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Summary of Qualifications

U.S. and international experience in the pharmaceutical industry including:

- Corporate management
- Association management
- Legal liaison/due diligence
- Fifteen years developing Corporate-level compliance programs, CGMP auditing and technical evaluation. Expert in U.S. and international GMP regulations and requirements.
- FDA/USP liaison, including development of industry consensus comments on proposed regulations, guidelines, monographs and information chapters
- Quality systems
- Operations
- Aseptic processing and sterilization technology

Work Experience

The Williamsburg Group Gaithersburg, Maryland 2003 – Present
President
Pharmaceutical consulting, specializing in CGMP compliance and auditing, quality systems, aseptic processing and sterilization technology, process validation, regulatory liaison and related technical services including design review.

Parenteral Drug Association, Inc. Bethesda, Maryland 1994 – 2003
Acting President/Senior Vice President Science and Technology
Responsible for the overall administration of PDA and the scientific, technical and regulatory affairs activities which include publishing internationally respected technical reports, writing consensus positions on proposed FDA and international regulations and guidance documents, developing the scientific content of PDA's meetings and forums, working with associations such as PhRMA, CHPA, HIMA, AAMI, GPIA, A_3P and R3-Nordic to coordinate and harmonize technical activities, and involving FDA and other regulatory bodies (e.g., USP, EMEA, ISO, PIC) in PDA technical committees.
Specifically:

- FDA technical and regulatory affairs liaison
- PDA technical reports and other scientific and regulatory documents including landmark reports on blend uniformity, aseptic processing and sterilizing filtration
- Delegate to USP
- Coordinated a pivotal study on latex extractables from stoppers at Johns Hopkins University.

- Developed consensus comments to FDA on stability, NDA-ANDA and various PAC and SUPAC guidances.
- Chaired the program committee for the 1996 North American Conference on Setting Specifications for Drug Products and Drug Substances that established the U.S. position for the ICH Q6A document.

Bristol-Myers Squibb Company Syracuse, New York 1987 – 1993
Director, Technical Services
Developed and directed Corporate Technical Services, providing effective global technical consulting services to all Bristol-Myers Squibb Company operations. The activities encompassed production, quality assurance, research, development, product liability, and regulatory affairs issues pertaining to drugs, medical devices, infant formula, and consumer products as well as general consulting involving occupational safety and health, energy and environment protection. Specifically:

- Responsible for evaluating technical problems, conducting investigations, developing conclusions, and recommending corrective action to Corporate and Divisional management.
- Worked with Corporate, Divisional and Legal staff regarding long-range plans, business acquisitions and due diligence investigations.
- Directed the Bristol-Myers Squibb energy management program, reviewing the energy management aspects of capital appropriation requests and preparing annual reports for senior Corporate management resulting in savings of more than $100 million.
- Consulted with experts within and outside the company to reach consensus and develop strategies to resolve technical issues of importance to the company. The external experts included representatives from FDA, USP, PhRMA, and other associations.
- Benchmarked with other pharmaceutical companies to help them develop CGMP auditing and compliance programs.

Bristol-Myers Squibb Company Syracuse, New York 1984 – 1987
Manager, Planning and Administration, GMP
Developed systems, procedures and personnel to conduct CGMP audits of company and third-party operations on a global basis. These audits covered quality control, manufacturing and packaging operations related to drugs, medical devices, and their ingredients and components. Reviewed action plans and prepared status reports for Corporate and Division management.

Bristol-Myers Squibb Company Syracuse, New York 1977 – 1984
Senior Technical Auditor
Audited U.S. and international company facilities for compliance with CGMP regulations. Prepared comprehensive management reports and reviewed action plans to ensure appropriate corrective actions had been implemented.

Sterling Drug, Inc. McPherson, Kansas 1975 – 1977
Chemistry Supervisor/Stability Coordinator
Managed the Chemistry, Particle and Receiving laboratories, responsible for testing all components, containers, closures, WFI and in-process waters, and bulk and finished products. Also managed the stability program, including scheduling, analysis, and trend reports. Supervised a staff of 14.

- Responsible for the design, installation, equipping and staffing of these laboratories.
- Heavily involved in the design and validation of many plant systems including water treatment, WFI system, security, computer controlled weighing and batching, and controlled substance handling.
- Developed unique approaches for validating ethylene oxide sterilization processes including sterilant and water vapor concentration mapping within the chamber.
- Other responsibilities included SOP development, qualification protocols for validation of plant systems, instrument calibration, methods development, preparation and review of analytical quality control monographs for components, closures, containers, in-process and finished products, specifications and standards for raw materials, and vendor inspection and certification.

Winthrop Laboratories Rensselaer, New York 1965 – 1975
Assistant Laboratory Supervisor/Stability Coordinator
Held a series of increasingly responsible positions beginning with routine analytical quality control of solid and liquid oral dosage forms. Participated in several AOAC collaborative studies involving fluorometric assays, developed analytical methods, and established a comprehensive stability program. The path culminated in supervision of a laboratory engaged in quality control, applied research and methods development employing 17 people.

Education

St. Lawrence University, Canton, New York; B.S., 1965
Rensselaer Polytechnic Institute, Troy, New York; M.S. Analytical Chemistry, 1970
(Thesis: "Atomic Absorption Determination of Arsenic Subsequent to Arsine Reaction with 0.01N Silver Nitrate")

Publications

"Simultaneous Quantitative GLC Determination of Chlorpheniramine Maleate and Phenylpropanolamine Hydrochloride in a Cold Tablet Preparation," J. Pharm. Sci. 65, 924 (1976).

Others on request.

Professional Affiliations

Past member PDA Board of Directors
PDA
USP
ISPE

Avocations

Commercial pilot
Computers
Hiking and walking
Photography

Skill Areas

Administration
Analytical Chemistry
Auditing and Evaluation
CGMP Compliance
Calibration
Communications
Equipment Maintenance
Facility/Laboratory Design
Management
Operations
Organizational Development
Program Planning
Quality Assurance/Control
Regulatory Liaison
Total Quality Management
Validation

References

On request.

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