

US: 42 Lake Ave Ext PMB 261
Danbury, CT 06811
+1 (203) 702-4912

WW: <http://www.lilgerry.com>
lilgerry@alum.mit.edu

Gerry Fitzgerald

I conceive, design, and implement award winning systems to support Manufacturing, Quality, Procurement & Supply Chain, and R&D business processes. I have directed projects from the technical and business process roles as well as from a joint business & IT role. Over one three year period, the systems I implemented contributed to a 22% (\$1.8bn) reduction in costs for indirect goods and services. In typical projects, I apply Lean Six Sigma principles and match an appropriate IT architecture (ITIL) to create a new business process supported by KPIs and SLAs where appropriate. I have been the project leader for an enterprise-wide ERP project, building the system as the Bills of Materials were prepared for the company's first product launch. I implemented a Global Messaging System for internal, contract, and toll manufacturing that communicated forecasts, orders, and shipments of all company SKUs globally throughout the supply chain, eliminating over 99% of stock outs, producing \$15m pa in net income. I am a Certified Information Systems Auditor and have integrated the business and regulatory requirements of each of these systems. I have 3 years' experience as an internal IT auditor, and seven years' experience developing cGMP and cGLP systems for Pharmaceutical quality laboratories, R&D, pilot plant, and manufacturing. I hold an MBA from McGill in International Business and a MS in Biochemical Engineering from MIT.

Professional Experience

[Ab Initio](#), Lexington, MA (2011-present)

Field Engineer

I operate as a data scientist, business & data analyst, and project manager ensuring that users of Ab Initio software succeed. I have done major projects with Heath Insurers, Pharmacy Benefits Managers, Retailers, and Telecommunications companies.

[MannKind Corporation](#), Danbury, CT (2008-2011)

Director, Technical Operations Systems & ERP

As the Director for IT in Technical Operations (Manufacturing, Quality, Supply Chain, Device Development, Facilities) for MannKind Corporation, I implemented systems to support the commercialization of Afrezza®, a novel inhaled, rapid acting insulin. I was responsible for the strategy and architecture of more than half the IT systems in the company.

Selected Accomplishments:

- Developed and standardized business and IT processes for procurement, receiving, accounts payable, item and bill of material management, costing, and forecasting.
- Led the implementation of ERP (MS Dynamics GP as an interim to SAP) for the company, covering not only the new commercial processes, but also R&D and clinical processes
- Validated ERP for cGMP and Sarbanes-Oxley compliance
- Implemented a standard, validated workflow engine for incident and change management & investigations of deviations
- Standardized laboratory data collection and metadata search for quality and development laboratories, and implemented a single backup, archive and business continuity solution across the research, development, and manufacturing areas

[GlaxoSmithKline](#), Philadelphia, PA (2001-2008)

Director, Global Procurement IT

GlaxoSmithKline is a global pharmaceutical company, with 107,000 employees in over 90 countries and \$40b in sales. Headquartered in London, it is a leader in the important area of vaccines and is developing

new treatments for cancer. Led a global team of 17 (reduced from 42 at the time of the merger by outsourcing). Defined strategy, architecture, and planning for Procurement systems. Negotiated with vendors, outsourcers, and offshore service providers. Managed risks associated with procurement systems, including FDA & EMEA regulatory and Sarbox audits.

- Built SpendTrak, using Six Sigma statistical techniques first identifying and selecting the best spending targets for changes that improved negotiations with vendors, producing a net reduction in cost of 22% over 3 years for non-inventory goods and services.
- Defined single eProcurement process across all GSK business units, and multiple ERP systems and standardized and outsourced vendor catalogs, resulting in savings of \$25m pa from preferred vendor switches, \$28m pa in processing and headcount reductions and increased quality.
- [Defined process](#) and set up IT support for an [outsourced reverse auction pilot](#) with a projected savings of \$270K from the first 3 auctions. Later switched outsourcing arrangements, resulting in annual cost reduction from \$3m to \$0.3m and increased the number of auctions from 100 to 1000 pa.
- Adapted standard eProcurement business process to SAP SRM for use in manufacturing saving \$17m pa on \$500m in indirect expenses globally.
- Switched Procurement staff from transactional duties to strategic sourcing, implementing a Procurement Card for small purchases, and eliminating 100K paper invoices per year.
- Created system to set and track standard costs for creative services for advertising and Public Relations with first year savings of \$2.1m from reductions in overbilling and second year realized \$3m reduction in creative costs from analysis of standardized costs.
- Integrated diversity spending measures and targets into eProcurement system, automating the identification of items and commodities where diversity vendors had the best deals relative to other preferred suppliers, increasing diversity vendor usage by 20%, without impacting overall costs.

SmithKline Beecham, London, UK 1998-2001

Director, Global Messaging System.

Designed and built a message-based integration for SB's global supply chain, covering over 200 marketing units, 88 owned factories and over 60 toll and contract manufacturers. Provided cGMP validation for the system and its infrastructure. Established and maintained ITIL procedures for the service, including a registry of standard message types.

- Turned around a failed EDI solution, leading the implementation of an MQ Series and XML based [Global Messaging Services for Enterprise \(GMSe\)](#), delivering the new messaging system on time and on budget, the system operated at 1/3rd of the EDI system costs using internal networks and encrypted Internet links.
- Expanded the GMSe system to external vendors, toll manufacturers and contract manufacturers, all targeted suppliers and partners online in the first year. Their accurate forecasts reduced their overall costs, cost reductions were recovered to SB in later negotiations.
- Adopted Check-IT, which was, during the implementation, re-branded as ITIL, which aligned with the CoBIT audit framework. Documentation for the project earned high commendations during cGMP audits. Overall productivity was higher, as was job satisfaction, as staff were able to flex their job roles by following the documented procedures.
- Established use of external standards, reducing the cost of developing messaging interfaces, and received buy-in from partners to develop their interfaces when the target was an open, published standard and not proprietary.

SmithKline Beecham, Philadelphia, PA 1995-1998

Assistant Director, Global Internal Audit

Led Audits of compliance for Shared Services Governance (IT, Finance, HR, Procurement). Liased with Regional management to assess risks and schedule audits. Consulted on Risk Management issues, including data protection and privacy. Presented audit reports to senior management, and provided remediation. Wrote company standards where needed on controls. Represented the company to outside standards boards on audit and control issues.

- Adapted shared services guidelines developed for European countries to Latin America, eliminated duplication of 3-5 operating units into a single shared service per market. All shared

services operations met their financial and operational goals at 6 months, and established two regional data centers, significantly reducing operating costs.

- Created awareness of control principles and best practices, allowing Shared Service operations to determine their own control gaps, making them better prepared for audits, and better focusing audits on areas of concern.
- Designed and implemented the system and data control processes for an OTC AIDS test (ORASURE). Product launched on schedule. No data loss or IT issues during the launch.

SmithKline & French Laboratories, Upper Merion, PA 1988-1995

Assistant Director, Laboratory Automation

Defined and delivered systems to support R&D. Managed 10 staff, half in US, half in UK. Developed standards for lab applications. Managed budgets for system maintenance and support as well as project budgets. Prepared cost/benefit cases for new lab systems and assessed impact on existing infrastructure.

- Designed and built a flexible system for connecting laboratory instruments with a serial connection, reducing the cycle time to bring new instruments online from 4 weeks to 3 days and eliminating backlog of requests in 6 months.
- Developed business case, agreed requirements, and delivered a standard chromatography data system which drastically reduced support and integration costs.
- Created a global R&D policy for Computer Systems Validation, reducing the costs of compliance and lowering a major barrier for new system development.
- Redesigned the instrumentation on analytical ultracentrifuges, re-tasking them to measure protein binding constants, reducing the screening time for new HIV protease inhibitors from 6 weeks to 48 hours.
- Consolidated the department computing resources to a central service, standardized service level agreements, and used the cost savings to fund expanded laboratory system support hours.
- Project director for deployment of 200 Lotus Notes servers and over 4000 clients. Created standard "Team Connect" workflow applications for common R&D team activities. The standard team structures easy for people to transition among several teams, and for teams to share information and deliverables.
- Sponsored several Six Sigma green belt process improvement activities, including standardizing data archival, creating a library of common parsing utilities, and areas for scientists to share their statistical and data analysis routines.

Wyeth-Ayerst Laboratories, Chazy, NY 1985-1988

Manager, Pathology/Toxicology IT

Wyeth-Ayerst at this time was part of the American Home Products conglomerate, with business units covering not only prescription and OTC pharmaceuticals, but Brach's candies, Jiffy Pop, and Ecco houseware. Path/Tox was a shared facility, where I was the senior IT person on site, focused on providing safety data to regulatory agencies for new pharmaceutical and OTC products.

- Brought the first VAX into Wyeth-Ayerst, tripling the productivity of the programming staff.
- Completed 3 FDA computer and facility inspections without a comment.
- Interfaced laboratory equipment directly to the computer, increasing lab throughput by 20% and eliminating transcription errors.

Biogen, N.V., Cambridge, MA 1983-1985

Systems Manager

Biogen was at this time a small start up biopharmaceutical company with less than 100 employees. The company was heavily focused on a few research and development efforts, licensing most of its compounds, but developing a clinical trials capability and production capacity.

- Automated pilot plant, allowing investigators to easily set control strategies on any combination of over 20 variables, enabling optimal production processes to be found faster and reducing variation so that fewer expensive runs were needed

- Supported researchers in their use of genetic and protein sequence search software, including instructions, software modifications, and database maintenance, contributing to the company's IP portfolio.
- Prepared the company's first online clinical case report forms, allowing clinical data to be collected every night from every site, enabling close monitoring of beta-interferon clinical trials and improving communication with clinical investigators.

Education

[McGill University](#) Montreal, Quebec

- MBA with concentrations in both International Business & Information Technology

[MIT](#) Cambridge, MA

- Completed 3 degrees in 4 ½ years: MS Biochemical Engineering, BS Chemical Engineering, BS Biology. MS Thesis: [Studies on Immobilized Heparinase and the Heparinase-Heparin Reaction](#)
- Top honors academically and for teaching & charitable activities.

[Villanova University](#) Radnor, PA

- Master Black Belt in Lean Six Sigma. First class to graduate with Healthcare Focus

Certified Information Systems Auditor, CISA #070405. NYC Chapter ISACA active member. Wharton (U Penn) Business Plan Competition, Judge, 2008-present.

Interests

Member of SAP Advisory Board for Sourcing Relationship Management module. Board Member of MIT Alumni Association of Delaware Valley. Volunteer with the Parents Advisory Network of the Bryn Mawr Neonatal Intensive Care Unit, helping parents of very little patients. Active with Pyramid Club of Philadelphia to promote business training and opportunities for underserved areas of Philadelphia.

Publications & Patents

[Gerald L. Fitzgerald](#), "Implementing and Deploying a Groupware Environment Throughout Pharmaceutical R&D," [PharmAnalysis Conference](#), Atlantic City, NJ, June 1995.

[Gerald L. Fitzgerald](#), "Future of Automated Chromatography Systems," [Perkin Elmer Laboratory Systems Symposium](#), Tokyo, Japan, 1993.

[Gerald L. Fitzgerald](#), "The Role of Metrics in Computer Systems Validation," 1992 [Pharmaceutical Manufacturers' Association Analytical Subcommittee Meeting](#), Denver, CO.

[Gerald L. Fitzgerald](#) and [James D. Swanson](#), "Measuring the Effects of Laboratory Automation: the value of empirical models," [J. Auto Chem](#), 14 (1992) 55-57.

[Gerald L. Fitzgerald](#), [William J. Cassano](#), [Karl K. Soneson](#), [Frank L. Tobin](#), and [Preston Hensley](#), "Development of a Data Acquisition and Analysis System for Measuring Protein Binding Constants Through Ultracentrifugation," 1990 [Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy](#).

[Gerald L. Fitzgerald](#) and [James D. Swanson](#), "[Measuring the Effects of Laboratory Automation](#)," 1991 [Federation of Analytical Chemistry and Spectroscopy Societies, Anaheim, CA](#).

[Robert J. Linhardt](#), [Gerald L. Fitzgerald](#), [Charles L. Cooney](#), and [Robert Langer](#), "Mode of Action of Heparin Lyase on Heparin," [Biochemica et Biophysica Acta](#), **702**, (1982) 197-203.

[Arthur C. Grant](#), [Robert J. Linhardt](#), [Gerald L. Fitzgerald](#), [Janice J. Park](#), and [Robert Langer](#), "Metachromatic Activity of Heparin and Heparin Fragments," [Analytical Biochemistry](#), **132**, (1984) 25-32.

[Robert J. Linhardt](#), [Zohar M. Merchant](#), [Kevin G. Rice](#), [Yeong S. Kim](#), [Gerald L. Fitzgerald](#), [Arthur C. Grant](#), and [Robert Langer](#), "Evidence of Random Structural Features in the Heparin Polymer," [Biochemistry](#), **24**, (1985) 7805-7810.

[US Patent #4,396,762](#) Heparinase Derived Anticoagulants

[US Patent #4,341,869](#) Process for Producing Heparinase

[US Patent #4,373,023](#) Process and Composition for Neutralizing Heparin
Lecturer on Laboratory Automation at Medical College of Pennsylvania, 1990
Quoted as expert on MQSeries messaging:
[Computerworld Article on Wireless MQSeries](#) 26 June 2000
[User Friendly MQSeries](#) 15 May 2000