



John Lorence - Project Manager

STATEMENT:

John completed his degree in 1980 with a BS in Mechanical Engineering concentrating on machine design. Over the next five years John was able to experience multiple machine design and controls projects working in Parkersburg, West Virginia. In the mid-eighties John returned to New York State to continue his career with Procter & Gamble Pharmaceuticals. Over the following two decades he honed his projects management skills and developed a holistic approach to design that takes into consideration all aspects of the project from budget and design issues to operators and maintenance staff concerns. John is known for using his background, education and varied experience to find a new high value approach to design challenges while keeping the initial vision out in front of the projects team.

Additional experience in validation protocol writing and execution, final reports, product development reports and a general background in FDA regulatory issues.

John has managed over \$70,000,000 in projects that have ranged from new greenfield construction to prescription product launches. In addition, he is in the process of renovating a 44,000 sq ft building as a space to grow pharmaceutical businesses in his community.

Education:

Clarkson University Bachelors of Science in Mechanical Engineering, 1980

Affiliations:

Society of Manufacturing Engineers

International Society of Pharmaceutical Engineers

Chair - Building Committee: Unadilla Valley Central School

Past Member of the Board of Directors of the Norwich Family YMCA

Past Member and Chairman of the South New Berlin Water Board

Continuing Education

Potent compound handling
Managing by Leading
Design of Experiments I & II
Total Quality - Demming

Patents:

Patent holder for a child resistant user friendly packaging. Patent number 5033634, July 23, 1991

Personal Affiliations:

Board Member Chenago Chargers Soccer Club

Founder of the Southtown Ski Club

Founder Unadilla Valley Central School Educational Foundation

PROJECT EXPERIENCE:

PROJECT DESIGNS & FEASIBILITY STUDIES:

Chenango County West Park Place Office Project Norwich NY

Completed an initial study to determine a new use for the former sheriff's office and jail. The proposal was accepted and converted to a fully renovated office complex. Completed the MEP designs including a sophisticated variable refrigerant flow HVAC system and utilization of an existing generator.

Chemung Canal Trust Company Cayuga Heights, NY

Completed MEP design for a new branch office. The project was fast tracked and included security system designs and communication of the HVAC system to company's main office.

Kaplan Ithaca, NY

Renovated a 10,000 square foot facility as a lease fit out for the testing company. Coordinated Kaplan's needs with the college facility requirements to ensure both parties were satisfied.

PHARMACEUTICAL AND LABORATORY PROJECTS:

OSG Norwich Pharmaceuticals - Norwich, NY

Approximately 2800 square foot clean room laboratory renovation for a pill manufacturing facility. Project involved detailed mechanical, electrical and plumbing calculations and commissioning to meet FDA standards. Contract project manager of a fluid bed dryer and high shear granulator installation for a large contract house on a fast track project scheduled. Completed a study to install a second process train based on the first design with multiple enhancements. Developed process flow sheets and facility layout, hired engineering resources, managed the design construction and start-up of the process. Debug and start-up of a blister packaging line including specification development, equipment rebuild, and validation protocol writing with execution.

Lore Pak Pharmaceuticals - New South Berlin, NY

Purchase, conversion and start-up of a 44,000 square foot former school building now housing PharmAssist Labs with renovations continuing to house Lore Pak Pharmaceuticals, LLC. Developed OTC and medical devices for various customers. Developed and presented course work for a large pharmaceutical manufacturer.

Procter & Gamble - Manati, Puerto Rico

Process debugging of a \$28 million expansion of a solid dose form facility in Manati, Puerto Rico. Processes debugging included USP water, potable water, optimization studies and addition of a contained mill to a dry blend process. For this sub-project developed the strategy to maintain less than 10 micro grams operator exposure during operation while minimizing construction and validation impacts to the existing production train. Had sole responsibility to direct the project team consisting of validation engineers, process safety engineers, operating technicians, contract engineers and vendors. The project was a \$400,000 fast track project, critical to a new product launch.

Procter & Gamble - Norwich, NY

Responsible for the management of projects to renovation and update the High Rise automated storage and retrieval system, potent compound sampling & dispensing system and bar coding RF solution. Had additional responsibilities as capital manager. Maintenance manager of a pharmaceutical plant manufacturing and packaging operation. Responsibilities included maintenance of blenders, presses, encapsulators, coaters etc. as well as all packaging technologies including bottle lines, form fill seal line and liquid filling. Re-vamped the maintenance system from a traditional approach to Total Productive Maintenance. This change targets breakdown elimination and pre-scheduling all maintenance work well in advance of any equipment failures. Also included in my responsibilities was the technical development of eighteen mechanics and electricians. Aligned training, qualification and expectations of the mechanics role with the business need. reconfigured reporting relationships, wrote a new role description and developed a new training/qualification procedure. I gained alignment to this new approach with plant management and union leaders. The result is a role that meets current and future business needs and a process that produces consistently high quality mechanics in all departments at the site.

Procter & Gamble - Norwich, NY

Project Manager for new product facility needed for the production of two of the company's largest ethical drugs. 1994 to 1997, I managed a \$12+ million project from cradle to grave. This project utilized containment technology that was new to the site as well as the company. In addition, the selected approach was our custom design. Initial work consisted of selecting the engineering firm, CM firm and validation firm, as well as writing and gaining approval of the funding instrument. Directly managed all interfaces with the engineering firm, CM, validation firm and vendors. In addition, managed the interface with plant and engineering management including the plant manager and divisional directors. This project included operators and management on the start up team. The result was a project that was completed well ahead of the original schedule and successfully completed the first development batch of product with no major issues the week following IOQ complete. This project included design responsibilities for facilities, product and process technology including P&IDs, layouts, clean in place and equipment selection. This project was completed utilizing a very aggressive scheduling approach shaving 10 months off of the original completion date and with-in the 12+ million-dollar budget. As a result, the company was able to submit the product registration nearly one year in advance of the original schedule.

Procter & Gamble - Norwich, NY

Project manager for a new drug launch system for the operations section of the site including systems development, technical engineering oversight and mechanical engineering assistance for the packaging development section on a special child resistant container. Core assignment was to manage the manufacturing and packaging technology group for the pharmaceutical division engineering. The group I managed and trained consisted of four engineers that ranged in experience from six months to 30 years. Beyond my core assignment, I was requested to help create a road map of the drug development process as it progresses through our division. This effort required WBS and other project management tools. As a result, I was responsible for the management of new products through our Product Supply System. Using the tools, successfully launched our first new product in many years. The results were new and more streamlined launch processes with a team structure, multiple machine and packaging projects were completed with a minimum of engineers and a patent was awarded for the CR container. In parallel to this ongoing business support, managed a \$1.2 million security project on a crunch schedule for the launch a class 5 narcotic product. This project was located at the Puerto Rico site.

Procter & Gamble - Norwich, NY

Project Manager for capital projects servicing multiple sites including Puerto Rico. During this time managed the design, installation and start-up of multiple capital projects that ranged in value from \$150,000 to \$500,000. These projects included asbestos removal, controls upgrades, chemical processes installation of a guaifenesin drug product and machine purchases. Projects were successful and consistently on time and with-in budget.

Corning Incorporated - West Virginia

Equipment Engineer responsible for managing three to six projects annually for a medical glass production facility engaged in the production of raw tubing, beakers, disposable culture tubes and pipettes. During this period of time the plant completed a re-tooling of its production equipment. Responsible for projects that included glass forming upgrades, automation of glass cutting equipment with robotics, integration of disposable culture tube finishing with a packaging line and general equipment re-builds and upgrades. During this time through put was increased by over 10% and over 15 positions were eliminated while scrap was reduced.

