

BRUCE FIEGGEN

973.628.4597 (hm) · 973. 768.3831 (cell) · Bruce@RoundTablePM.com
41 Coventry Road · Wayne, NJ 07470

SUMMARY OF QUALIFICATIONS

Project and Program Management Expert with extensive experience initiating and maintaining project management systems in the Life Sciences industries. Sets up Project Management Offices. Trains and mentors project managers to increase project efficiency and accelerate product time-to-market.

PROFESSIONAL EXPERIENCE

Cadence Management, Global Headquarters: The Netherlands 2001 - Present

Managing Director, United States Business Unit.

- Customize Project Management courses for clients that incorporate Agile, Predictive and Change Management.
- Trained thousands of individuals with an average satisfaction level of 4.8 out of 5.
- Coordinate with global content providers and seminar leaders from four continents to ensure the Cadence methodology remains leading edge in today's changing world.
- Facilitate Project prioritization sessions with senior staff to ensure efficient use of company resources

Round Table Project Management, Wayne, NJ 2013 - Present

Principal Trainer and Consultant.

- Improve the Project Management maturity of organizations by setting up Project Management Offices, prioritizing and resourcing projects, developing project management guidebooks and training executive staff, decreasing time to market.
- Train clients in project management, managing project management, presentation and personality skills, improving their success in delivering projects.
- Developed Project/Program Management guidebooks for multiple clients to codify effective management.
- Generate content for PMP boot camp using multiple cutting-edge techniques to maintain student's interest while teaching online and via web.
- Teach for PMP and CAPM certification using a four-day boot camp that guarantees student passing the PMI administered test.

Q Pharma Corporation, Morristown, NJ 2007 - 2016

Vice President of Project Management and Training.

- Successfully completed a global packaging project, harmonizing the way packaging design, development material selection, stability and verification is done across the entire company.
- Coordinated multiple project scoping sessions within large Unique Device Identifier (UDI) program to achieve funding for program
- Created recruiting arm of Q Pharma, developed systems to streamline recruiting process, resulting in a steady stream of excellent employees.
- Facilitated the transition from Project to Program Management of a new steel mill.
- Formalized Project Management Office, prioritizing projects and focusing resources on top projects to ensure on-time delivery.
- Trained thousands of project managers, team members, their managers and executives in the Cadence™ project management methodology, decreasing time to market.

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CSSC Inc., Morristown, NJ

2001 - 2006

Director of Project Management.

- Built Project Office, instituting methodologies, standards, metrics and policies and ensure adherence to procedures; achieving recognition for CSSC as a company that embraces project management.
- Developed formal ProgressixSM project management curriculum to improve project efficiencies. Train project managers and validation managers using this 25-week course.
- Program manager for major pharmaceutical client, overseeing nine project managers and twenty projects and bringing the client into FDA compliance from a warning letter.
- Facilitated over 200 project kick-off/planning sessions, gaining clients' support through their understanding of the complexities of each project and their roles within the projects.

Boston Scientific/Meditech, Wayne, NJ

1997 - 2001

Manager, Project Management

Set up and maintained Project Management systems that increased project efficiency; trained and mentored project managers.

- Customized two-day project management training course with outside vendor to address BSC-specific issues and meet Project Management Body of Knowledge standards.
- Developed, sold and achieved company approval of comprehensive project plans for \$100M per year next generation aortic graft and endograft teams designed to increase market share.
- Led three teams designed to maintain \$80M/year market share, maintaining contracts between teams and senior staff. Resolved Mad-cow disease issue with collagen-sealed grafts.
- Facilitated project prioritization sessions with company vice-presidents, ensuring every important project was fully resourced. Reduced active project list from 175 to 25.
- Wrote definitive, 80-page manual on using project management to efficiently design and market safe and effective medical devices. Included risk management and reimbursement.

Datascope Corporation, Fairfield, NJ

1996 - 1997

Senior Project Manager

Managed projects to improve core products with expected revenues above \$100M per year.

- Wrote 120-page design control manual to help design medical devices in compliance with ISO and FDA regulations.
- Mentored five project managers in effective project management and ISO documentation, improving teamwork and reducing confusion.
- Led project team developing new membrane for intra-aortic balloon that reduced number one customer complaint ten-fold.

Boston Scientific/Northwest, Redmond, WA

1994 - 1996

Project Manager

Managed projects to improve guide-wire lubrication.

- Managed project team that designed a lubricant for intra-coronary atherectomy device.
- Developed a coronary artery compatible lubricant that reduced guide-wire wear 80-fold.
- Led team that validated current guide wire lubricant per ISO standards, resolving FDA 483 item and permitting continued sales of \$80M per year of product.

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Quinton Instruments, Seattle, WA

1993 - 1994

Quality Engineer

Facilitated dialysis catheter product development projects by providing quality engineering perspective.
Audited R&D functions.

- Developed knowledge of federal and international regulations surrounding design control.
- Designed \$100K biocompatibility testing program for all the medical use raw materials to comply with 1995 ISO requirements.

Abbott Research, Inc. (Formerly International Biomedics, Inc.), Bothell, WA

1986 - 1993

R&D Engineer, Manufacturing Engineer, and then Senior R&D Engineer

Completed development of fiber-optic blood gas sensor. Managed two technicians.

- Invented, optimized and patented an algorithm that removed inaccuracies caused by fiber-optic kinking, eliminating 90% of clinical failures.
- Led clinical response project team that resolved problems surfacing during animal and clinical trials.
- Hired, trained and supervised eight technicians in a variety of technical duties, requiring seven day workweeks, to meet tight testing deadlines.
- Built microscopic, three-parameter, intra-arterial probe and transferred technology to manufacturing, maintaining feedback loop for future improvements.
- Resolved critical issue and reduced development time by eight weeks by applying key carpentry knowledge to fiber-optic connectors.

EDUCATION

B.A. Biochemistry, University of Oregon, Eugene, OR

Certification: Project Management Professional, 1999

Scrum Study: Scrum Master, Product Owner and Scaled Scrum Master Certified

PROFESSIONAL AFFILIATIONS

Member of Project Management Institute since 1999

Member of PMI's Product Development and Pharmaceutical Special Interest Groups since 1999

Member of Mensa since 2003

PATENTS

Configuration fiber-optic blood gas sensor bundle and method of making	US 5,047,627
Method for hydrating and calibrating a sterilizable fiber-optic catheter	US 5,328,848
A method and apparatus for detecting and compensating for a kink in an optical fiber	US 5,565,976
Medical emulsion lubricant	European 01920707.5-2114-US0109405
Medical emulsion lubricant and delivery of drugs	US 6,054,421
Medical emulsion lubricant and delivery of drugs	US 6,281,175
Medical emulsion lubricant and delivery of drugs	US 6,391,832
Anatomically curved Aortic Arch graft	European 02790033.1-2310-US0238865
	US 6,770,090

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PUBLICATIONS

- “Planning a Computer Systems Validation Project” Contract Pharma:
April/May 2002
“Assumptions improve project and product quality” Quality
Assurance Journal: June 2003
“A Practical Method to Track % Complete using Earned Value Analysis” PMI
Pharma/SIG Newsletter Mar 2005

COMPANIES ASSISTED

- Abbott Labs
- Abdulla Fouad
- Acuitive
- Acuity Systems
- Allergan
- Alkermes
- Alvogen
- Affymax
- Astellas
- Aventis-Dermik
- Baltimore Aircoil
- Bank Hapaolin
- Bausch & Lomb
- Bayer
- Blue Origin
- Boston Scientific
- Boston University
- Carpenter Technologies
- Charter Medical
- Crane Aerospace
- Coherent
- Corning
- Cricut
- Cymer
- Datascope
- Daimler
- Detroit Diesel
- Discount Tire
- Duraflex
- Forest Laboratories
- Fresenius Medical
- GC America
- Google
- Hardware Resources
- Hoffman-La Roche
- integrated Pharma
Technologies
- i-Robot
- IVAX pharmaceuticals
- JSR Micro
- Junior Achievement
Europe
- Kos Pharmaceuticals
- KV Pharmaceuticals
- LifeCell Corporation
- Lydall
- MannKind
- Merck
- Merial
- Meridian Medical
- Meso-Scale Diagnostics
- Millennium
- Moses Lake Industries
- Nebraska Public Power
District
- Nike
- Nipro-Diagnostics
- Net App
- Novartis
- Noven
- Nutravail
- Otsuka
- PEP Marketing
- Pharmagistics
- PPG
- Quinton Instruments
- Respirationics
- Sanofi-Aventis
- Saudi Aramco
- Schering-Plough
- Sepracor
- Sigma Design
- Silgan Dispensing
- Special Olympics
- Starbucks
- Stel-kast
- Stryker Orthopaedics
- Teleflex Medical
- Terumo
- Triple-i
- Uber
- Varian Medical
- Velcro
- Wyeth-Ayerst

PRESENTATIONS

- Planning a CAPA Validation Project, *Medical Design and Manufacturing Conference West*: Feb. 2003
Develop Strategies for Overcoming Lack of Supporting Documentation for Compliance of Legacy Systems,
Validating Legacy Systems. Barnett International: March 2003
Systems Validation to Ensure Compliant Sample Accountability, *Center for Business Intelligence*: May 2003
Computer Systems Validation. A growing and Profitable industry, *NJ PMI Symposium*: May 2004
Systems Validation to Ensure Compliant Sample Accountability, *Center for Business Intelligence*: May 2005
Techniques for Managing Vendor Projects to Budget, *Institute for Validation Technology*: February 2006
Effectively Planning and Executing a Comp. Syst.Validation, *Regulatory Affairs Professional Society*: June 2006
Project Management Techniques (Webcast), *Regulatory Affairs Professional Society*: April 2007
Project Planning and Reporting (On-Line Course), *Regulatory Affairs Professional Society*: May 2007
Earned Value, *Project Management Institute Pharmaceutical Specific Interest Group*: April 2008

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Linking Budgets and Resources with Project Timelines, *International Pharmaceutical Academy*: June 2008

Medical Device Risk Management, *Quality and Productivity Solutions*: September 2008

Risk Management in King Arthur's Time, *American Society for Quality. Tappan Zee Chapter*: Feb & Mar 2012

North Jersey Section: Feb & Mar 2013. *Project Management Institute. New Jersey Chapter*: May 2014