**Divya** Reddy

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**Summary**

SAS programmer with 5+ years of experience working with SAS emphasizing on Design, Development, Analysis, Validation, and Reporting for Pharmaceuticals and Clinical Research Organizations.

**Skills**

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| * Statistical Software: SAS (Base SAS, SAS/STAT, SAS/GRAPH, SAS/ODS, SAS/SQL, MACROS), R. * Operating Systems: Windows and UNIX. | * Microsoft Tools: MS office Word, Excel, Access, Project and Powerpoint. |

**Experience**

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| **01/2021 to 03/2023** | **Senior SAS Programmer**  **Syneos Health**   * Provided SAS Programming and analysis support for various studies and therapeutic areas. * Created SDTM specifications document based on SDTM Implementation Guide. * Developed and validated SDTM and ADaM datasets according to CDISC criteria. * Developed tables, listings, and graphs according to study-specific Mock shells and SAP. * Reviewed Case Report Forms (CRF), Statistical Analysis Plan, Mock-up’s/shells/templates and provided comments as needed. * Developed Oncology specific domains Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS), ADRS, ADTTE. * Verified with stats for any revisions to the statistical analysis strategy, mock-ups/shells/templates, etc. * Contributed to the development of define.xml and assisted in establishment of reviewer's guide (SDRG, ADRG). * Extensively involved in generating various types of graphs using PROC SGPLOT. * Generated Kaplan-Meir estimates are using the PROC LIFETEST. * Estimated the hazard ratio using Cox regression model with PROC PHREG. * Validated the datasets and Tables by using Double programming Technique and compliance checks by using Pinnacle 21. * Used Output Delivery System (ODS) facility to generate safety and efficacy reports in PDF, RTF and HTML formats. * Involved in generating TLG's for Integrated Summaries of Efficacy (ISE) and Safety (ISS) for FDA submission. * Involved in creating various SAS Reports satisfying the 21CFR-11 Code for Federal Regulations for electronic data submission. * Attended study specific meetings with internal and client team. |

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| **10/2018 to 11/2021** | **Clinical SAS Programmer**  **Grifols Biologicals** － Los Angeles, CA   * Understood and followed department's working practice documents and SOPs. * Extracted data from database and created new Datasets from raw data files. * Created SDTM datasets like DM, EX, CM, AE, MH, LB, VS, EG, PC, PP etc. based on SDTM mapping specifications and validated them. * Created ADaM datasets like ADSL, ADEX, ADLB, ADVS, ADDS, ADAE, ADEG, ADVS, ADPC, ADPP and etc. * Worked on ADaM Dataset derivations like Treatment Emergent Adverse Event, Visit Windowing, Baseline, CTCAE grading, DType (LOCF, WOCF, BOCF) based on SAP. * Generated tables and listings by using Data step and statistical procedure like PROC MEANS, PROC FREQ, PROC SUMMARY, PROC TRANSPOSE, PROC SEQ and PROC REPORT. * Calculated p-values using different statistical analysis such as CHISQ, EXACT, Mantel-Haensze(MH), Cochran-Mantel-Haenszel(CMH) using PROC FREQ, PROC ANNOVA. * Converted various validated SAS datasets into transport files (.XPT) using XPORT engine and PROC COPY. * Worked on Pinnacle 21 validator to check the compliance of the SDTM and ADaM datasets. * Generated define.xml and define.pdf as part of CRT for FDA submission. * Created RTF and PDF reports using SAS ODS output statements. * Created ad hoc programs to provide information to the project team and/or client, as required. * Developed Edit checks for different studies and in reporting those issues to the data manager in excel sheet. * Created Macros at various instances for automating listings and tables of clinical data for analysis. |

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| **09/2016 to 04/2018** | **Development Chemist II**  **Hologic** － San Diego, CA   * Coordinated strategy meetings to modify and develop operating procedures, techniques and research protocols for continued success. * Ordered supplies, inventoried chemicals and materials and summarized and recorded data to meet control and research requirements. * Monitored packaging and storage of hazardous materials and waste to comply with laboratory, state and federal safety regulations. * Made decisions and executed changes based on process data, quality checks and test results to keep products at target and within specifications. * Provide support in production for troubleshooting in validation runs/ production runs. * Planned and completed group projects, working smoothly with others. * Provide daily maintenance, calibration, and runs quality control testing on analytical machinery before testing samples for the client. * Proactively checks and stays current with all training across multiple learning platforms. |

**Education and Training**

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| **05/2016** | **Masters**: Chemistry And Biochemistry  **San Diego State University** － San Diego, CA |

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| **06/2014** | **Bachelor of Science**: Chemistry  **Osmanity University** － Hyderabad, India |