

## **Donald R. Keer, P.E., Esq.** **Consultant**

### **Education**

- BS, Chemical Engineering, University of Pittsburgh, 1982
- MBA, Finance and Operations, University of Pittsburgh, 1985
- JD, Temple University, 1995
- MS, Chemical Engineering, Drexel University, 12 credits toward degree

### **Registrations**

- Licensed Attorney, Pennsylvania
- Licensed Attorney, New Jersey (Inactive)
- Professional Engineer – Delaware

### **Professional Affiliations**

- American Bar Association – Full Member
- Pennsylvania Bar Association – Full Member
- Institute of Management Consultants
- International Society of Pharmaceutical Engineers

### **General Experience**

Mr. Keer has over 20 years of experience in all aspects of the construction process. He is a licensed attorney with a BS in Chemical Engineering and an MBA in Finance and Operations. His experience encompasses the pharmaceutical industry, oil and gas exploration, water treatment, utilities and land development. Specific construction experience includes: land development; engineering design, contract negotiations; arbitration; litigation; claim and change order analysis; commissioning; pharmaceutical validation.

In addition to his construction experience Mr. Keer is a recognized leader and technical expert in water treatment. He is a frequent lecturer and has numerous articles on water treatment technology and project execution.

Mr. Keer is an accomplished business person. He owned and operated a capital equipment and service company. His business experience includes merger analysis and company integration, organizational evaluation, start-up consulting, strategic planning, Sarbanes-Oxley compliance and evaluation of financial reports.

## Project Experience

**University of Connecticut, Storrs, CT.** Construction Management and Process consultant for co-generation water treatment construction, installation and start-up.

**LookFirst, LLC, Doylestown, PA.** Management consulting and legal services for start-up of a web based portal.

**William Bowman and Associates, Berlin, NJ.** Resolution of over \$30 million in surety bond issues for residential and light commercial real estate development.

**ACL Solutions, LLC, Easton, PA.** Evaluation of legal and business issues concerning greenfield construction, land use planning and industrial development projects.

**Altair Equipment Company, Warminster, PA.** Technical and business accounting consulting.

**National Institute of Health, Bethesda, MD.** Project management of installation and service of clean utilities.

**Dealing Direct, Warrington, PA.** Establish start-up structure and documents for web based business.

**Biopolish, Singapore.** Lead technical advisor for ultrapure utilities servicing main Singapore biotechnology research center.

**Sun Oil, Marcus Hook, PA.** Coordinate the conceptual design of mobile water treatment system installed on the site.

**Sun Oil Company, Houston, TX.** Document review and time line analysis of distillation unit claim.

**Johnson & Johnson, New Brunswick, NJ.** Designed and installed a 500 GPD Purified Water System.

**Merck Sharpe & Dohme, West Point, PA.** Design/build and assisted in validation of an extension to an existing water system.

**Wyeth, Pearl River, NY.** Reviewed and prepared a report on the requirements to upgrade and validate an existing water system.

**Anthony Products Company, Arcadia, CA.** Renovated and upgraded a WFI system

which was the subject of FDA objections.

**Lederle Laboratories, Pearl River, NY.** Purified water system design for a pilot plant facility.

**Wyeth-Ayerst Laboratories, Marietta, PA.** Clean utility systems design for Influenza Vaccine Production Facility. Coordinated pipe design and layout for the project.

**Bayer De Mexico, Mexico City, Mexico.** Purified Water System design for tablet and encapsulation facility.

**Sterling, China.** Purified Water System design for an oral dosage facility.

**Warner Lambert, Lititz, PA.** Review of validation documentation and water sample results.

**Lederle Laboratories, Pearl River, NY.** Detailed design of a Purified Water System for a Fermentation Facility.

**B.I. Chemicals, Petersburg, VA.** Design of a USP Purified Water System for a bulk pharmaceutical facility.

**Taylor Pharmacal, Decatur, IL.** Utility capacity review study to determine expansion ability.

**Kemet Electronics Corp., Greenwood, SC.** Economic study of various system upgrade options for electronic water system.

**Fujisawa, USA, Inc., Grand Island, NY.** Design of fully automated point of use heat exchangers.

**Danbury Pharmacal, Carmel, NY.** Performed site waste water analysis and evaluation regarding facility expansion potential.

**Elkin-Sinn Inc., Cherry Hill, NJ.** Evaluation of system requirements. Conceptual design. Currently working with vendor on system design.

**Syntex, Humacao, Puerto Rico.** Purified Water subsystem design and specification. 50 GPM circulation rate, solid dosage facility.

**Pharmaceutical Basics, Inc., Morton Grove, IL.** Troubleshoot existing Purified Water system, recommend upgrades in response to FDA concerns while designing a replace-

ment system, currently working on implementation of the recommendations.

**Upjohn, Inc., Kalamazoo, MI.** Evaluate microbial problems in existing potable water system, established a comprehensive program to implement upgrades. Water system demand is 2000 GPM maximum currently awaiting approval to design a chlorination system to control biofilm and remove iron.

**Radiometer, Inc., Cleveland, Ohio.** Conceptual design and budget for construction of a Purified Water system during a renovation of a new facility for Grade 2 Medical Devices.

**G.D. Searle, Skokie, IL.** Upgrades to Purified Water and Water for Injection system. Upgrades included replacement of the pretreatment system, utilization of ultra filtration to polish the Purified Water system distribution loop and point of use heat exchanger design.

**MEMC, Spartensburg, SC.** designed a pilot study to reduce TOC contamination in electronic grade water system. Utilized ozone and ultraviolet light to reduce TOC to 10 ppb.

**Schering-Plough Research, Union, NJ.** Preliminary design, layout and distribution loop isometrics for a bulk pharmaceutical Water for Injection system. All instrumentation was designed for explosion proof operation.

**Merck, Sharpe and Dohme, West Point, PA.** Purified Water, Water for Injection and Clean Steam system design and construction support. Utilized PVDF pipe and sanitization by ozonation. Circulated 100 GPM to research labs and pilot plant operation.

**Glaxo, Stevenage, UK.** Site master plan for purified water for research.

**Glaxo, Research Triangle Park, NC.** Troubleshoot start-up on new Purified and Water for Injection systems.

**Bristol-Myers Squibb, Morrisville, NC.** Design Purified Water system. Supported construction and validation. Circulated 80 GPM to cosmetic and syrup production facilities.

**Sterling Research Group, Phoenixville, PA.** Designed a pretreatment system to feed the Purified Water, Water for Injection and Deionized Water systems. Utilized continuous deionization.

**Bristol-Myers Squibb, Morrisville, NC.** Designed a subsystem off the main Purified Water system for use in production of nasal spray.

**Pfizer, International, Venezuela.** Supported in-house efforts to validate a Purified Water system to FDA standards. System serviced a penicillin operation as well as aseptic operations.

**Alcon, Inc., Humacao, Puerto Rico.** Assisted the client in identifying heavy metal contamination in the Water for Injection system, developed a re-passivation procedure and supervised the re-passivation effort.

**Schering-Plough Research, Kenilworth, N.J.** Assisted the client in troubleshooting a new system they were unable to validate. Developed a complete system commentary, which the Client utilized to direct the vendor to take corrective action.

**Merck, Sharpe and Dome, West Point, Pa.** Reviewed high purity water specifications.

### Publications and Lectures

- "Upgrading Purified Water Systems To Today's Standards", ULTRAPURE WATER 10(5), pp. 40-44 (July/August 1993).
- "Providing Support Facilities to Biological Processes", presented at ASME '93 WAM Bioprocess Engineering Symposium, New Orleans, Louisiana, November 29, 1993.
- "Laboratory Utilities for Research and Development", Introduction to the Pharmaceutical Industry", ISPE Delaware Valley Chapter course offering. 1994
- "Simulation of Purified Water Systems", Scheduled for Presentation, May 9, 1994, Ultrapure Water Conference, Philadelphia, Pa.
- "Prescription for Finding a Strategic Partner", BIOPHARM 7(9), pp. 34-38 (November 1994).
- "Prescription for Finding a Strategic Partner for a Biotech Company", Pharmaceutical Engineering 15(5), pp. 30-36 (May 1995).
- "Gathering Validation Documentation for Pharmaceutical Water Systems." Ultrapure Water, December 1995
- "Gathering Validation Documentation for Pharmaceutical Water Systems-Part 2." Ultrapure Water, April 1996
- "FDA/Regulatory Issues Concerning the Introduction of New Technology into Pharmaceutical Facilities" Ultrapure Water, March 2000 (presented at the Ultrapure Water Conference Executive Committee Meeting April 1999).
- "Water Reuse Initiatives in the Pharmaceutical Industry", Ultrapure Water Executive Committee presentation April 2003.
- "Review of Critical Documentation For Small Companies", Ultrapure Water Executive Committee presentation April 2003.