SHUBHRANSHU SHEKHAR ACHARYA

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Professional Career :-

- Having almost **4.5+ Years** of experience in Clinical Data Management (CDM) domain in Study Startup phase with UAT (Validation) work in various tools and work items.

- Working as **Clinical Database Validation Specialist** at IQVIA RDS INDIA PVT LTD since 23rd Jan 2023 to till date

Working Experience:-

- **Company – 3**

Company	IQVIA RDS INDIA PVT LTD, Benagluru
Time Period	23rd Jan 2023 to Till Date
Position	Clinical Database Validation Specialist
Job Role	- Working on SDTM validation, SAS dataset validation and Data transfer validation. - Playing a role as Validation Team Lead (VTL) and Study Matter Expert (SME) for vendor data validation process. - Handling a small team size of 6 resources and process trainer for data transfer. - I am working on the Reporting Data Extract (RDE)/ Data transfer process, Vendor file update, Vendor File Structure validation, Merge Report validation, Custom report/Issue Report validation. - Having excellent knowledge on various types of the Dynamic checks, Edit checks, SAS listing checks, SAE Reconciliation, Import Set-up validation etc. - Having excellent knowledge on Rave database, SAS Universal Viewer, ALM tool, Rave Build Specification (RBS), Architect Loader Spreadsheet (ALS), Data Transfer Specification (DTS) and other required supportive document for CDM process. - Having experience in Creating, Reviewing and Validating the test cases for various work items in various tools. - Worked on Data entry for all the SDTM validation, Custom Reports/Issue Report and Merge Validation in the EDC tools and vendor test files as per the validation requirements. - Having good knowledge in validation process with both Production and Development data. - Preparing, Approving and Filing the testing documents post to the validation activities. - Also involved in mentoring to the new joiners and task allocation process. - Assuring to complete the task with the time frame to meet the study deliverables. - Good Knowledge in Study Startup, Conduct & Close out phases.

- **Company - 2**

Company	ICON Plc (L-PRA) Pvt. Ltd, Bengaluru
Time Period	03rd Dec 2020 to 13th Jan 2023
Position	Clinical Validation Analyst-1
Job Role	- Having experience in Creating, Reviewing and Validating the test cases for various work items in various tools. - Worked on Edit Checks, Dynamic Checks, Listings (Normal Listings, Lab Listings, External/Vendor Listings), Custom Reports, and Custom Programs work items. - Worked on Discrepancy, Custom Functions (CFs), Dynamic Search List (DSL), Data Validation Outputs (DVOs) and Data Analytic Outputs (DAOs) check types. - Worked on Simple, Moderate and Critical Edit and Dynamic checks. - Worked on Data entry for all the Listings, Custom Reports and Custom programs in the EDC tools and vendor test files as per the validation requirements. - Having good knowledge in validation process with both Production and Development data. - Having experience in Various tools like Rave, InForm, Data Labs and Marvin. - Worked on only creating the test cases of Edit Checks and Dynamic checks for ALM tool. - Also worked on PL/SQL, Java Review and SAS Listings testing to Validate Normal Listing, External/Vendor Listing and Custom Reports work items. - Having good knowledge on TFS and Microsoft Test Manager (MTM) applications for the use of validation work. - Preparing, Approving and Filing the testing documents post to the validation activities.

- **Company - 1**

Company	Accenture Solutions Pvt Ltd, Bengaluru
Time Period	23rd Apr 2020 to 30th Nov 2020
Position	Data Management Associate
Job Role	- Creates and maintains/perform User Acceptance Testing (UAT) procedures for Electronic Data Capture (EDC) systems and Clinical Data Management Databases (CDMDB). - Coordinates and manages EDC and CDMDB UAT related efforts within the department and across different functional areas. - Ensures that high degree of standardization, efficiency, and quality are met and maintained. - UAT of new EDC trials and CDMDB applications/software and may run Quality Assurance test scripts on eCDM systems, Reports and Outputs. - Prepares Edit Check Matrix (ECM) to conduct UAT. - Involve in Documentations and Quality Approvals.

Skills & Tool Experience:-

- Having **4.5+ Years** experience in **Rave EDC** in various work items like Edit Checks, Dynamic Checks, Listings, SAS checks etc.
- Having **1+ Year** experience in **InForm EDC** in Edit Checks work item.
- Having **6+ Months** experience in **Data Labs EDC** in various work items and **3+ Months** experience in **Marvin EDC** in Edit Checks and Dynamic Checks work items.
- Good knowledge in MS-Excel, MS-Word and MS-PowerPoint.

Trainings And Project Work:-

- ➤ Completed "Advanced Programmed PG Diploma in Clinical Research and Clinical Data Management" course from Clini India, Bengaluru in 2019.
- ➤ Completed three months project on "Isolation and characterization of some predominant halotolerant bacteria from mangrove soil of Bhitarkanika National Park (BNP), Odisha" at dept. of Biotechnology, MITS school of biotechnology, Bbsr.

Educational Qualification:-

- Completed **Master of Science (M.Sc.)** in **APPLIED MICROBIOLOGY** from MITS School of Biotechnology, Bhubaneswar in **2019**.
- Completed **Bachelor of Science (B.Sc.)** in **Biotechnology** Honors with **Distinction** from MITS School of Biotechnology, Bhubaneswar in **2017**.

Declaration:-

I hereby declare that the information furnished above is true to best of my knowledge.

Date :-
Place : - Bengaluru   **SHUBHRANSHU SHEKHAR ACHARYA**