# Ankita Thakkar

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## CORE COMPETENCIES

- Oracle Apex system tester with professional experience in Clinical Database Management System (CDMS) including **Analysis, Design, Functional Testing, Regression testing, User Acceptance Testing, Integration Testing, Maintenance** and **Documentation** in all phases of projects**.**
- Worked with the projects that were based on an implementation of Software Development Life Cycle (SDLC), Software Testing Life Cycle (STLC), and Defect Management Life Cycle.
- Involved in writing **Test Script, Debugging the Test scripts, Preparing and Maintaining Data table sheet**, executing the test scripts also, Plan and coordinate database design, development, implementation, maintenance, and user support of in CDMS systems.
- Performed independent programming activities on multiple projects concurrently with Development and implementation of solutions to global technical service issues and concerns regarding EDC, CTMS, IWRS and RSDV tools in Oracle Apex system programming.
- Coordinated with clients for documents/Specifications, database design and programming, Reports design for metadata and conduct quality control processes including database review and other tools for data cleaning and reporting.
- Developed and Validated programming specifications for mapping of SDTM datasets as per CDISC compliance and Produce Define XML/PDFs, annotated eCRFs and Reviewers Guide for submission deliverables for individual project.
- Performed any post-production changes, publish checks, complex structure dynamics to the EDC database or enhancements to the programs such as edit checks, listings, Protocol Deviations, metadata etc.
- Trained and mentored the team on various solutions like EDC, IWRS, CTMS, rSDV tools as required and have them ready to perform independent enough on day to day activities.
- Served as Lead Quality Analyst and providing programming support for development and maintenance of SAS datasets as per CDISC / Client Standards.
- Planned and executed to oversee all programming activities on a study, including but not limited to resource estimation, meeting timelines, maximizing quality, interaction with other departments and the client, etc.
- Performed quality check and ensure the work is delivered with quality and with knowledge of regulations pertaining to computerized systems to ensure compliance with 21 CFR part 11, ICH GCP guidelines and CDISC standards.
- Continuously learn and improve communication, technical and problem-solving skills and Interact with project team members in related discipline and provide solutions to the operational issues.
- Worked independently on multiple sponsors and take initiative to accept new challenges in Clinical Programming Applications.
- Reconciled database build, project files, reports, listings and other documents related to programming for accuracy, completeness of Data Management processes.
- Performed Browser **Compatibility Testing** (IE, Firefox, Chrome) of a Web based application.
- Demonstrated customer focus and a collaborative, team-oriented approach.
- Good **analytical**, **Programming** and **Communication** Skills with excellent work ethics, easy adaptability to demanding time schedules coupled with positive user interaction and excellent team spirit.
- Practical experience with creating Test Scenarios, Cases, User Stories, Test Scripts and Regression Tests based on project requirements.
- Experienced in quality assurance testing based on design and client requirements with documentation of issues in Excel/support ticket service Now ensuring alignment with business partners and data architecture.
- Capable of writing fully exhaustive test cases covering business requirements as well as mapping documents generated by system analysts.

- Proven ability to meet agreed upon project and customer satisfaction targets with timely tracking and documentation of milestones.
- Proven teamwork and cross-functional Communication skills with ability to organize and prioritize work and manage time.

## Education and Training

**Masters in Clinical Research** 2011 – 2013
*Gujarat University, India*

**Bachelor of Science in Chemistry** 2007 - 2010
Gujarat University, India

## Certifications and Recognitions

- Attended seminar on ICMR sponsored “One Day Workshop on ICH-GCP training”
- Participated in Obesity study conducted by Shivrath COE in clinical research affiliated with Gujarat University.
- Attended national work shop on “BIOTECHNOLOGY: Its Application & Biosafety Concerns” organized by clinical research programs, Shivrath COE in clinical research at Gujarat University.
- Received Valued Team Member award for delivering project right on time, within budget and for supporting peers on various tasks.

## Technical Skills

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| Testing Tools | SQL Server, Oracle Apex |
| Bug Reporting Tools | Support Ticket |
| Methodologies | Manual testing |
| Database | Oracle, SQL server, PLSQL |
| Operating Systems | Windows, Linux |

## Professional Experience

**Octalsoft, Glorant LLC, Ahmedabad, India** **Jan 2023 – Till Date**

**Industry: Custom Software Development (Healthcare)**

**Project Manager**

Octalsoft is Collaborated with cross-functional teams to develop and deliver custom software solutions for clinical research, specializing in the following areas:

- Clinical Trial Management System (CTMS)
- Electronic Data Capture (EDC) Software

- Interactive Web Response System (IWRS)
- Remote Source Data Verification (rSDV)
- Electronic Trial Master File (eTMF)
- Clinical Trial Supply Management (CTSM)
- Electronic Patient Reported Outcome (ePRO)
- eDOCS Custom Software Solutions

**Roles and Responsibilities:**

- Led the design, development, and implementation of custom solutions utilizing Oracle technologies to meet clients' needs.
- Worked closely with clients to understand their requirements and translate them into effective software solutions.
- Collaborated with a team of developers, ensuring the successful delivery of projects within agreed timelines and budget.
- Provided ongoing support and maintenance for databases and applications, ensuring their optimal performance and reliability.
- Conducted thorough testing and quality assurance activities to ensure the accuracy and integrity of the developed software solutions.
- Engaged in regular communication and collaboration with stakeholders, including project managers, clinical research teams, and IT support, to ensure alignment and satisfaction.
- Stayed up-to-date with industry trends and advancements in clinical research software solutions, contributing to the continuous improvement of Octalsoft's offerings.
- Provide support in developing and analyzing business cases for projects along with Identify and evaluate potential risks and benefits associated with proposed projects.
- Develop project plans, including timelines, milestones, and resource allocation together with Monitor project progress, track deliverables, and ensure adherence to schedules. Identify and address potential bottlenecks or issues that may impact project timelines.
- Analyze and document user needs, goals, and constraints. Collaborate with stakeholders to ensure requirements are accurately captured. Establish a requirements management process, including documentation and change control.
- Communicate requirements effectively to project team members and stakeholders. Facilitate discussions and negotiations to resolve conflicting requirements. Analyze and prioritize requirements based on business objectives and constraints.
- Identify gaps, ambiguities, and inconsistencies in requirements. Collaborate with technical teams to propose feasible solutions. Lead the development of functional designs based on user requirements. Collaborate with cross-functional teams to ensure alignment with technical capabilities.
- Provide guidance and support to developers during the implementation phase. Define and manage the project scope, including scope boundaries and change control. Assess and evaluate change requests against project objectives and constraints.
- Ensure project deliverables are within the defined scope. Create and maintain project documentation, such as requirements specifications and design documents.
- Review project documents for accuracy, completeness, and compliance with standards. Ensure documentation is accessible and up-to-date for project stakeholders. Verify and confirm that technology solutions meet specified requirements.
- Conduct testing and quality assurance activities to ensure solution reliability. Coordinate with technical teams to address any identified issues or gaps.
- Oversee the deployment process and ensure smooth transition to production. Coordinate with operations and support teams to facilitate a successful deployment.

- Monitor post-deployment activities and address any issues or concerns. Undertake any other duties assigned by the management representative.
- Adapt and contribute to evolving project management methodologies and practices. Foster a collaborative and positive work environment within the project team.

**Environment:** Oracle Apex Custom Applications.

**Octalsoft, Glorant LLC, Ahmedabad, India** **Aug 2020 – Dec 2023**

**Sr. Quality Analyst/ Data Manager**

**Roles and Responsibilities:**

- Execute Testing in Oracle Apex systems, test Strategy, test Summary Reports, bug reports and traceability matrices.
- Draft quality assurance policies, procedures and review of the documents to Interpret and implement quality assurance standards
- Develop and implement quality assurance problem reporting processes and systems to evaluate, test and validate software and/or IT services
- Manage subordinate staff in the day-to-day performance of their jobs and to analyze deficiencies in service or performance and recommends product or service improvements to address problems
- Document internal audits and other quality assurance activities to investigate customer complaints and non-conformance issues
- Analyze data to identify areas for improvement in the quality system and act as a system/software tester for Oracle custom development such as Clinical Trial Management System(CTMS), Electronic Data Capture (EDC) Software, Interactive Web Response System (IWRS), Remote Source Data Verification (rSDV), Electronic Trial Master File (eTMF), Clinical Trial Supply Management (CTSM), Electronic Patient Reported Outcome (ePRO), eDOCS Custom Software Solutions, Database and Application Support.
- Operating the test case in system to identify and resolve any issues/deviations in the system and to Coordinate with system developer to resolve issues/deviations.
- Act as Independent QA reviewer of the Validation document when not involved in the software testing activity
- Conducting Manual Testing, prepared test plan, test Strategy, test Summary Reports, bug reports and traceability matrices.
- Identifying and analyzing defects due to in-consistencies in software program functions, outputs, online screens, and content. Also, performed documentation of defects, tracking and communication of bugs identified.

**Environment:** Oracle Apex Custom Applications.

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**Veeda Clinical Research, Ahmedabad, India** **Sep 2015 – Oct 2018**

Veeda Clinical Research Private Limited provides medical research services. The Company offers clinical research studies and testing such as bio-availability, equivalence, drug interaction, proof of concept, and therapeutic treatment studies.

**Clinical Research Associate**

**Roles and Responsibilities:**

- Implements and monitors clinical trials to ensure sponsor and investigator obligations are being met and are compliant with applicable local regulatory requirements and ICH-GCP guidelines.

- Assessed the qualification of potential investigative sites, initiates clinical trials at investigative sites, instructs site personnel on the proper conduct of clinical trials, and close clinical trials at investigative sites
- Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely and Provides regular site status information to team members, trial management, and updates trial management tools
- Completes monitoring activity documents as required by Veeda SOPs or other contractual obligations
- Works closely with other clinical team members to facilitate timely resolution of trial and/or clinical issues
- Escalates site and trial related issues per Veeda SOPs, until identified issues are resolved or closed.
- Performs essential document site file reconciliation and source document verification and query resolution.
- Assesses IP accountability, dispensation, and compliance at the investigative sites.
- Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines.
- Communicates with investigative sites and updates applicable tracking systems.
- Ensures all required training is completed and documented Serves as observation visit leader to Facilitates audit s and audit resolution
- excellent knowledge of ICH/GCP to manage investigative sites to facilitate trial deliverables to escalate issues appropriately
- Conducts monitoring to confirm subject safety and data integrity and Describes and demonstrates the principals of IP accountability
- Identifies scientific misconduct at the site level and Demonstrates working knowledge of Microsoft Office applications, Clinical Trial Management Systems (CTMS), IVRS/IWRS and Electronic Data Capture (EDC) platform
- Conducts monitoring evaluation visits to Assists team lead in the development of trial tools or documents

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**Advantmed, LLC, Ahmedabad, India** **Dec 2013 – Sep 2015**

Advantmed, LLC is a healthcare information management company that provides healthcare organizations with the solutions they need to elevate their financial and clinical performance.

**Hedis Index Specialist & Medical Coder**

**Roles and Responsibilities:**

- Interpreting & screening medical records and assigning/verifying ICD 9 appropriate diagnostic codes.
- Capability of different turn-around times on various projects.
- Report to respective Supervisor/Manager adequately, appropriately and accurately.
- Think & proceed independently and to work collaboratively towards goals.
- Good knowledge of Anatomy/Physiology/Pathology/Pharmacology/Medical Terminologies and required to maintain strict HIPAA compliance on all projects.
- Conduct targeted reviews of medical documentation for patients identified by health plans, providers or HCPP as needed.
- Utilize provided guidelines to determine if criteria have been met relative to HEDIS, HCPP, MIPS, CMS Quality Reporting (formerly known as GPRO), PQRS and/or other quality of care standards as well as administrative or efficiency measures.
- Document in clinical reporting system and/or medical record any findings of medical record review as directed by Medical Director.
- Communicate findings with providers and other stakeholders and Assist in the education of providers and staff on the use of clinical reporting tools.
- Extract, query, send and/or present data quality reporting for stakeholders.
- Identify areas of improvement and plan corrective actions

- Investigate confidential patient health care data for purposes of determining patient qualification for placement of patients into appropriate care management programs or alerting Population Care Management RNs of health care needs and when appropriate generate necessary patient referrals/follow-up by outreach Fax/E-mail referrals.
- Inform providers, provider staff and patients of potential needed appointments, procedures, or services. Assist with care coordination.
- Work with health plan representatives to assist in updating, correcting and/or remediating quality or efficiency of care measure documentation as directed by management.
- Demonstrates the ability to effectively communicate with patients to facilitate and negotiate optimal care coordination and resolve patient inquiries with minimal supervision.
- Coordinate with Population Health Nurse actively working the case.
- Health plan liaison for quality and administrative data; Utilize health plan data and portals
- Proficient in the access of various health plan applications for the purposes of viewing, modifying, editing, extracting and/or saving clinical and administrative data pursuant to departmental goals.
- Utilize HCPP, HCH, HCMG or other applications (EHR) to validate or compare health plan data.
- Update or modify health plan data pursuant to medical record review upon direction of management.
- Utilize knowledge of insurance and coding to ensure proper health plan reporting by providers.
- Update, Support and verify accuracy of departmental data.
- Demonstrate reliability in accepting and fulfilling various roles. Perform other job-related duties within job scope as requested
- Self-motivated and able to work independently and manage multiple projects simultaneously with a high degree of logical judgment, analytical thinking, patience, attention to detail, and diplomacy
- Analyzes available patient information as necessary in Allscripts, Meditech, Care Evolution, and other available data systems.
- Knowledge of internal and external resources/services which provide assistance to identified population.
- Demonstrates working knowledge of ICD-10 and CPT coding and medical terminology.
- Perform other job-related duties as assigned.
- Mentoring the given candidates and guiding them to improve efficiency.