

## Curriculum Vitae



**John R. Goldshalk**  
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Senior Consultant  
Biologics Consulting Group, Inc.  
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### **EXPERIENCE**

**Biologics Consulting Group, Inc., Senior Consultant**  
Gaithersburg, MD (Dec. 2005 to present)

**FDA, CBER, Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality, Chemist/Reviewer/Inspector, Rockville, MD.**  
(June 2002 to Nov. 2005)

- Responsible for reviewing Chemistry, Manufacturing and Controls sections of Biologic License Application files and conducting Pre-Approval Inspections for new biologic products.
- Received FDA-wide plaque award for Excellence in Review Science
- Received four awards for project work: resolving CMC and inspectional issues for Baxter's IGIV single cycle approval of IGIV; exceptional performance in the conduct of meetings with industry to provide guidance and enhance compliance with regulatory requirements for production of CBER regulated products; leadership in designing and building an internal knowledge management system based upon FDA's e-Room software; and a customer service award for Type C meetings with industry
- Lead inspector for cGMP inspections of biologics manufacturers, for pre-approval inspections
- Technical lead for Type C meetings with industry
- Chair for numerous BLA, PAS and CBE submissions from industry, including some device and drug reviews (PMA, NDA, 510-k, DMF and IND)

**Zerxes Consulting, Principal Consultant, Silver Spring, MD**  
(Nov. 1998 to Jun. 2002)

- Business planning and startup consulting; requirements analysis; financial, technical, and quantitative marketing analysis.
- Responsibilities in various positions within companies
  - Prepared extensive business plans, financial projections, analysis and strategy for the manufacturing division (\$200M plus contract)



- Performed quantitative marketing analysis, idea generation and conceptual program planning for the marketing division
- Designed several computer systems including requirements analysis and business process engineering
- Completed budgeting for two divisions of a company (\$180M)
- Advised on division strategy
- Helped two startups with business planning and modeling
- Performed quantitative merchandising and analysis for a large retail chain

**Sylvan Learning Systems, Inc.,** *Internal Business Consultant, Prometric Division* Baltimore, MD

(Jun. 1997 to Nov. 1998)

- Business process re-engineering and consulting, quality enhancement, ops strategy, requirements analysis
- Provided business consulting services for operations strategy, supply chain partnering, workflow efficiency, project management, database design, cost/benefit analyses, and business processes in order to improve the quality of customer and client services
- Re-engineered the facilities expansion team's management process to increase efficiency and reduce cost. Led to a > 50% reduction in inventory, labor cost savings and smoother operations
- Improved quality of franchisee services for network build-out and startup
- Created a project management system for software development workflow
- Core team member for finance and budgeting processes

**Energy BioSystems Corp,** *Pilot Plant Manager,* Houston TX

(1994 to 1995)

- Technical Areas: Management, Biotechnology, Process Engineering, Quality Assurance
- Program manager for a \$1.5 M Biotech Pilot Plant.
  - Responsible for project planning and oversight, startup and managing a team of three engineers and three operators in cooperation with the operating company (Petrolite).
  - Responsible for interfacing between the two companies, planning experiments, quality assurance of experimental results, process troubleshooting and re-design, writing technical reports, SOPs and safety documents, implementing the entire pilot plant program, setting priorities, and contributing technically to the program.
- Provided leadership to set up entire pilot plant program including process and instrumentation design changes and review, writing standard operating procedures, data gathering and data reporting procedures, scheduling, workflow, data systems, training, and safety.
- Developed EPA containment & safety documents
- Team leader for process optimization, equipment retrofits, and quality assurance
- Developed and wrote an experimental plan and one year schedule for the pilot plant
- Wrote all chemical and biochemical process safety documents and standard operating procedures for the plant (team lead)
- Performed technical tasks such as database management, P&ID review, contributed to process design, sensor calibration, running the plant via the Distributed Control System,



electronics and equipment troubleshooting, assay development, bench-scale testing and bioseparations testing

**Westvaco Corp.,** *Research Engineer, Applied Research, Microbiology, Paper Science, Manufacturing, Product Development,* Columbia, MD. (1984 to 1994)

- Responsible for planning and executing experiments, directing the work of research assistants, preparing research goals and project summaries, and performing research for five plant locations.
- Perform troubleshooting and process optimization of complex papermaking and coating systems.
- Analyze data and write scientific reports. Interact with managers and engineers at four plant locations to plan and execute large-scale trials based upon laboratory and pilot plant results. Team member for process and lab safety team.
- Developed and tested a device which simulated web offset printing
- Designed and built 2 pilot reactors
- Introduced and optimized a papermaking component that saved over \$2M annually
- Developed several innovative tests for paper, biocide, microbiology, and waste treatment plant applications
- Wrote over 50 technical reports on topics relevant to technology strategy and operations
- Coordinated testing/trials/implementation of several papermaking additives between research, production, and suppliers

**Westvaco Corp.,** *Senior Engineer* Columbia, MD

- Lead development engineer for an enzymatic biocide product.
- Performed biotechnology research and development, including enzymatic reaction kinetics research, design, building, and testing of several test reactors and associated pilot-scale equipment, and analysis of pilot plant experiments.
- Performed microbiology research as it relates to wastewater treatment and microbial control in papermaking process waters.

#### **EDUCATION**

M.B.A., *Finance and Marketing*, Univ. of Maryland, College Park, MD, and Merrick School, University of Baltimore, Baltimore, MD. (1997)

M.S.E., *Chemical and Biochemical Engineering*, Johns Hopkins University, Baltimore, MD (1984)

B.S., *Chemical Engineering*, North Carolina State University, Raleigh, NC (1982)