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| **Vipin Kumar** | | | |
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| **Overview** |  | | |
| * Carries over sixteen years of IT experience out of which ten and half years in Project Management, Argus Suite Products Consulting, User and Administrator Training and Third Level Support across US, Europe and Asia and software validation of VB/ASP/C# NET, ASP-VB, PHP, Oracle, SQL Server and My SQL projects * Extensive experience managing diverse multiple teams in implementing the entire Argus Safety Product Suite which includes different versions of Argus Safety, Argus Safety J, Argus Insight, Argus Perceptive, Argus Dossier, ESM, Data Lock Point (DLP), Argus EoSU, Argus Affiliate (LAM), integrations and third party components * Specializes in Analysis, Planning, Designing Implementation and Validation * Can provide an extensive support for maintenance activities in the development and handling of IT support and solutions * Experience in working with clients in a wide variety of domains like Health Sciences, Pharmaceuticals, B2B, B2C, E-Commerce, Travel and Entertainment. Extensive experience in both manual and automated testing tools like WinRunner, LoadRunner, Test Director, Rational and Open Script tool * Associated with reputed software organizations in his career span including Oracle HSGBU (Health Sciences), Relsys International Inc., Continuum Systems, Ace Star and Raj Info Systems pvt. Ltd. Vipin led the Quality Assurance team for the Health Sciences and Pharmaceutical group within ORACLE India Pvt. Ltd * Extensively worked on ORACLE Argus Safety (English and Japanese ver.) from 4x to 7x branches * Reviewing progress of resources on ongoing enhancement tasks and validation for Argus Safety suite * Researched, Designed and Developed Traceability Matrix, Project Status Report, Fabricated Test Plans and Test Case scenarios for all hardware/software systems in all phases of project lifecycle * Planned, Designed, Re-Engineered and Functionality testing of products to enhance the flexibility and increase the performance * Provided support and guidance to tier one customers and planned the validation of key Oracle Argus Safety modules/requirements and their end to end to functionalities:   + Global Enterprise Management/User Management/Worklist Management   + Multi and Single Tenant Environment Management and Set-up   + English and Japanese Case Form (FAT Case Creation)   + English Periodic Reports (CTPR/IND/NDA/PSUR/DSUR) with DLP   + Japanese Periodic Reports (PSR/CSPSR/SEIYAKUKYO LINE LISTING) with DLP   + End-to-End transmission (Export and Import) of E2B and Expedited Reports in English and Japanese environments   + End-to-End Transmission of Japanese PMDA Paper (Expedited) Reports   + End-to-End Transmission of Aggregate (System) Reports (Case Listing/CDA/CIOMS II Line Listing) with DLP   + End-to-End Workflow States and Rules Designing for Intake Cases   + End-to-End Worklist Screens Management   + Dossier Reports and template and their integration with Periodic reports   + Local Affiliate Module (LAM) and Integration with Global Argus Safety   + Console English and Japanese Module (End-to-End configuration and set-up)   + All Utilities and Dashboards Management   + Audit Log (English and Japanese)   + Interchange/ESM and AG Services Management   + Validation and Training on CFR 21 Part 11 Compliance   + EOSU Module Management   + Argus Database Migration   + Case Intake and PSL Modules Management * Planned validation activities of Oracle Argus Safety English and Japanese Version (4x to 7x)   + Argus Safety English and J Applications (Web, Report and Service) Installation   + Argus Safety English and J Database (New and Upgrade) Schema   + Configuration and Installation of EDI Gateway for English and J modules   + Configuration and Installation of Interchange for English and J modules   + Argus English and Japanese Module Integrations     - English and Japanese MedDRA     - English and Japanese WHO Drug     - Product License Study (PSL) Interface     - Lot Number Interface     - English and J Literature Intake integrations with English and J modules     - Extended E2B Interfaces for English and J-PMDA   + End to End Mapping of Expedited and PMDA Paper Reports for all Categories   + Argus English and J PMDA Expedited Reports Updates in 4x to 7x versions   + Argus English and J PMDA Periodic Reports Updates in 4x to 7x versions   + Argus English and J Interchange Module Updates in 4x to 7x versions   + Argus English and J MedDRA Re-Coding   + Argus English and J Case Form Updates in 4x to 7x versions   + Troubleshoot and provided support on all the Argus set-up and Integration issues * Extensive Knowledge of Argus Application Integration with 3rd party components like:   + LDAP, Documentum, Cyclone, RightFax   + Argus Insight and it’s integration with Argus Safety   + Argus Perceptive and it’s integration with Argus Safety * Platform Regression on English/J Periodic and Expedited reports on Argus Safety patches and Hot fixes that covers the high level of regression on Argus Safety * Performed the security validation on 6x and 7x Argus safety (English and Japanese) branches by using OPEN SCRIPT TOOL * Extensive knowledge in both Manual and Automated testing of Web-Based/Client Server and Midrange related application environment using V and V model * Functional/moral support to Team members and Preparation of Test Objectives and Operational and Installation Qualification Scripts * Experience in creating and executing various Load and Stress testing scenarios for performance and scalability testing * Done Audit preparation and Reviews * Training of Argus product and FDA/EMA/MHRA/PMDA guidelines to the entire team and creating test scripts for the requirements assigned * Define quality standards and processes for the project and performing resource and task allocation and conducted performance reviews of resources and publishing status reports to senior management * Conducting daily/weekly review of ongoing maintenance tasks and reviewing progress on ongoing enhancement tasks and done analysis and root cause and created Issue Verification Logs (IVL’s) for Customer Support (CS/Internal) issues * Audit log verification of all Argus Safety/LAM/Console modules * Created QA environment for testing, done installation of new build and up-gradation, installation and configure Argus and DLP database, taken cold backups, restoration, up-gradation and schema validation on Argus and DLP databases * Creating and upgrading database and maintenance of database servers and environment and build deployment * Tested Argus application with new Hot-fixes/Patches for various clients. Reporting and tracking issues and complete bug management along with the development and Product management team * Design and implement (UNIT / WHITE BOX / BLACK BOX / INTEGRATION / SYSTEM / DATABASE / REGRESSION / BRICK / SMOKE) testing by using (TOAD 10.0/SQL Developer) for Software Regression, Beta deployment and Alpha products * Reporting issue and tracking them individually * Knowledge about ISO 9001-2000, CMM, Six Sigma, FMEA, QC-Tools * Expertise in developing Long term and mutually beneficial relationships with clients, resulting in good will and faith and thus more business for the company | | | |
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| **Technical Proficiencies** | | | |
| ***Applications:*** | | *Oracle Argus Safety, Argus Safety J, Argus Insight, Argus Perceptive, Argus Dossier, Argus LAM, Synchrony Axway (Cyclone), Third party tools (LDAP and Documentum), DLP (Data Lock point), Oracle Argus EOSU, Argus Safety Service, MedDRA Recoding, Reconciliation, AERS, DS Navigator, Copy Config Utility, English and Japanese Reporting, NRG PRIMO, Arisg (English and Japanese)* | |
| ***Languages:*** | | *PLSQL, SQL, Unix Shell Scripting, VB, C# dot net, Oracle Database/SQL* | |
| ***DBMS:*** | | *Oracle 8i,9i,10g ,11g, SQL Server 2000, MS Access* | |
| ***Operating Systems:*** | | *Unix, Linux, MS DOS, MS Win (7, 8, 9x, 2x, XP, ME)* | |
| ***Tools:*** | | *Toad, Data Stage , SQLPLUS, VSS , Putty , Telnet , SSH , Microsoft Project Plan, Word, Excel, Access, PowerPoint* | |
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| **Professional Experience** | | | |
| ***Consulting Manager-PV, HighPoint Solutions, LLC.*** | | | ***Mar-2016 – Present*** |
| *Lead Business/Technical Analyst, Nektar*   * Led the business configuration, E2B migration and data migration tracks * Closely worked with client and technical team as a business SME in planning and finalization of business configurations development of migration mappings * Responsible for the impact assessment and analysis for all the problems and give alternate/accurate solutions * Provided Argus Safety 8.0.1 Admin and End user training to admin, business and super users * Created Argus User and Functional Requirements as per business needs * Created and updated Nektar database field mapping document for complex and simple logic * Created cut-over plan, data migration strategy, CSD, RTM, IQ, PQ, OQ, E2B import/validation, Data Migration verification/validation scripts, Argus Safety and Interchange Validation Plan and other project related documents * Handled client’s questions and problems, and always keeping the client updated with timely and frequent information about progress towards resolving the issues * Provided support on Argus Safety hosting, configurations and reporting issues * Provided support to PM and management team to track project status and meet deadlines * Attended CRP meetings and provided guidance on Argus safety configurations, Case Form Processing, Expedited and Periodic reporting, workflow design and gap analysis * Provided guidance on various Argus safety integrations and on database mapping * Provided support on configuration and validation of Argus safety configurations and data migration as per requirements * E2B configuration and end to end E2B transmission * Customize placeholders in Letters and Narrative templates   Highlights:   * Argus Safety and Interchange Implementation * Argus Safety Configurations and Change Control Management * Argus Safety E2B Migration and Validation * Argus Safety Field Mapping and Data Migration and Validation * Argus Safety Admin and End user training * Project Documentation   *Project Manager, P&G support*   * Managed project and closely worked with client in finalization of Business Requirements, Configurations, Validation and leading a team of two members * Coordinated with P&G business team and responsible for the impact assessment and analysis for all the problems and give alternate/accurate solutions * Handled client’s questions and problems, and always keeping the client updated with timely and frequent information about progress towards resolving the issues * Provided support on Argus Safety hosting, configurations and reporting issues * Provided clarity with 100% resolution to clients with clear and crisp communication * Understood client’s business requirements and changes and provide support with 100% accuracy and resolution to clients * Provided support on client’s questions and problems, and always keeping the client updated with timely and frequent information about progress towards resolving the issues * Provided solutions by implemented a procedure that ensures the problem does not occur again, or recommends products or services to better meet client's needs * Assigned tickets within team and supported client to resolve priority issues   *Project Manager, Telerx support*   * Closely worked with Telerx 22 clients and provided support to their technical team on day to day activities * Managed Argus Safety verticals and closely worked with client in finalization of Business Requirements, Configuration, Validation and lead a team of five members * Focused on client’s business requirement and changes and provided support and suggested best practices * Provided core solutions by implemented a procedure that ensures the problem does not occur again, or recommends products or services to better meet client's needs * Understand the range of client’s reaction to the challenges associated with particular special circumstances and communicate accordingly * Responsible for the impact assessment and analysis for all the problems and give alternate/accurate solutions * Handled client’s questions and problems, and always keeping the client updated with timely and frequent information about progress towards resolving the issues * Provided support on Argus Safety hosting, configurations and reporting issues * Provided clarity with 100% resolution to clients with clear and crisp communication * Assigned tickets within team and supported them resolved priority one issues of tier one customers and provided support to different business process teams * Coordinated and provided support to different business process teams * Provided support to Telerx quality and operation teams to build a change control documentation process   Highlights:   * Argus Safety and Interchange Cloud Installation * Argus Safety E2B Plus Development * Argus Safety Configurations and Change Control Management * Argus Safety E2B transmission Break-fix Issues | | | |
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| ***Sr. Principal Consultant, November Research Group*** | | | ***Mar 2012 – Feb 2016*** |
| *Project Manager, Parexel support*   * Managed the project and closely worked with client in finalization of Business Requirements, Configuration, Validation and leading a team of six members * Provided support on client’s questions and problems, and always keeping the client updated with timely and frequent information about progress towards resolving the issues * Understood client’s business requirements and changes and provide support with 100% accuracy and resolution to clients * Provided solutions by implemented a procedure that ensures the problem does not occur again, or recommends products or services to better meet client's needs * Assigned tickets within team and supported them resolved priority one issues of tier one customers * Coordinated with Parexel business and documentation team and provided support | | | |
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| *Lead Business Analyst, Shire*   * Managed the project and closely worked with client and team of data migration technical team as a business SME to create migration code which can be reused for migration of multiple clients * Understood client’s business requirements and changes and provided support * Reviewed the Arisg database guide as reference document for field mapping * Updated SHIRE database field mapping document for complex and simple logic * Attended Shire client and internal meetings on database field mapping * Created strategy on PLS extract and coordinated with SHIRE configuration team * Attended Shire Viropharma Database Mapping Workshop and Meetings * Provided support to team to update SHIRE database business logic field mapping document | | | |
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| *Subject Matter Expert/Product Specialist, Shire Japan*   * Closely worked with client in finalization Configuration, Validation * Provided guidance on configurations on Shire Japanese OQ’s and PQ’s dry run * Provided guidance on scheduling and generating the PMDA paper and periodic reports * Troubleshoot and provided guidance on PMDA paper and Periodic reporting issues * Provided guidance on Japanese case form data entry issues * Provided guidance on Japanese PMDA reports logic * Provided guidance to create E2B export and import scenarios for OQ dry run * Provided guidance on E2B import issues * Provided guidance to create the scenarios for E2B end to end transmission OQ’s | | | |
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| *Lead Business Analyst, Exelixis: Primo and Argus Safety Integration (Design, Implementation, Configuration and Validation)*   * Provided guidance on Primo and Argus safety integration and database mapping * Provided guidance on Primo to Argus safety integration by using E2B XML’s * Provided guidance on Argus safety workflow swim lane design * Attended CRP meetings and provided guidance on Argus safety configuration and workflow design * Attended the workflow design review and Argus integration meetings and provided feedback * Attended Argus safety migration sales meetings with management * Performed and executed the high level smoke test scenarios and provided feedback * Drafting of PQ’s as per workflow design * Performed high level dry run and formal execution of PQ’s on development and validation environments | | | |
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| *Lead Business Analyst, Prosar*   * Led the business configuration and data migration track * Closely worked with client and technical team as a business SME in planning and finalization of business configurations development of migration mappings which will be used for migrating 50 plus clients * Attended CRP meetings and provided guidance on Argus safety configuration, workflow design and gap analysis * Provided guidance on Siebel to Argus safety integration and on database mapping * Provided support on configuration and validation of Argus safety configuration as per requirements * Multiple enterprises configuration as per requirements * Workflow on multiple enterprises as per design * E2B end to end transmission on multiple enterprises * Customize placeholders in Letters and Narrative on multiple enterprise | | | |
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| *Subject Matter Expert/Product Specialist, Mylan and Mylan-J*   * Closely worked with client and technical team as a business SME in planning and finalization of business configurations * Provided guidance on Mylan E2B literature and PDF attachment import issues * Performed end to end E2B transmission for Literature cases * Troubleshoot the E2B XML issues and made corrections in E2B’s * Provided resolution on E2b transmission for Denmark (Mylan Validation) * Provided support to Mylan team on J issues-E2B J WHO drug issue by using'J Reportable Product Keyword' * Provided support to Mylan team on post go live issues and attended Mylan status meetings and presented the live issue scenarios in Mylan J environment (Cover Japan Issue Log) | | | |
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| *Subject Matter Expert, PharmaMar/Merck/Syntract*   * Closely worked with client and technical team as a business SME in planning and finalization of business requirements * Understood client’s business requirements and changes and provided support and accurate/alternate solutions * Provided guidance and troubleshoot issues on end to end E2B transmission * Provided guidance and troubleshoot issues on Bulk E2B import issues * Provided guidance and support to team on PharmaMar set-up and configurations * Set-up end-to-end transmission for E2B reports for FDA and EMA | | | |
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| *Subject Matter Expert, BMS*   * Closely worked with client and technical team as a business SME and performed Argus safety and database installation and upgraded the system from AS 42 SP1 HF3 to AS 5.0.4.1.7 * Provided guidance to database team on Argus Audit Trail POC * Provided guidance on analyzing Argus import data issues * Performed database upgrade and schema validation (lily) after import and reported all the findings * Performed all the configurations under AG Box which is required for Audit Log Export * Performed the validation of Argus Audit log process under NRG environment * Performed Argus safety database backup | | | |
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| *Subject Matter Expert, Deloitte/Daiichi Sankyo*   * Closely worked with technical team as a business SME * Provided guidance on ARIS J to ARGUS J database migration and mapping * Provided guidance on ARIS to Argus database migration and mapping * Provided guidance on Argus English and Japanese application functionality * Provided guidance on creation of IQ’s for Argus Safety installation * Participated in all the client meetings * Provided guidance and oversight on verification and validation activities * Provided support and guidance and troubleshoot/helped the IT team members on Argus Safety J installation and pre-requisites configuration | | | |
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| *Lead Subject Matter Expert, DSA*   * Closely worked with technical team as a business SME and provided support on Argus Safety and Insight 7.0.1 environment setup and configuration on DSA * Prepared IQ’s for Argus Safety and Insight Web Server/Database/COGNOS/OAM policies installation and configuration * Successfully performed high level smoke testing and validated the integration between Argus Safety and Argus Insight * Provided Admin and super user training of entire Argus Safety and Argus Insight 7.0.1 | | | |
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| *Lead Subject Matter Expert, CTI*   * Closely worked with technical team as a business SME and provided support on Argus Safety and Insight 7.0.1 environment setup and configuration on DSA * Provided guidance and oversight on validation activities * Successfully executed the IQ’s and PQ’s script on CTI environment * Participated in all the client meetings * Troubleshoot/Helped/Educate team members on E2B-Interchange end to end transmission issues and configuration * Provided Admin and super user training of entire Argus Safety and Argus Insight 7.0.1 | | | |
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| *Lead Subject Matter Expert, UBC*   * Provided guidance and oversight to team members on all validation activities * Prepared presentation and given training of Argus Safety 6.0.3 to UBC * Successfully executed the IQ’s and PQ’s script on UBC environment * Participated in all the client meetings * Troubleshoot/Helped/Educate team members on Argus Safety AG Service and E2B configuration issues * Executed the E2B processing of 10000 xml’s by using batch report generation * Provided guidance on E2B batch report generation issues * Provided support after analyzing the ESM error logs on performance degradation issues | | | |
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| *OHSUG*   * Prepared presentation and given training on following:   + Impact of the New EU Pharmacovigilance Legislation   + Lessons Learned after Going Live with Argus 7.0 Multi-tenancy   + Implemented and integrated Dossier module with periodic reports on Argus Safety 7.0.1 environment and given in-house training | | | |
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| *DSJ*   * Performed requirement gathering for the Japanese Reporting Frequency * Japanese PMDA reports discussion and translation of Japanese add-on reports * Supported and educate the Japanese team members on J PMDA reports templates | | | |
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| *Santen*   * Provided guidance and oversight to team members on all validation activities * Supported and guidance to team members on Argus Safety implementation activities | | | |
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| *NRG Internal*   * Prepared NRG Induction and Training Plan for new joiners * Prepared presentation and given in-house training on following: * Entire Argus Safety 6x to 7x suites and their differences * E2B Interchange transmission * Argus Safety configuration of all modules * Japanese PMDA reports and their logic with end to end transmission * Bench Plan for NRG Resources * NRG Succession Planning Objectives and Key Elements * NRG Argus Safety Training Topics * NRG Oracle Certification Topics * NRG In-house Training Topics | | | |
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| ***Sr. Lead Quality Assurance Analyst, ORACLE India Pvt. Ltd.*** | | | ***Feb 2010 – Mar 2012*** |
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| ***Sr. Quality Assurance Analyst, RELSYS International Inc.*** | | | ***Jul 2006 – Jan 2010*** |
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| ***Sr. Software Engineer (QA), Continuum Systems Pvt. Ltd.*** | | | ***Oct 2005 – May 2006*** |
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| **Education** | | | |
| Master of Business Administration (MBA) Finance  Master of Computer Application (MCA)  Post-Graduation in Computer Applicationin Information Technology(PGDCA-IT) | | | |
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| **Certifications** | | | |
| SDLC Certification, 21 CFR Part 11 Training | | | |