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**SUMMARY:**

- **5 years** of **SAS** programming experience in **Clinical trials (Phase1-IV)** and **Prescription (IMS/NDC) Data** (Market Research, Prescription & Retail Auditing).
- Experience with various therapeutics **like CVS, Pain, Metabolic, Pulmonary, Oncology, CNS and GI.**
- Familiarity with **ICH, GCP** guidelines and **Electronic Submission** standards.
- Knowledge of industry practices with **CDISC** standards, **SDTM** and **ADAM.**
- Good knowledge of **medical terminology** and **clinical trials data structure.**
- Participated in **protocol review and CRF design.**
- Thorough knowledge of Clinical Trials data like **Demographic data, Vital Signs, Adverse Events (AE), Serious Adverse Events (SAE), Laboratory data and Efficacy related data.**
- Generating **Safety and Efficacy tables, data listings and graphs.**
- Knowledge in creating datasets and table programming for **ISE** (Integrated Summary of Efficacy) and **ISS** (Integrated Summary of Safety) submissions to the **FDA.**
- **Integrate data from different sources (e.g., SAS datasets from different CRO's, CRF data and electronic laboratory data).**
- Experience in **cleaning and resolving data** issues as well as merging data from different sources into a single integrated dataset.
- Performed **Cleaning Techniques, QC Validation** and **Edit Checks** as per protocol designs on Clinical Data.
- Used **Data migration** procedures for Importing and exporting data from Excel spreadsheets, CSV, Tab DLM and any DLM to SAS Data sets.
- Extensive experience with **Base SAS, SAS/Macros, Proc SQL, SAS/STAT** in the Windows environment.
- Demonstrated ability to work collaboratively in a team environment as well as independently.

**TECHNICAL SKILLS:**

<b>OPERATING SYSTEMS</b>	DOS, Windows 98/2000/XP, UNIX
<b>RDBMS/ DATABASES</b>	MS Access, SQL, Oracle 8i
<b>LANGUAGES</b>	SAS Programming, PL/SQL, SQL PLUS, ABAP/4 Unix, C, FORTRAN,
<b>SAS TOOLS</b>	SAS/Base, SAS/Stat, SAS/Graph, SAS/Access, SAS/Macro, SAS/Connect. (V8&V6), SAS/SQL, SAS/Access, Ultra Edit
<b>FRONT END TOOLS</b>	VB6.0, MS Office 2000MS Word, Word Processing, MS Project, MS Excel, SQL tools, MS Visio, HTML

**EMPLOYMENT DETAILS:****Quintiles Inc. Overland Park, Kansas City (MO)****Oct '07 – Dec' 07****Position: Statistical Programmer (SAS)****Responsibilities:**

- **CDISC SDTM** Experience - mapping of various phases of clinical trial data into the **SDTM** format.
- Develop and maintain programs to meet internal and external clients' needs.
- Plan and coordinate programming, testing, and documentation of statistical programs for use in creating statistical **tables, graphics, and listing summaries.**
- Responsible for providing proper **validation**, including testing and documentation (e.g., requirements document, **program validation**), in accordance with GCP and company standards.
- Participate in the design and maintenance of a **standard programming environment** (i.e.file structure and development to production implementation strategy).
- Provide timely and efficient technical support to the clinical study teams regarding issues encountered when creating programs.
- Programming and Validating tables, listings, analysis datasets and figures for inclusion in clinical study reports.
- Developed dynamic SAS programs **using SAS BASE, SAS MACROS, STATS & GRAPHS** with Phase I –II Clinical Trial data.

**PRA International, Charlottesville, VA**

**May' 07– Sept '07**

**Position: Analysis Programmer (SAS)**

**Responsibilities:**

- Involved in SAS programming with Clinical Trials data for **Phase I-III** Clinical Trials in **Oncology**.
- Developed dynamic SAS programs using SAS Tools like SAS/Base, SAS/Macros.
- Programmed **edit checks** and analysis for clinical studies.
- Developed new SAS programs and modified existing SAS programs.
- **SAS Macros** were used extensively in analysis of standard clinical data and generated reports, graphs, listings, summaries and tables.
- Developed, maintained and utilized standard **SAS** naming conventions for **macro library** supporting consistency and reusability of programs.
- **Proc SQL** is being used extensively.
- Developed procedures to standardize analysis programs, including a macro library.
- **Developed Tables, Listings and Figures for various on-going studies.**
- **SAS Macros** were used extensively in analysis of standard clinical data and generated reports, graphs, listings, summaries and tables.
- Involved with the QC and Validation of SAS programs.

**HepTronik Corporation, Plainsboro, NJ**

**Jul '05– Apr'07**

**Position: SAS Programmer (Clinical)**

**Responsibilities:**

- Involved in SAS programming with Clinical Research data for **Phase I-IV** Clinical Trials **CVS and Pain**.
- Developed dynamic SAS programs using SAS Tools like SAS/Base, SAS/Macros
- **Programming** for NDA submission item 11 in accordance to report specifications.
- Created and maintained analysis datasets from raw datasets.
- Programmed **edit checks** to satisfy data collection, storage, and analysis for clinical studies. Created and validated programs for Phase I, II, III clinical trial initiatives, responsible for production of analysis datasets, data listings and summary tables
- Developed new SAS programs and modified existing SAS programs.
- Performed data validation and checking for program errors using SAS.
- Formatted HTML, PDF and RTF reports, using SAS - Output Delivery System.
- Created Ad-hoc reports for analysis datasets by using Proc Reports and Proc Tabulate.
- **Developed listings, tables and Graphs for Efficacy and Safety for the clinical studies.**
- Created standard programs including macros.
- Extensive use of the **TRANPOSE, UNIVARIATE, SUMMARY, MEANS, FREQ, TABULATE, CONTENTS, SORT, PRINT, GLM, SQL, GLOT and GCHART** procedures.
- Produced statistical tables, listings and analysis. Analyzed data using **SAS/Stat** procedures
- Involved in the development of **clinical trial data tables** – demographic data tables, discrepancy data tables, **Adverse Events (AE)** tables, **Serious Adverse Events (SAE)** tables and **Laboratory data tables**.

**Nostrum Pharmaceuticals, NJ**

**Aug '04 – Jun' 05**

**Position: SAS Programmer (Clinical Trial)**

**Responsibilities:**

- Involved in clinical trial studies, **data migration/extraction of data** from Flat files, Oracle SQL Tables and SAS Datasets **CVS and Metabolic**.
- Extensive interaction with the functional users to understand the requirements on statistical methods and measures.
- Designed flowcharts indicating the input data sets and the techniques that would be used (sorting, merging, etc.) to get the desired output. Wrote SAS code according to the design.
- Preliminary data validation (clinical data quality checks) is done on the clinical trial data using SAS/SQL.
- Clinical trial data is made available to the SAS system. Worked in **Phase I and II data**. Some of the data used includes prescription data, sales rep activity data, and physician profile information.
- Produced **data listings, summary tables and graphs** for interim and final analyses and publications using different statements/functions/procedure for data manipulation.

**Onyx Pharmaceuticals -Emeryville, CA**

**Feb' 03 – Jul' 04**

**Position:-SAS Programmer**

**Responsibilities:**

- Created and maintained analysis datasets from raw data sets using import and export procedures (.xls, csv, txt, tab, any DLM).
- Recognized inconsistencies and initiated resolution of data problems.
- Analyzing and Evaluating the **Pharmaceutical Sales Data** in SAS, TA -**Oncology**.
- Developed analysis plans including specs for **tables, listing, graphs** and **Validation**.

- Provided statistical programming expertise in the production of datasets, analyses, tabulations, graphics, and listings from sales data.
- Contributed to the success of the Analytics team through design, development, evaluation, and modification of programs.
- Developed **Tables, Listings and Graphs** for **Efficacy and Safety** for the clinical studies using different statements/functions/procedure for data manipulation.
- Clinical trials programming for **NDA submission item 11**.
- Created Ad-hoc reports for analysis dataset by using **Proc Reports** and **Proc Tabulate**.
- Used **SAS/Base** and **SAS/Macro** to develop and analyze the report for clinical drug trails.
- Familiarity with pharmaceutical industry data, in particular **IMS or NDC** data experience.

**Applabs Technologies Inc. PA**

**Jan' 01 – Jan'03**

**Position:- LIMS Consultant**

**Responsibilities:**

- Implementing Watson LIMS which is a highly specialized protocol-driven Laboratory information management system specifically designed to support DMPK / Bio-Analytical studies in drug development.
- Promoting compliance with GLP Regulations and the FDA 21CFR Part 11 guidance.
- Supporting the advanced functionality for study design, virtually for all types of studies including discovery, pre-clinical and clinical research.
- Supporting single and multiple dose studies and constructing study designs for serial and non-serial sample collection studies.
- Handling all details of shipments of samples that are received, stored, moved within an organization, returned or discarded. Configuring sample storage facilities from the facility level down to the individual storage containers for the samples.
- Generating bar code labels automatically according to study protocol using user-defined label designs and can be used for the selection and identification of samples.
- Generating reports that comply with corporate standards and regulatory guidelines.
- Performing non-compartmental pharmaco-kinetic and toxico-kinetic data analysis.
- Create and Edit analytical runs. Perform standard regression within an analytical run.

**VERA PHARMA LIMITED**

**DEC' 99 to DEC '00**

**Position: Regional Business Manager**

**Responsibilities:**

- To monitor closely, performance of all the major products and to implement all strategies designed by the company for achieving the product wise target set on a monthly basis.
- To ensure the implementation of all the sales promotional strategies developed by the company through the frontline managers to achieve the monthly and the annual Regional target.
- Controlling Depot (Distribution) network by planning adequate stock inventory to meet the demand and in realizing the payments from the Distributors within the due period of 21 days, thereby reducing out standings.
- Recruiting ABM'S and TSE'S whenever vacancies arise by picking them from the field. Giving classroom and field training before inducting them into the field.
- Periodical communications to ABM's and TSE's on their performances-Product wise, territory wise, doctor wise Contributions.
- Conducting Sales Review meetings and motivating the field force to achieve the set goals for products and Doctor wise volumes. Development of weak territories. Appraisal systems. Objective fieldwork with Personal Order booking and Doctor Conversion. RBM reports to BDM.

**LEKAR HEALTHCARE LIMITED, Mumbai**

**Jun' 96 to Nov' 99**

**Position: District Manager**

**Responsibilities:**

- Achieving product wise and Rupee wise targets through MR's (Medical Representatives).
- To monitor closely the performance of each MR and ensure the implementation of strategies designed for achieving product wise targets set on quarterly basis.
- To review closely product selection and customer selection by the MR's and corrects the situation if necessary.
- To monitor and control the territory coverage as per the approved standard tour programmed and to control the expenses.
- Providing up to date information to marketing head and the product department about competitor's activities and the performance of newly introduced pharmaceutical products in various therapeutics segments.
- Identifying new markets for business developments whenever there is saturation.
- Selecting and appointing new distributors. Conducting classroom & field training before inducting new MR's.

**AVENTIS PHARMA, Mumbai**

**Dec '86 to Jun' 96**

**Position: Technical Service Representative**

- At Rhone-Poulenc suggested a few strategies, which the management received positively. Turned into a successful representative implementing the company's strategies and became a good detailer.
- Retail and Physician audit including Call planning
- Physician profiling, territory mapping etc.

**WOCKHARDT Ltd. Mumbai**

**Feb' 84 to Nov' 86**

**Professional Service Representative**

- At WOCKHARDT suggested product promotion strategies, which were implemented by the company. Successfully launched its new division "TRIDOSS".

**EDUCATIONAL QUALIFICATIONS:**

- **Masters in Business Administration (Information Technology)/MBA IT, INDIA.**
- **Post Graduate Diploma in Computer Applications (PGDCA),INDIA**
- **Bachelor of Science (B.S) from OSMANIA UNIVERSITY, HYDERABAD, INDIA.**