical research (BA/BE, Phase I/II Clinical trials), Pharmacology and Toxicology (Chronic, Acute and Sub-acute toxicity studies, Reproductive toxicity studies, animal health monitoring data) of Zydus Research Centre.

JOB PROFILE:

- Oversaw the activities of the department of Biometrics and Systems to generate statistical deliverables and to meet the project timelines.
- Protocol designing, report writing and Performed statistical analyses for different type of Pre-clinical studies like Single and repeat dose toxicity Studies, Chronic and Sub-chronic toxicity Studies, Reprotoxicity Studies, Genotoxicity studies, Mutagenicity studies, Carcinogenicity Studies, Supplemental toxicity studies and cardiovascular safety Pharmacology studies.
- Handling and analyse the different types of data like pharmacokinetic, Hematogy, clinical chemistry, Organ and body weight data, Food consumption data, fertility data, litter data, pup survival data, Microbial monitoring data, Sperm mortality data, Implantation data, Skeletal data, Lactation index and pre-postnatal data, embryonic data, ECG data in animals.
- Find the Reference Range of Hematogy and Biochemistry parameters of different types of species like beagle dog, Wistar Rat, SAM (Swiss albino mice), C 57 mice, BALB_c, SD Rat , FAFA Rat to set up in house development of specific species at ARF.
- To write, revise and ensure implementation of Statistical SOPs as per needed and Responsible for IQ, OQ and PQ for SAS and WinNonlin Software and Respond to QA and Regulatory queries.
- Interact with other departments, such as safety pharmacology, Biotechnology, Mutagenesis, Reptox and ARF (Animal Research Facility).
- Overall management of Biometrics Department and involvement in the study beginning from protocol designing, randomization, till final data analysis and reporting).

Family Planning Association India Accredited to IPPF.
(International Planned Parenthood Federation London)
► Visit the website
Statistical Officer (25th May 2006 – 9th August 2007)

Worked as a **statistical officer** in **Monitoring & Evaluation department** at FPA India working for Sexual and Reproductive Health & Rights including Family Planning projects.

JOB PROFILE:

- Handling a team of Data Entry Operators & Field supervisors and giving training to make capacity building of staff.
- Collect data form field workers, counsellors and all co-coordinators of all Reproductive Health and Family Planning Centre's, hospitals and all Urban Health Centre which is associated with FPA India.
- Cross check the data to verify the quality of data by randomly checking all forms and files by visit all centres' and hospitals.
- Compiles Monthly, Quarterly and Annual Statistical Report including charts, trends and tables showing all project based information using standard office automation applications related to word processing, graphics presentations etc.
- Design the project field survey forms & counselling forms and report format for collecting data of the required detailed information of the households and families, Emergency contraception, Abortion (medical and surgical) , Maternal health ,Child health, Adolescent sexual and reproductive health, Counselling, Prevention and management of HIV/AIDS.

- Analyse data and by the interpretation of data recommend to the management for modification, changes and action for better result and project implementation process.
- Monitoring and evaluation of all running projects like SRH (sexual and reproductive Health, RCH, YFS, MNGO, SCERT, REACH i.e., "Rural Effective Affordable Comprehensive Community Health Care" implemented in rural.
- Extensive field visits for review and spot checks, compiling progress reports and input-output statistics and analysis with specific reference to young child survival and safe motherhood, Clinic Management Systems, awareness and advocacy programmes both at community & national levels as per the approved work plan /M&E Plan.

Personal Profile:

Birth date : 21 August 1982
Gender : Male
Marital Status : Married
Nationality : Indian
Passport No. : M8576183
Language Known : English, Hindi, Gujarati

COMPUTER PROFICIENCY:

- **SAS® 9** Professional software for Statistical analysis
- **SPSS (12.0)** Professional software for Statistical analysis.
- **WinNonlin® 5.3** Professional software for Pharmacokinetic analysis.
- **GraphPad Prism (5.0)** (Statistical Software)

SPECIAL CHARACHTERISTICS:

- Self-motivated and Optimistic personality.
- Ability to work on multiple tasks and can handle positive pressure.
- Excellent in problem-solving skills and can work independently as well as in a team.
- Flexible and having ability to interact effectively with people
- Eager to learn new things, quick learner, hard worker, disciplined, honest and high integrity.
- Creative & Trend Setter mentality.
- Last but not least: I believe in myself.

Yours Faithfully

Manoj Anandi Patel