**VINDHYA GANESH**

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**Professional Summary:**

* More than 7 years of experience as a SAS programmer/Analyst in Healthcare, Clinical, Pharmaceutical and Biotechnological industries.
* Strong understanding on regulatory guidelines and standards specific to procedures such as **CDISC, ICH** Guidelines, **MedDRA, WHO DRUG,NDA**, and **FDA** procedures of **FDA 21 CFR part 11**.
* Strong experience in **Phases I – IV of clinical trials including edit checks, protocol violations, safety reviews and patient profiles**.
* Extensive experience in using various SAS tools such as **SAS/BASE, SAS/MACROS, SAS/STAT, SAS/GRAPH, and SAS/ODS, SAS/ACCESS, SAS/CONNECT, SAS/SQL.**
* Experience in analyzing **Case Report Forms (CRF)** data, **Study Protocol**, **Statistical Analysis Plan (SAP)** and Clinical Data Analysis and good understanding of data cleaning process.
* Strong experience in producing various**SDTM and ADAM datasets in accordance with CDISC standards.**
* Excellent work experience in generating and validating tables, figures, and listings (TFL).
* Has knowledge of Integrated Summaries of Efficacy (ISE) and Integrated Summaries Safety (ISS).
* Extensive experience in problem solving skills and providing programming support.
* Considerable experience with the preparation of **SAS datasets and generation of ad-hoc reports, tables, listings and graphs according to guidelines lay down in Statistical Analysis Plan (SAP), Standard Operating Procedures (SOP) and Data Specs.**
* Good knowledge of new drug & device release process from IND submission for getting approved by FDA.
* Strong experience in various SAS procedures like **Contents, Print, Freq, Means, Univariate, Summary, Report, Plot, Format, Transpose** and **SQL** in generating reports.
* Extensive experience in developing routine codes with SAS Macro and debugging macros using options such as **MPRINT, MLOGIC** and **SYMBOLGEN**
* Strong working experience in modifying existing SAS programs and creating new SAS programs using MACROS, including application for data cleaning.
* Strong skills in Oracle Database, Oracle Clinical, SAS, SQL, PowerPoint, MS Excel, MS Word, and MS Access.
* Strong interpersonal communication skills, ability to work independently as well as in a group, highly dedicated, quick self-starter, ability to adapt and learn new things and excellent at solving complex problems under strict deadlines.
* Excellent presentation skills with the ability to present and discuss the statistical aspects of Clinical trials.

**EDUCATION**

* Bachelors - Biotechnology from JNT University, India
* Masters – Biotechnology from Houston Univ. Texas, U.S.A.

**TECHNICAL SKILLS**

**SAS Tools:** SAS V 9.1.3/ V 9.2/V 9.3, SAS Enterprise Guide, SAS/BASE, SAS/ACCESS,

SAS/SQL, SAS/MACROS, SAS/GRAPH, SAS/STAT, SAS/ODS, SAS Connect

**Databases:**  Oracle Clinical, SQL, PL/SQL.

**Operating systems:** UNIX, Windows.

**Office Tools:**  MS-Office, Word, Excel, PowerPoint.

**Independent Health, Buffalo, NY Nov 2013-Current**

**SAS Programmer/Analyst**

Independent Health takes data and aggregates, transforms, develops reports and sometimes loads it into a dedicateddatabase for easy online access and querying. The role involved providing IT support to the statisticians by creating customized reports and datasets. Performed Data Integrity checks, Statistical Analysis were done on the data, and reports were generated.

**Responsibilities:**

* Performed Validation and QC of datasets, tables, listing and graphs.
* Wrote SAS programs to generate appropriate listings (inc. patient profiles) and reports to support data cleaning activities according to data manager requirements as part of QC.
* Created Summary reports and tabular reports using PROC REPORT.
* Performed Impact Analysis on various Enterprise Data Management related SAS programs.
* Performed data validation by creating SAS code to clean up the invalid data entries
* Hands on experience using Enterprise Guide, X-Win 32 2012, SAS 9.3 for LINUX and UNIX platforms to execute various SAS modules.
* Used Base SAS (MEANS, FREQ, SUMMARY, TABULATE, REPORT etc.,) and SAS/STATprocedures (REG, GLM, ANOVA, UNIVARIATE etc.) for summarization, Cross-Tabulations and statistical analysis purposes.
* Executed report programs and imported the results into Excel for data analysis.
* Collaborated with Data Management to annotate raw data with standardized variables and formats using Proc Datasets, Proc Formats.
* Created reports in PDF, HTML, XML and RTF using SAS/ODS statements for Ad-Hoc report generation.
* Assisted in validation, edit checks and data review listing.
* Experience in PROC SQL joins and PROC SQL set operators to combine tables horizontally and vertically.
* Wrote programs in SAS to generate reports, creating RTF, HTML listings, tables and reports using SAS/ODS for Ad-Hoc report generation.

**Environment**: SAS 9.2 SAS/BASE, SAS/ODS, SAS/MACRO, SAS/SQL, SAS/GRAPH, SAS/STAT, SAS/ACCESS, SAS/EG UNIX and Windows, MS Excel/Word/PowerPoint

**SCRI, Nashville, TN Feb 2013- Oct2013**

**Clinical SAS Programmer**

SCRI is a CRO to the pharmaceutical, biotechnology, generic drug companies in the therapeutic areas of Oncology, Central Nervous System (CNS), and Infectious Disease & Vaccines. Involved in phase II, III Clinical studies and worked with statisticians and data managers on various drug studies.

**Responsibilities:**

* Understanding and using departmental utilities, processes, and procedures where applicable.
* Involved in publications programming and testing of utility macros for standard reports and validation.
* Involved in analysis of Phase I and II clinical trials.
* CreatedSDTM datasets according to CDISC standards.
* Hands on experience using SAS Enterprise guide 5, SAS Enterprise guide 4.3, UNIX and PC platform.
* Developed and Validated SAS programs and macro codes to produce analysis datasets and reports.
* Generated analysis datasets in ADaM standards and performed statistical analysis on data as per the requirements in the SAP and Protocol
* Generated tables, listings and graphs with the help of SAS/BASE, SAS/STAT and SAS/GRAPH in Windows environment.
* Developed programs for pooling of SDTM data for ISS (Integrated Summary of Safety) analysis.
* Produced Safety and Efficacy reports in RTF format.
* Worked with Data management team, investigating data issues and solving technical problems.
* Accuracy, completeness, quality, and timeliness of clinical programming deliverables.
* Performed QC of derived datasets, TLG’s and coded programs and involved in Data Validation.

**Environment**: SAS 9.2 SAS/BASE, SAS/ODS, SAS/MACRO, SAS/GRAPH, SAS/STAT, SAS/ACCESS, SAS/EG Windows, MS Excel/Word/PowerPoint

**Agennix, Houston, TX Feb 2012- Jan 2013**

**Clinical SAS Programmer/Analyst**

Agennixis a biotechnology company, focused on developing and commercializing novel drugs to addressunmet medical needs in the hospital market.

**Responsibilities:**

* Created, derived and pooled datasets, listings and summary tables for Phase-I and Phase-II of Clinical Trials.
* Verified the accuracy and integrity of Clinical data by performing validation checks written in SAS and investigate data related errors, outliers, and missing values.
* Developed SDTM data mapping and create SDTM datasets per CDISC standard for FDA.
* Created Analysis Datasets from SDTM datasets as per CDISC standards for Analysis purpose.
* Used SAS SQL Pass through facility and Libname facility to import and create datasets from Oracle Clinical database.
* Used Base SAS (MEANS, FREQ, SUMMARY, TABULATE, REPORT etc) and SAS/STATprocedures (REG, ANOVA, UNIVARIATE etc.) for summarization, Cross-Tabulations and statistical analysis purposes. The generated reports were reviewed and then sent to the FDA.
* Developed standard reports for safety data including laboratory and adverse events summaries for IND (Investigational New Drug).
* Developed Macros for various instances for automating listings and graphing of Clinical data for analysis.
* Developed statistical reports by using Proc Report, Data \_null\_ and SAS Macro.
* Executed report programs and imported the results into Excel for data analysis.
* Created AdHoc reports using the SAS procedures and created reports using ODS statements and Proc Template to generate different output formats like html, pdf and excel to view them in the web browser.
* Collaborated with Clinical Data Management to annotate CRFs with standardized variables and formats using Proc Datasets, Proc Formats.
* Understood importance of validation/verification process and compliance with regulations and policies by creating Constraints.

**Environment**: SAS Windows/Unix, SAS/BASE, SAS/MACROS, SAS/ACCESS, SAS/STAT, SAS/ODS, SAS/GRAPH, SAS/CONNECT, MS-Excel, MS-Access

**XTL BiopharmaceuticalsLtd., NY Sep 2010- Feb 2012**

**Clinical SAS Programmer**

XTL is a Biopharmaceutical company involved in the development of therapeutics for the treatment of diabetic neuropathic pain,HCV and many other treatments.I was involved in phases II and III of development of drug ‘Bicifadine’ for treatment of neuropathic panic in diabetic patients.The study was to evaluate the safety and long term efficacy of two dosages of Bicifadine.

**Responsibilities:**

* Prepared/reviewed protocol documents, case report forms, annotated CRF, and statistical analysis plans for clinical trials.
* Carry out Annotations of CRFs based on CDISC SDTMv3.1.1 and prepare the related transfer specifications.
* Transformed existing raw data into standardized CDISC SDTM/ADaM domain datasets using various SAS procedures.
* Accessed SAS clinical tables using SAS Access facility to connect to oracle database.
* Performed Edit check programming to identify potential data issues and conducted data validations as per data dictionary guidelines.
* Used BASE SAS to perform sorting, indexing, merging of the datasets.
* Worked on data analysis, statistical analysis and generated Reports, Listings and Graphs using BASE SAS and SAS procedures such as PROC SUMMARY, PROC TABULATE, PROC FREQ, PROC GPLOT and ODS procedure.
* Extensively used SAS/MACRO facility to provide reusable programs that can be conveniently used time-to-time and created tables, graphs and listing reports.
* Responsible for writing and debugging statistical programming and documented programming procedures.
* Created reports using ODS in various file formats such as RTF, PDF and HTML.

**Environment**: SAS Windows, SAS/BASE, SAS/MACROS, SAS/ACCESS, SAS/STAT, SAS/ODS, SAS/GRAPH, SAS/CONNECT, MS-Excel, MS-Access

**Axcan Pharma, Birmingham, AL** **Jan 2010- Aug 2010**

**Clinical SAS Programmer**

The projects were on phase II and III studies of anti-cancer drugs. As a SAS programmer I was responsible for managing and analyzing the clinical trial data in addition to providing reports as per company SOP's and Statistical Analysis Plan (SAP).

**Responsibilities:**

* Generated statistical analysis files, summary tables, listings and graphs using SAS/BASE, SAS/MACROS, SAS/MERGE, SAS/GRAPH and SAS/STAT.
* Used SAS/ACCESS to extract data from Oracle and other relational databases for analysis.
* Prepared new datasets from raw sets files using Import Techniques and modified existing datasets using Set, Merge, Sort, Update, Formats, and Functions.
* Developed and customized reports using PROC REPORT, PROC SORT, PROC FREQ and PROC MEANS and DATA\_NULL\_.
* Created new datasets from existing data-sets by using concatenation, merging, interleaving and using conditional statements.
* Generated routine and ad-hoc reports using PROC PRINT, PROC SORT, PROC FREQ and PROC REPORT.
* Generated required Charts, Graphs and reports using PROC REPORT, PROC GPLOT and SAS/GRAPH for graphical analysis.
* Developed and improved the efficiency of programs through the use of SAS macros.
* Created an annotated CRF document that maps CRF data sets to SAS data sets.   
  Used SAS/ODS facility to generate custom reports and thus directing SASoutput to RTF, XML and PDF files.
* Reviewed the existing SAS code to eliminate any possible errors and improved functionality.

**Environment**: SAS/BASE, SAS/STATS, SAS/MACROS, SAS/ODS.

**Suven Life Sciences Ltd., India Apr 2006 – July 2008**

**SAS Programmer – Clinical Trials**

**Responsibilities:**

* Created new or modify SAS programs to load data from the source and create study specific datasets, which are used as source datasets for report generating programs.
* Cleaned, validated, and managed various Clinical trial datasets, and handled missing values.
* Provided pertinent Clinical and statistical data by interacting with statisticians, physicians, medical writers and IT staff.
* Conducted statistical analyses using SAS/STAT including PROC FREQ, PROC, ANNOVA, UNIVARIATE
* Developed SAS Macros to generate graphs and reports based on combined datasets, and performed statistical analyses with output delivery procedures.
* Developed numerous ad hoc SAS programs to create summaries and listings.
* Created SAS MACROS and SAS GRAPHICS. Customize the existing programs using SAS Macros as per the statistician’s requirements
* Analyzed different drugs sales activity metrics and generated reports and graphical representation of these sales for comparison of different drugs using SAS/GRAPH and SAS/STAT.
* Used PROC GPLOT to create graphs in SAS.
* Generated interpretive charts, tables and reports in accordance with regulations including patient demography, discontinuation, and adverse events.
* Participated in producing integrated summaries of safety and efficacy.
* Collaborated with statisticians and medical researchers in preparing formal reports.
* Generated SAS Customized reports using the DATA \_NULL \_ and PROC REPORT techniques.
* Created TEMPLATES to modify the appearance of the Displayed ODS Tables using PROC TEMPLATE.
* Extensively used PROC FREQ, PROC TABULATE, PROC MEANS, PROC SUMMARY, PROC CONTENTS, PROC COMPARE and PROC UNIVARIATE.

**Environment**: SAS/ACCESS, SAS/BASE, SAS/STAT, SAS/ODS, SAS/SQL, SAS/GRAPH, MS-Excel/Word.