**SUMMARY**

High-performing Senior Business leader with a strong background in successful strategic planning, process improvement and program development. Proven ability to deliver products and projects with a customer focus, working as internal and external consultant. Excels at seeing the big picture, identifying gaps and managing initiatives. Plays an integral role within an organization by providing collaboration, motivation and direction across teams in diverse and high-growth environments. Manager and team leader in highly matrixed organization, leading global teams ranging in size from 10 to 150 members.

**AREAS OF EXPERTISE**

|  |  |  |  |
| --- | --- | --- | --- |
| * Strategic Planning and Leadership | * Customer Relationship Management | * Decision Analytics | * Cost Benefit Analysis |
| * Organizational Impact Assessment | * Change Management | * Stakeholder Management | * Risk Analysis |
| * Productivity and Efficiency Improvement | * Technology Enablement | * Metrics Definition and Performance Measurement | * Project Planning and Execution |
|  |  |  |  |

**PROFESSIONAL EXPERIENCE**

**SHIRE PHARMACEUTICALS, Lexington, MA 2015 –Present**

**Consultant – R&D Quality**

Consultant to Head of R&D Quality Operations and Head of QMS Standards, Training & Risk Management focusing on:

* Institutionalization of the Quality Management System
* Harmonization of SOPs and Policy Documents
* Strategies for optimization of procedures in an environment of continued growth through acquisition.

**VERTEX PHARMACEUTICALS,** Boston, MA **2013 –2015**

**Director – Clinical Development Execution**

Provided oversight of clinical compliance within the Clinical Development area. Managed staff of more than 30 employees and contractors for compliance support, Trial Master File operations, and overall training and procedure development.

* Drove inspection readiness activities for GCP compliance and risk-based evaluation.
* Identified areas of deficiency in or potential risk to clinical trials and the company – providing detailed analysis and collaborating with functional areas to implement correct and preventative actions and general process improvement in compliance with global regulatory requirements. This included the successful implementation of system and processes to identify events and oversee through to resolution and remediation.
* Coordinated and provided oversight and compliance guidance, addressing CAPAs and process improvements resulting from audit and inspection findings. Co-chaired the quality leadership governance process and provided reports including compliance metrics and updates on progress and risk evaluations.
* Instituted a process to respond effectively to the demands and changes in the regulatory environment, advising operational management and staff on the impact of changes and determining the adequacy of ongoing programs.
* Developed and managed the standards, processes and tools to ensure the quality, completeness and inspection readiness of the Vertex Trial Master File. Engaged “SWAT” team to provide quality control evaluation of all files in preparation for inspections and successfully applied learnings to revise processes for quality product moving forward.

**Consultant – Clinical Development Execution**

* Developed and delivered a Clinical Quality by Design framework for integration as part of the Quality and Risk Management Systems.
* Consulted in the development and managed the documentation of processes supporting the implementation of systems supporting the Sunshine Act and other regulatory authority transparency reporting requirements.

**ELI LILLY AND COMPANY,** Indianapolis, IN **2012 –2013**

**Consultant – Clinical Development**

Consultant to Lilly’s Clinical Data Flow Modernization Program.

* Facilitated cohesion of the business processes, standards and technologies used through the clinical data flow program, with change management considerations to instantiate Lilly’s implementation of the CDISC standards.
* Developed customized value chain methodology, providing quality checkpoints aligned with the instantiation activities to measure progress and successful implementation of standards and business processes.

**TRIDENT UNIVERSITY,** Cypress, CA **2011 – Present**

**Assistant Professor – MBA Program**

Taught on-line courses for MBA program including Strategic Management, Organizational Behavior, and Entrepreneurship. Guided students through the MBA Capstone course as the culmination of their MBA programs.

**BERLING AND ASSOCIATES,** New London, CT **2006 – 2012**

**Financial Consultant**

Developed and implemented strategies for financial success for small businesses and individual clients, resulting in a 30% increase in the number of clients to the firm. Introduced office processes that enabled staff to absorb transaction activity generated by 50% increase in business.

**PFIZER INC.,** New London, CT **1993 – 2006**

**Director – Clinical Operations Strategy**

Internal Consultant to the R&D organization, focused on the execution and delivery of strategic initiatives that improved operational aspects of clinical trials. Managed up to 10 employees and led teams of as many as 150 cross-functional members.

* Developed and successfully deployed strategies that enabled large scale process change resulting from two large scale merger/acquisitions.
* Delivered and deployed policies and improved processes for operational execution including data specifications and reporting tools for clinical trials; filings to National Institutes of Health registry; process improvement methodology, metrics and governance systems; and data archive from company merger/acquisitions.
* Established a business model that enabled the Pharmaceutical Sciences organization to transition from a research to a business operations paradigm to deliver the clinical supplies for a growing research portfolio. Developed and delivered high level capacity model that was used consistently for budgeting, forecasting spend, operational planning and long term capacity projections.
* Developed and instituted use of a governance model for the control of a portfolio of IT initiatives to address strategic business initiatives. Resulted in successful alignment and continued governance of business planning and financial processes to connect the performance improvement initiatives of the business area to the information technology infrastructure.
* Delivered several reengineered processes and systems in accordance with SDLC and validation requirements. These included systems to support bulk inventory and raw materials acquisition.

**ADDITIONAL RELEVANT EXPERIENCE**

Marketing Consultant/Product Manager, Ship Analytics, North Stonington, CT

Assistant Professor – Computer Science, Rensselaer Polytechnic Institute, Hartford, CT

Operations Research Analyst/Computer Scientist, US Naval Underwater Systems Center, New London, CT

**EDUCATION AND PROFESSIONAL DEVELOPMENT**

MBA, Rensselaer Polytechnic Institute, Hartford, CT

Ph.D., Applied Mathematical Sciences, University of Rhode Island, Kingston, RI

MS, Operations Research, University of New Haven, New Haven, CT

BA, Psychology, College of Mount St. Vincent, Bronx, NY

Trident University, Graduate Certificate in Quality Management with Six Sigma Black Belt, Cypress, CA