Goverdhan Puchchakayala
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SUMMARY:

- Experience in generating Analysis Datasets/SDTM/ADaM
- Can produce Tables, Listings and Graphs TLG's using Base SAS, SAS/Graph, SAS/Macros and SAS/ODS according to Statistical Analysis Plan SAP.
- Broad Knowledge of Life Sciences and drug development process from protocol through FDA submissions in the clinical trial process
- Experience in Data cleaning and edit checks
- Knowledge and experience CDISC guidelines and of different clinical trial domains like Demographic, Adverse Events AE, Serious Adverse Events SAE, Disposition, Medical History MH, ECG, Exposure Ex, Concomitant medication CM, Vital Signs VS and Laboratory Data lab data. Etc.
- Ability to work well with others and independently
- Excellent organizational and communicational skills with high self-motivation, team leadership experience.
- Experience in producing RTF, HTML and PDF formatted files using SAS/ODS.
- Knowledge of FDA regulations 21 CFR part 11, ICH guidelines and GCP requirements in new drug development and application process

TECHNICAL SKILLS:

- SAS: Base/SAS (certified), SAS/MACRO, SAS/ODS, SAS/GRAPH, SAS/SQL, CDISC, SDTM, ADaM
- Languages: SQL, SAS

Professional Experience:

Clinical SAS programmer **Dec 2018 to till date**
Arcellx , Maryland

- Develop SAS programs and output to create SDTM, ADaM and client-defined analysis datasets, tables, listings and graphs.
- Analyse data using SAS Statistical Procedures such as Proc Means, Proc Tabulate, Proc Freq, Proc Summary.
- Annotation of Case Report Forms according to SDTM standards.
- Performed programming for creation of SDTM Datasets as per SDTM IG and specification.

- Prepare new datasets from raw data files using Import Techniques and modify existing datasets using Data Steps, Set, Merge, Sort, and Update, Formats, Functions and conditional statements.
- Validates SDTM and ADaM datasets created by peer programmers through parallel programming technique.
- Generate reports using the DATA _NULL _ and PROC REPORT techniques
- Will be able to use SAS/ODS for generating different output formats as requested.
- Will be able to define variables, merging datasets, creating derived datasets, data validation before processing.
- Knowledge of current FDA regulations, Good Clinical Practice (GCP), International Conference of Harmonization (ICH), Clinical Data Interchange Standards Consortium (CDISC) and other regulatory guidelines.
- Involved in annotating the blank CRF's based on the specifications provided and reviewing the specs.
- Reviewed the CRF annotation done and corresponding peer Quality check (QC) is done with required comments documented on tracking tool for each work request.
- Ensure review of study documents such as Protocol, CRF, and SAP.
- Develop programs for data transfers and assist in their review to ensure the data transfer has been produced to specification
- Create Patient narratives and generate .XML outputs
- Prioritize personal workload to meet specified completion dates
- Develop good problem solving skills and a willingness to learn and seek advice from senior Statistical Programming staff
- Carry out all activities according to SOPs working within the framework of the Quality Management System and to Good Clinical Practice (GCP).
- Perform other duties as assigned by senior Programming staff

Education

Ph.D. in Pharmacology | Kakatiya University, Warangal, India

Master in Pharmacology | Andhra University, Vizag India

Bachelors in Pharmaceutical Sciences| Kakatiya University, Warangal India

CERTIFICATION

- Certified Base SAS Programmer for SAS 9.4