John R. Godshalk

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OVERVIEW

- A professional with over 30 years quality, regulatory, business and technical experience
- Industry thought leader in Regulatory and Quality in the pharmaceutical/biologics industry
- Experience in Quality Strategy, QA leadership, Product Development, Manufacturing, establishing and enhancing GxP systems for the US and EU, auditing and training
- MSE in Chemical & Biochemical Engineering, MBA in Marketing & Finance, BS in Engineering
- An innovative thinker and creative problem solver with an analytical and strategic focus
- Excellent presentation, writing and communication skills
- Technical skills combined with leadership/people management skills
- FDA Experience and Industry experience

WORK EXPERIENCE

Feb 2020 to present
JG BioConsult, LLC
Principal Consultant and President

Quality and regulatory consultant to various pharmaceutical and biologics companies worldwide, including large world-class companies. Act as interim quality director; prepare plans, objectives, and strategies for quality groups. Lead remediation projects for major issue inspection reports. Lead quality strategy projects with major clients worldwide. Write and review SOPs and protocols. Write sections of BLAs/INDs. Technical experience includes cell and gene therapies, vaccines, and therapeutics.

Nov 2005 to Feb 2020
Biologics Consulting, Alexandria, VA
Senior Consultant
Quality and regulatory consultant to various pharmaceutical and biologics companies worldwide, including large world-class companies. Perform mock FDA inspections, quality system audits, GXP audits, training (regulatory, quality, GXP, technical), act as interim quality director; prepare plans, objectives and strategies for quality groups. Help prepare and review FDA applications—BLA, NDA, 510(k)s. Attend FDA meetings as a client representative. Advise companies on regulatory and quality strategies, mentor, coach and train on Q processes/systems, write or review risk assessments. Prepare written reports and analyses for client companies. Lead remediation projects for warning letters and major issue audit reports. Lead quality strategy projects with major clients worldwide. Technical experience includes cell and gene therapies, vaccines, APIs and therapeutics.

Current experience includes the following with client companies:

- Interim director of quality
- Strategic evaluation and advice
- Remediation project lead
- cGMP evaluation of pharmaceutical facilities, processes, and support infrastructure
- cGXP and CMC consulting, evaluation and strategy
- Evaluation of clinical trial manufacturing facilities for compliance with appropriate requirements
- Pre-submission review and support, including product development and manufacturing
- Regulatory strategy development

- Evaluation of technical issues and requirements; for example: API production, sterilization, equipment cleaning, personnel monitoring, aseptic processing, lyophilization, vaccine/viral production/inactivation, facility design, quality systems, and finishing operations
- Internal training programs on cGMP and quality issues
- Project management

June 2002 to Nov 2005
Food and Drug Administration, Center for Biologics Evaluation and Research, Rockville, MD
Reviewer/Investigator, Division of Manufacturing and Product Quality
Responsible for reviewing the Chemistry, Manufacturing and Controls section of new Biologic License Applications and leading Pre-Approval Inspections for new biologic, device, and biotechnology products. Responsible for conducting meetings with industry, developing regulatory strategies with industry representatives, solving customer service problems/issues, teaching/training junior staff, writing guidance documents, leading knowledge management (IT) initiatives.

- 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
- Team Lead for Database Projects
- Chair for numerous BLA, PAS and CBE submissions from industry, including device and drug reviews (PMA, NDA, 510-k, DMF and IND)

Product level experience: biologics, vaccines, drugs, drug/device, biologic device, IVDs
Inspection level experience: PAIs for new biologics, vaccines, fill/finish facilities, API mnfg facilities, contract mnfg facilities, biotech facilities
Recognized expert areas: pharmaceutical water, processing and instrumentation, lyophilization, cleaning methods and validation, facilities, influenza vaccines, IGIV, CMC/quality/facility issues for cell and gene therapy

November 1998 to June 2002
Zerxes Consulting, Silver Spring, MD
Principal Consultant and Owner
Business planning and startup consulting; requirements analysis; financial, technical, and quantitative marketing analysis.

Clients:
Interact Commerce Corp, Scottsdale, AZ
Sr. Product Manager/Consultant
Opportunity definition and analysis; business planning; technology assessment; business development; vertical CRM product management.

- Created program and business plan for all SalesLogix CRM software industry solutions (vertical products)
- Created cost, revenue and profit models for several planned vertical products
- Created product definitions and strategies for the vertical product line
- Advised company on technology and market value of proposed external software partners
- Advised company on revenue opportunities and product management group on process enhancements

MedImmune, Inc., Gaithersburg, MD
Online at: www.medimmune.com
Business Planner/Marketing Research

- Prepared extensive business plans, financial projections, analysis and strategy for the manufacturing division of MedImmune ($200M plus contract)
- Performed quantitative marketing analysis, idea generation and conceptual program planning for the marketing division of MedImmune

Maryland State Gov't, Beltsville, MD
Analyst/Consultant

- Designed several computer systems for the Maryland Dept. of Corrections; including requirements analysis and business process engineering

Sylvan Prometric, Baltimore, MD
Strategy/Financial Consultant

- Completed budgeting for two divisions of Sylvan Prometric ($180M)
- Advised on division strategy
- Logistics Interim Group Leader

Small Business/Retail, Maryland, California

- Helped two startups with business planning and modeling
- Performed quantitative merchandising and analysis for a large retail chain

June 1997 - November 1998
Sylvan Learning Systems, Inc., Baltimore, MD

Internal Business Consultant and Lead of Ops Group, Prometric Division
Leader of Operations Group: business process re-engineering and consulting, quality enhancement, ops strategy, requirements analysis

ACCOMPLISHMENTS

- As operations group leader, 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

1994 - 1995
Energy BioSystems Corp, Houston TX

Pilot Plant Manager
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.

ACCOMPLISHMENTS

- 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

1984 - 1994
Westvaco Corp., Columbia, MD

Research Engineer
Applied Research, Microbiology, Paper Science, Manufacturing, Product Development

Responsible for planning and executing experiments, directing the work of 1-3 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.

ACCOMPLISHMENTS

- 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

Senior Engineer
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, 1997, magna cum laude
Univ. of Maryland, College Park, MD, and Merrick School, University of Baltimore, Baltimore, MD.
Selective 1-year full-time executive MBA program

M.S.E., Chemical and Biochemical Engineering, 1984, magna cum laude
Johns Hopkins University, Baltimore, MD

B.S., Chemical Engineering, 1982, summa cum laude
North Carolina State University, Raleigh, NC