

Director of Quality Director of Quality Director of Quality - Common Sensing Inc Houston, TX Over 12 years of experience in Information technology skilled in the area of database management, database administration, backups, performance tuning in development, testing and implementation. Experience in Microsoft SQL Server Database Administration, SQL Server development, Oracle Database, Oracle Development, Netezza Administration, Redshift AWS Cloud, Data Warehousing, Data Modelling on Production, test and development environments. Managing large databases sizes ranging from 30GB to 64terabyte. Managing multiple MS SQL Server 2014, 2012, 2008R2 databases and instances in a Clustered environment. Involved in the migration of SQL Server 2000 databases to 2005, 2008R2 and 2012 environments Experience in Central Management servers in SQL Server. Expertise also includes Oracle Installation, creating Oracle 12c,11g, 10g, 9i databases, upgrades, migrations, patches and creation of over a terabyte size production databases, backup and recovery and performance tuning. Creating PL/SQL blocks, procedures, functions and packages Effective in managing multiple projects simultaneously, troubleshooting and finding solutions to the most challenging technical problems and meeting the deadlines. Results driven professional with a keen understanding of business priorities, and the ability to architect and deliver quality strategies in support of business operations, compliance and controls to achieve competitive advantage and scalability. Leader of cross-functional teams responsible for the implementation of complex multi-phase projects; proven track record of managing interdependencies, developing contingencies and delivering projects on-time on-budget. Natural team player with unwavering integrity, exceptional interpersonal skills and the ability to lead large and diverse teams to achieve positive change in organizations. Expertise in managing relationships with internal and external stakeholders. Authorized to work in the US for any employer Work Experience Director of Quality Common Sensing Inc - Cambridge, MA October 2017 to Present Responsbilites: Provides leadership and support in establishing and directing the Quality, Risk & Compliance Programs consistent with the delivery system directives Creates and distributes analytical results that monitor trends, drive continuous learning and improvement and influence future decisions. Created plan for Business Continuity & Data Integrity CAPA, NCMR, Supplier

Management Develops and maintains policies and procedures that support the corporate initiatives that meet state, federal and legal requirements and standards Collaborates with physicians and scientists to execute the implementation of the clinical quality data initiatives

Manages vendor and contractual negotiation and qualification Managed project for ISO 13485:2016 certification, CE Marking, MDD/MDR & GDPR Quality Director Cambridge Biomedical Inc - Cambridge, MA September 2015 to October 2017 Responsibilities: Collaborated with physicians and scientists to execute the implementation of the clinical quality data initiatives Provides expertise to the training department on all standard and regulatory measures and tools that support collection of and communication about GLP/GCP/GMP Implementation of a full enterprise risk management system CAPA, Deviations, Supplier Management Facilitated, integrated and/or coordinated the implementation and evaluation of identified quality improvement activities as requested by CBI or related entities Promoted understanding, communication and coordination of all quality improvement program components Participated in requested evaluations, customer and regulatory audits Participated in IT security analysis Led Systems Validations Developed operating budget as necessary Participated in various teams, committees and meetings at any level required to maintain business necessity Maintained Quality program documents, reports, and committee minutes and followed all internal privacy and confidentiality policies and procedures Maintained current knowledge of regulatory requirements associated with the Quality program.

Led accreditation efforts HIPAA Compliance Officer Quality & Systems Validation Manager Danaher Corp/Kavo Kerr Group - Wilmington, MA August 2013 to September 2015 Responsibilities: Introduced project management methodologies to improve planning, prioritization and execution; implement new systems, technologies and processes to monitor, audit and strengthen compliance department Created and distributed analytical reports that monitor trends, drive continuous learning and influence future decisions Presented to management, stakeholders and senior leaders with updates on projects, deliverables and other operational matters CAPA, Risk Management, NCMR, Supplier Management Led regulatory and corporate compliance projects involving software and hardware systems from design through validation Developed quality and

test procedures for product development; managed the design control process for product enhancements

Worked within R&D to ensure compliance with quality and regulatory requirements for DBS, FDA, EN/ISO

Attracted, hired and trained a team of professionals; focused on accountability, development and talent retention

Quality Manager & Senior Applications Analyst
Partners Healthcare, GeneInsight - Cambridge, MA July 2011 to August 2013

Responsibilities:

- Spearheaded a comprehensive quality assessment and led strategic planning sessions to support future improvements
- Designed and developed quality training; worked with leadership to implement a communication plan and delivered training
- Collaborated with audit teams to identify Corrective and Preventative Actions (CAPAs) and track controls after implementation
- Synthesized and analyzed audit results to recommend improvements in compliance and business operations
- Developed, documented and implemented a quality plan to bring quality systems and policies into compliance with 21 CFR, Part 820 and Part II governance for Class I medical device; ensured compliance with national and international standards and legislation, including ISO, IEC, MDD and FDA regulations
- Organized and managed quality assurance function; identified relevant employee skills to support process improvement model

Senior Quality Engineering Consultant Philips North America - Andover, MA June 2009 to July 2011

Responsibilities:

- Supported Critical Care, R&D and Patient Support business units by improving quality procedures and performing quality audits for Class II and III medical devices.
- Responsible for enhancing audit processes, supporting internal audit of software standards (e.g. ISO, IEEE, CMMI and FDA quality system regulations) and evaluating the impact on internal procedures, safety and efficacy of products
- Developed a risk remediation process supporting the research and development of a MRX Defibrillator project; ensured project compliance and developed process control documentation and procedures aligned to project requirements
- Provided hands-on validation and led pre-verification phase for MRX Defibrillator, Transcutaneous Pacer Analyzer, NBP Simulator, 12-Lead ECG Simulator, SP02 Simulator; partnered with senior managers to develop a compliance plan to perform an audit of risk mitigation supporting verification and regression testing

Quality Systems Manager Joslin Diabetes Center, Harvard Medical - Boston, MA May 2007 to June 2009

Responsibilities:

- Participated in

planning sessions with the goal of providing expertise and visibility around quality and compliance issues

Managed the team responsible for compliance systems, helpline, incident database, reporting and auditing systems; partnered on cross-functional teams in the operation, development and enhancement of those systems

Implemented a full quality system for JVN in compliance with FDA cGMP CFR21 for Medical Device manufacturers; interfaced with Physicians at Joslin Diabetes Center, Beetham Eye Clinic and Bursell Laboratories to support Class II medical device

Assumed responsibilities of the On-Site internal auditor, reporting into and interfacing with Joslin/Harvard Compliance Officers; developed and documented an in-house internal audit system Database Administrator

Lifetime Entertainment Services - New York, NY April 2006 to May 2007

Responsibilities: Creation of over 40 Oracle 11g, 10g, 9i databases on Linux, HP-UX, improved the creation of Oracle and UNIX shell scripts to refresh databases from production to test environments. Setup cron jobs to monitor alerts, down production system, refreshing databases, database statistics, running scripts to check the performance of the databases, running trace on the Oracle databases as requested by the application owners, monitor size of the tablespaces, extents and tables.

Experience with Oracle 11g database environment on Production, Test and development databases.

Installing Oracle 10g, 9i Client, database patches, and network configurations and worked with database security.

Worked with database security, running audit scripts against system tables, audit against users, setting up passwords, creating security views, applying critical patch security updates, running trace, scheduling jobs related to audit scripts to run against the databases, schedule jobs to trace failed logins related to Oracle and SQL Server databases and also perform other audit related tasks as requested by the auditors related to Sarbanes Oxley compliance (SOX).

Working off hours, weekends to perform troubleshooting relating to the database errors and requests received through email for Oracle and SQL Server 2005 databases.

Involved in the creation of PL/SQL procedures, functions and packages and scheduling them to run as needed.

Creation of over 50 SQL Server 2008, 2005 production and test databases, migration of SQL Server 2000 databases to 2005 for Production and Test servers. Setting up Maintenance Plans, scheduling jobs to refresh databases from one server to another, shrinking log files,

performance tuning, setup Linked server, using SQL*Profiler for trace events.etc. Involved in the creation of Procedures and functions using T-SQL. Worked with Crystal Reports XI using Oracle and SQL server databases for creation and designing of the reports related to earnings for Freelance workers for the payroll and finance department, also created Status reports using the Heat Ticketing System used by the IT helpdesk. Involved in the database upgrade of SharePoint 2003 to 2007 for our intranet site using SQL Server 2005 environment. Worked and involved in the installation of SQL Server 2005 with Active/Passive and Active/Active Production Clustering environment. Worked with database security and audit related tasks related to Sarbanes Oxley compliance. Improving the performance of the Oracle databases through creation of materialized views. Initially involved in creating SQL Queries in Oracle and SQL Server databases for the Human Resource project to match the queries between the two environments as a part of the project. Worked with the RAC environment for the site Lifetime Movie Network. Worked on the database part for the Sets, SharePoint, Lawson, Lifetime Move Network, Media Asset Management "MAM", Rights Logic, ScheduAll, Heat, Gabriel Form, EDocs, PeopleSoft Reporting, Enterprise Information System "EIS", SCR Budgeting, Gabriel, Scribe applications. Environment: Oracle 11g, 10g (release 2), Linux, HP-UX, Windows 2003, Oracle Streams, ERWIN, SQL Server, 2008/2005 in a clustering environment, UNIX shell scripting, RAC, Data guard, RMAN, Backups & Performance Tuning. Using pentaho software for ETL, Toad, SQL Navigator, and SSIS. Database Administrator Astoria Federal Savings Bank - New York, NY March 2005 to April 2006 Responsibilities: Initially involved in applying the patches and upgraded the Oracle version from 8.1.7.0 to 8.1.7.4.0 on Test and Production databases, applied other security Patches for Listener Passwords, database Links and also applying other security patches on Oracle 9.2.0.6 environment on production and test environments. Perform the Oracle Market Manager update process for Marketing every month end using PL/SQL Scripts. Improved the PL/SQL scripts, which involved strong expertise of PL/SQL. Improved the performance of the databases and troubleshooting the errors related to the memory parameters and providing solutions to increase the memory parameters for better performance. Collaborate with the programming Staff in the preparation and verification of data for developed

database applications. Manage database development environments. Responsible for the database administration and development related responsibilities including data loads using SQL * Loader, export and import utilities, SQL Scripts, procedure and function development, performance tuning and backup and Recovery operations. Providing solutions to the LAN department for any requests received related to SQL Server databases in a cluster environment. Creation of the Database Maintenance Plans for the SQL Server databases. Heavily involved in the creation of SQL Server databases in a Cluster environment, performing backup and restore operations, setup auditing for SQL Server 2000, Creating DTS operations and security operations. Involved in the upgrade of the ADP application for Human Resources from Oracle to SQL Server 2000. Involved in the creation of instances in a cluster environment, creation of databases, conversion of views from Oracle to SQL Server 2000 and scheduling the Maintenance plans for the ADP Testing and Production environments. Perform Disaster Recovery accountabilities as required. Consult and advise the users using various databases and LAN administrators on administrative client/server policies and procedures and methods. Assist in the procurement, distribution or transformation of data for specialized applications (Internet/Intranet links to database systems). Environment:-Oracle 10g, 9i, Oracle 8.1.7.4, Oracle Market Manager 4.0, SQL Server 2000 in a Education MBA Edinburgh Business School, Heriot-Watt University Technical & Scientific Communication Northeastern University

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