Life Science Project Leader

stevenavinson@gmail.com
(317) 709-0360
8240 Walnut Way
Indianapolis, Indiana 46256

EXPERIENCE PROFILE

- 24+ Years of Life Science Project Leadership
- Large Project and Program Management
- Strategic and Tactical Executive Consulting
- Clinical Laboratory: Automation, Information Systems, Workflow Optimization
- Computer Systems and Automation Validation (GxP, GAMP, FDA, CAP)
- Information Systems Project Management (including ITIL implementation)
- Chemical Processing Systems Project and Process Engineering
- Drug Substance and Drug Product Supply Chain Development and Optimization
- cGMP Compliance and Quality Systems Improvement
- Equipment, Facility, Utility Qualification

CLIENTS AND PROJECTS

Confidential Contract Research Organization (CRO) Central Laboratory Services – Indianapolis, IN
(June 2009 through Present as Vinson Corporation LLC)

Project Manager for $15 million Laboratory Information System Replacement

- Transformative project to modernize laboratory data system
- On time within budget completion of major workflow changes
- COTS configuration, validation, and implementation along with custom interfaces using Cache, HL7, .Net, and middleware tools

Project Manager for $4.5 million Laboratory Automation project

- Develop short term tactics and long term strategies to address growth-related business and process needs
- Workflow design, system selection, vendor management, and overall project responsibility
- Scalable solution to accommodate rapid workload growth
- Reduction in labor per test
- Medical Technicians able to work on difficult results interpretations

Zimmer Orthopedic Surgical Products – Dover, OH

(October 2008 through June 2009 with Project Leadership Group, Inc.)

Project Manager - Quality Improvement Program

- Details are confidential; program included major improvements to quality systems related to FDA compliance and medical device market introduction
- Daily interaction with Vice President of Quality, Vice President of Operations, and other Senior Managers and Directors
- Established Project Management Office (PMO) for manufacturing site.

Boston Scientific – Spencer, IN

(November 2007 through September 2008 with Project Leadership Group, Inc.)

Program Manager - FDA Audit Readiness Program

- Managed all aspects of project to ensure client was ready for FDA re-inspection following previous findings
- FDA re-inspection was successful

Project Manager - Project Management Office Launch Project

- Established PMO for medical device manufacturer
- Project Portfolio organized, prioritized, and successfully executing

Manager - Project Management Office

Clarian Health Partners – Indianapolis, IN

(September 2005 through August 2007 with Praxis Management International)

Project Manager - Information Systems Consolidated Service Desk Project

- Project Manager for $1.5 million project to replace outsourced service desk workflow and systems
- Implemented ITIL aligned work management system

Project Manager - Infection Control Workflow Analysis

- Performed intense high level analysis of work and data flow within the infection control areas of three major hospitals.
- Developed recommendation for systems upgrades based on the analysis.

Praxis Life Sciences – Indianapolis, IN

(September 2005 through July 2008)

Project Management Consultant and Instructor

- Project Management Essentials
- Project Risk Management

Quality Systems Practice Leader

- Computer System Validation Boot Camp®
- Risk-based Computer System Validation
- ABC's of Computer System Validation
- Validation for the Project Manager

Abbott Laboratories – North Chicago, IL

(2003 to 2005 with Project Leadership Group, Inc.)

Global Pharmaceutical Operations – Laboratory Instrument Program (December 2003 through September 2005)

- Project Leader for this phased program to address FDA audit observations.
- Scope included several divisions and sites in North America and Puerto Rico.
- First Phase was one year and >800 instruments.
- Second Phase was 18 months and >1500 instruments.

Diagnostics Division – Quality System Sustained (March 2004 to June 2004)

- Created project plans and coached project managers using critical chain method.
- Program to address quality improvement mandates resulting from successful consent decree reinspection.

Hospital Products Division – Automated Process Control and Human Machine Interface Revalidation Program (January 2003 to December 2003)

- Managed the Program Office for this one-year, $5M program, which covered 12 sites in North America and Central America.

Pharmacia/Pfizer – Portage, MI

(2001 through 2003 with PharmTech, Inc.)

Commissioning, Qualification, and Validation Manager

- Managed validation engineering for Active Pharmaceutical Ingredients (API) manufacturing site.
- Developed budgets and timelines, assigned and managed resources to ensure completion of IQ/OQ/PQ for API manufacturing equipment, facilities, and utilities.
- Provided consulting to assist with continuous improvement of client's quality systems, validation approach, and workflow.

Pharmacia – Skokie, IL

(2000 to 2001 with Integrated Project Management Company, Inc.)

Managed a variety of product development and business process initiatives.

- Accomplishments included: developing and executing project strategy that resulted in a favorable FDA pre-approval inspection for a high priority drug project; ensuring successful manufacture of Phase II clinical supplies for an in-licensed drug project; and identifying opportunities to more effectively apply resources that resulted in more efficient development of therapeutic antibody technology.
- Developed and implemented new reporting process to allow senior management to monitor success and make decisions regarding projects.
- Managed team of five project managers working to increase efficiency and decrease time to market for biopharmaceuticals.

Stepan Company – Joliet, IL and Maywood, NJ

(1999 to 2000 with Integrated Project Management Company, Inc.)

Managed and performed process engineering for over $3 million in capital projects.

- Completed projects on schedule and under budget. Projects included installation of new raw material feed and measuring systems for manufacturing of bulk chemicals.
- Completed conceptual design, generated P&ID's, specified major equipment, directed detailed design, managed construction, wrote and executed pre-startup safety review protocols, provided operator training for commissioning, and completed financial closeout.

G.D. Searle – Skokie, IL and Barcelonetta, PR

(1998 to 1999 with Integrated Project Management Company, Inc.)

- Developed recovery plan for faltering construction project to convert Barcelonetta, Puerto Rico Plant for production of four Searle products.
- Conceived, designed, managed construction, and performed validation for installation of improvements to the pharmaceutical water system
- Directed design and wrote qualification protocols for installation of a fluid bed dryer
- Designed, managed construction, and performed validation for installation of new gas chromatographs for research laboratories

Ecolab, Inc. – Joliet, IL

(1995 to 1998 as employee)

Maintenance manager of powders and solids packaging

- Supervised 7 mechanics
- Implemented process improvements to increase efficiency and reliability
- Managed hundreds of thousands of dollars in capital projects.

Production manager, chemical manufacturing

- Managed production of over 50 million pounds per year of organic and inorganic chemicals
- Managed 7 reactor operators and over $300,000 in capital projects.
- Managed installation of a new 4,000 gallon glass-lined reactor. Performed all process-related design and procurement, directed structural engineering, managed construction, wrote and executed startup protocols.

Eli Lilly and Co., Inc. – Lafayette, IN

(1991 to 1995 as employee)

Project/Process Engineer – Fermented Products

- Managed and performed process engineering for a $3 million project to implement new fermentation and isolation process.
- Responsible for all aspects of the project, including design, equipment specification, budget development, schedule and budget management, contract management, construction, validation, and start-up.

Process Engineer – Bulk Pharmaceutical Manufacturing

- Performed process engineering for several bulk pharmaceutical intermediate manufacturing departments.
- Responsible for writing and executing Operational Qualification protocols for all projects in the supported departments.

EDUCATION AND PROFESSIONAL DEVELOPMENT

Rose-Hulman Institute of Technology, Terre Haute, IN

- Bachelor of Science, Chemical Engineering, May 1991

Project Management Institute (PMI) Pharmaceutical Specific Interest Group (SIG)

- Board of Directors; Director – Marketing and Public Relations
- Chairman of the Project Management for Biopharmaceuticals Conference and Pharmaceutical SIG Annual Meeting (April 2006)
- Presenter at the Project Management for Biopharmaceuticals and Medical Devices Conference and Pharmaceutical SIG Annual Meeting (April 2007)
- Instructor for Project Management in Drug Development – Phase III and Commercialization

Project Management Institute (PMI) Central Indiana Chapter (CIC)

- Life Science Project Management Group of Central Indiana (LSPM) - Founder and past President
- Certified Project Management Professional (PMP)

Other Speaking and Instruction

- 2006 Professional Development Day – The Age of Leadership: The Next Mega-Trend in Project Management
- 2007 Professional Development Day – Einstein's Compass: Navigating the Age of Disillusionment
- SupplyNet at University of Indianapolis - 2006: Supply Chain Success Stories "Global Launch of a New Drug with a Complex Supply Chain: Thanks to Effective Project Management"
- SupplyNet at University of Indianapolis - 2006: Presentation and panel discussion covering the contribution of Project Management to the success of a supply chain project. (May 2006)
- Center for Business Intelligence Project Management for Discovery and Development - Project Management Accountability (September 2005)