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**Proven leader known for successfully creating and implementing quality and technology solutions for both small and big pharma and Life Sciences, consistently recognized for excellent project management, communication, leadership, mentoring, customer service and cross-functional team building.**

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| Major Accomplishments: | Created and launched the LS Quality and Regulatory University which includes over 150 training modules. Utilizing virtual networks and training methodologies the University is robust enough to accommodate future business expansion and acquisitions, well in excess of the current 40,000 employees worldwide.  Led the merger of two multi-billion-dollar Global Quality organizations at Sector and site level, optimizing best practices and personnel from each company. Manage cross-discipline teams of professionals and accountable for the performance and results of the teams.  A proven fixer, expert at synthesis and finding new patterns of problem definition and recognition to solve complex business issues in new ways to exceed expected synergies and drive return in investment.  Strong leader and mentor who excels at empowerment and development of employees and future leaders proven by consistent, year over year performance of top 15% in employee engagement company wide. |
| **Experience:** | MilliporeSigma Burlington, MA 2016 - present **Head of Quality Management Systems and Audits**  Responsible for global Quality and Compliance functions supporting the life science business sector of Merck KGaA, including direct and indirect oversight of Quality Management within Distribution, Commercial Subsidiaries, Business Units and other non-manufacturing functions. Provide leadership and guidance to both internal and external customers, partnering with business and system owners to ensure operational excellence and competitive advantage. Develop and lead continuous quality improvement initiatives utilizing proven statistical and scientific methodologies and performance metrics.   * Create and maintain a highly skilled, high trust Quality team aligned with business partners and capable of achieving current quality, cost and revenue initiatives and future projected initiatives.. * Responsible for the performance/results of the Quality Management System (QMS) throughout Merck Life Science. * Provide leadership and direction for successful, ongoing execution of QMS implementation. * Responsible for the life science validation strategy and architecture including validation of processes, equipment and software. * Direct quality and regulatory training and development activities within Merck Life Science, including the business and supporting functions. * Define and lead the life science audit program, responsible for audits of all manufacturing and distribution sites, commercial subsidiaries and supporting activities. * Responsible for quality compliance within the life science distribution network, ensure major distribution centers are in compliance with Good Distribution Practices. * Responsible for the Sector ISO 9001 certification as well as ensuring compliance to Merck, LS, regulatory and industry standards across LS though internal audits of all locations and functional areas.   Results:   * Harmonized the QMS across the Sector, including the harmonization of over 50 procedures and processes. Created the implementation plan and tracked progress across all manufacturing, distribution and subsidiaries, * Harmonized the LS validation manual and related procedures. Successfully validated the sector ERP system. Developed the QMS for Robotic Process Automation and the organization to support the development and lifecycle management of digital products. * Created a collaborative and interactive audit program that not only includes the audit function but also subject matter expertise in areas such as Animal Welfare and Food Defense. * Developed and deployed a comprehensive, fit to purpose QMS for distribution, introduced a heat map analysis for compliance strength to determine resource allocation. * Created the Project Management Office to consolidate strategic compliance and improvement projects, improving collaboration with the sector and engagement and best practice sharing within Merck. * Successfully led the certification of Merck life science to ISO 9001:2015 including development of the training program for management, auditors, and site personnel including compliance checks and corrective actions. |
|  | EMD Millipore Billerica, MA 2010 - 2016**Global Director of Quality, Biologics**  Responsible for global Quality and Compliance functions supporting Biologics sites, Corporate policies and initiatives. Provide consultation to internal and external customers, working across functions to ensure on-time delivery and customer satisfaction Led multiple quality improvement initiatives to bring site into compliance with pertinent regulations and corporate expectations.  Quality- Biologics:   * Ensure robust quality systems are present that permit on-going assessment, data analysis, consistency and continuous improvement. * Maintain and achieve quality standards appropriate for current / future business requirements. * Define and create new customer quality requirements and develop plans to meet accordingly. * Optimize performance across globe, managing core competency requirements and leveraging key resources. * Drive business and process improvements through the use of SPC and quality metrics tuned for the Biologics business.   Results:   * Aligned the Global Quality organization at each site with the Business, current and future requirements through the evaluation of staff core competencies, reorganization, reassignment and rationalization. * Initiated a 3-year Global Quality Improvement Plan for the Biologics area and all sites to reduce risk to product quality, ensure adherence to appropriate quality standards, focus and prioritize initiatives with business partners and appropriately resource for success. All plans completed to targets. * Oversaw the transfer of over 200 products while rationalizing the operation footprint for the organization. * Implementing site specific quality metrics to accurately measure the quality of the products and processes resulting in a 50% decrease in critical customer complaints to date. * Created and Developed SLAs between sites and the Business partners realizing 20% reduction in lead time. * Created a Global Biologics Quality Council to proactively address quality and compliance issues, assess business, customer and product impact and escalate to senior management. Provided first forum for cross function and site collaboration and dispute resolution. * Quality- Corporate: * Led multinational integration activities encompassing systems, procedures and organization. * Collaborate with Quality and Regulatory personnel to improve corporate procedures, performance and compliance metrics using applicable tools (Six Sigma, Lean, SPC). * In collaboration with Merck representatives identify and implement Best Practices for Risk Management based upon current corporate practice and international standards. * Member of the BioScience Leadership Team to determine strategy and future markets. * Lead Global Standards Quality initiative and support key initiatives though team participation and resources. * Serve as liaison between the company and various regulatory bodies; FDA, ISO, EMEA.   Results:   * Successfully integrated the Quality organization, led efforts for integrations of systems and procedures. On target with 2011 programs, 2012 programs initiated. * Created a Global Risk Assessment tool for all divisional sites to uniformly gather data and conduct impact analysis. Identified the 5 main areas for improvement and implemented plans to mitigate by end of 2011. * Implemented best practices for all sites for adaptation in 2011, streamlined CAPA and other QMS applications, decreasing overdue items by 15% while increasing capacity by 20% based on system metrics. * Developing a site Quality Program to proactively drive quality-related actions and implement leading metrics. Targeting a proactive ratio of 10:1. * Results generated in 2010-2011 led to increased scope of responsibilities from assignment on 3 new technology initiatives, divisional leadership teams and additional global oversight of 2 service locations.  AMAG Pharmaceuticals Cambridge, MA 2008 - 2010**Senior Director, Quality Control**  Responsible for overall Quality Control and Compliance functions supporting pharmaceutical products’ manufacturing and release, including second source providers and materials for clinical trials. Manage the QC supply chain both internal and external to support manufacturing and key corporate initiatives. Determine testing and sampling programs to ensure all material meets applicable safety, efficacy and quality standards.   * Quality Control- Internal Supply Chain Management: * Prepared long term and short term Quality Control plans and goals.  Ensure QC remains compliant with cGXP, quality and regulatory requirements, compendia standards and applicable ISO/ANSI standards. * Redefined the QC organization to address the continuing maturation of the department. Leverage resources and technical capabilities to complete all QC deliverables on time. * Improved QC performance by implementation of new SOPs and modernization of QC programs. * Determined and tracked QC internal capacity to meet supply chain demand. Continually strive to maximize efficiencies, improve processes, develop innovative scheduling and solutions to expand current capacity. * Served as QC lead on cross-functional initiatives such as regulatory inspections, Quality Council, clinical development, validation projects, change control, material and specification review boards. * Authored all applicable sections of Regulatory Submissions, Supplements, and Clinical Trial Applications.   Results:   * Reorganized the QC department to fully utilize the capabilities of current personnel while adding new functionality to address the maturation of the department and corporation. * Designed a comprehensive remediation plan to bring the QC Department into compliance with cGMPs and industry standard practice completing all critical / major tasks within 6 months. * Developed and implemented over 30 new SOPs creating essential QC systems and controls while leading all technical efforts to optimize and improve over 40 critical QC methods. * Created and chaired the Specification Review Board, a cross-functional team that oversees lifecycle management of specifications for all materials, achieving 50% reduction in time to completion. * Successfully mitigated inspectional deficiencies at the manufacturing facility resulting in the approval of the company’s first therapeutic drug product in under 9 months. * Major author for first NDA Supplement resulting in a CBE-0 clearing product for commercialization. * Quality Control- External Supply Chain Management: * Responsible for all QC technical transfer to second source locations including CMOs and CTOs domestic and abroad. Author all documentation and establish all transfer criteria. * Managed all QC communication between AMAG and partners, conduct technology update and review meetings; conduct audits, select second source suppliers, resolution management and CAPA.   Results:   * Created the test method transfer program and oversaw revision and implementation of a new test method validation program to align AMAG and partner initiatives and decreased transfer time by 1 month. * Successfully transferred over 30 drug substance and drug product test methods to second source CMO / CTO creating 100% redundancy in testing capabilities. * Led validation remediation efforts between multiple organizations resulting in enhanced test method functionality, robustness and compliance. Improved First Pass Quality by 50%.  Vertex Pharmaceuticals Cambridge, MA 2007 - 2008**Associate Director, Commercial Quality Control** Responsible for all systems to support Technical Support activities for Commercial QC, collaborating within and across departments and teams and delivering quality products within timeline and budget.   * Quality Systems: designed, implemented and maintained systems to: * Generate, change and terminate specifications and test methods. Generate and optimize test method revalidation and transfer protocols and reports. * Handle product technical complaints in regards to QC testing and data analysis.  3M St. Paul, MN 2000 - 2007**Program Manager / Technical Team Leader / QA Manager**  Led all areas of the technology partnership program, responsible for corporate and division deliverables, all technical aspects of the program and the relationship with the partner.   * Developed Project Plan to meet all corporate product introduction requirements. * Assessed market conditions/attractiveness, business case justification, and manufacturing capacity/viability. * Handled all communication between the development teams, conduct regular technology review meetings. * Responsible for technology evaluation, technology viability, protection and final technology decisions. * Conducted experimental design, directed personnel, and determined final technology configuration. * Validated all components, systems and processes from initial sample acquisition to final result. * Directed project deliverables and schedule to meet internal and joint management goals. * Developed the Drug Quality Program for the Medical Division:   Results:   * Led over 10 programs thought FDA submission, published over 20 Microbial Test Methods, 50 validation protocols and 50 reports. * Performed a risk analysis and evaluated the current EM practices; decreased the EM testing based upon this data to save over $100,000 annually. * Created an innovated media fill procedure for transdermal based products. * Created the global harmonization plan for all microbial testing of all materials and products. * Successfully reviewed submissions and participated in audits with FDA, EU Regulatory bodies and partners. * Drug Quality Program established and operational in 1 year; successfully audited by the FDA.  Other experience available upon request. |
| **Education:** | **University of Minnesota**  Doctorate of Philosophy (Ph.D.) in Analytical Chemistry 1996  **University of Wisconsin-La Crosse**  Bachelor of Science in Chemistry (ASC) 1986  Minor: Microbiology  **Smith College**  Executive Education for Women  Leading the Business of BioPharma 2011  Smith – Tuck Global Leaders Program for Women 2012  **Boston University**  Certificate in Leadership |