



Karl L. Hofmann, Jr.

SUMMARY

A senior level expert in pharmaceutical manufacturing and quality assurance operations, with specialization in active pharmaceutical ingredient (API) manufacturing, sterile drug manufacturing operations, pharmaceutical and API plant design, biologics operations and plant design, technology transfer projects, process and cleaning validation, and environmental monitoring programs. Extensive experience in preparation for US FDA pre-approval inspections (PAI), and remediation of adverse inspectional findings. Successfully coordinated numerous European Health Authority Inspections, many resulting in no adverse inspectional findings.

Published and lectured extensively on all aspects of sterile drug manufacturing. Extensive international travel and work experience in Japan, Europe, and Puerto Rico. Adjunct faculty member with State University of New York, currently teaching a course in GMP for biotechnology operations.

PROFESSIONAL EXPERIENCE

President, Quality Systems and Support, Rondaxe Pharma: 2006-present

- Manages a team of quality assurance professionals engaged in supporting client needs in the areas of: GMP audits, development of quality systems, clinical supply manufacturing, remediation of inspectional citations, technical document preparation (quality agreements, CMC for IND and NDA), regulatory affairs, due-diligence assessments, analytical chemistry and microbiology, sterile product operations, materials controls systems, validation and risk analysis.
- Clients include an array of start-up firms through well-established large pharmaceutical and biotechnology companies, located within the US, Europe, India, China, and Japan.

Director: Third-Party Quality and Compliance, Bristol-Myers Squibb: 2003-2006; retired 2006.

- Developed new organization within the BMS Quality Unit, charged with quality oversight for all BMS external (third-party) vendors.
- With staff members located and hired in Australia, Singapore, Ireland, France and the US, led department that conducted GMP audits providing direct QA oversight of 855 external vendors worldwide.

Project Director, Biotechnology Manufacturing Operations, Syracuse NY and Manati, Puerto Rico: 2002-2003, Special Year-long Assignment

- Reported to the Senior VP, API and Biotechnology Manufacturing Operations for management of clinical supply material manufacturing in support of the NDA for Orenicia®, the first biologic developed and launched by BMS.

Director: Bulk Pharmaceutical Quality Assurance, Bristol-Myers Squibb: 1992-2002

- Responsible for all quality assurance and regulatory compliance activities for BMS API manufacturing activities worldwide, including manufacturing sites located in the US, Puerto Rico, Ireland, France, Italy and Germany. Prepared sites and facilitated inspections by international health authorities including, EU, EMEA, IMB, and MCA.
- From 1999 through 2000, as an additional responsibility, coordinated the CMC preparation, development and staffing of the manufacturing site quality unit, FDA site inspection, sNDA approval, and ultimately the manufacture of launch material for the plant-cell fermentation



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(PCF) route for paclitaxel.

- QA representative on the core-design team for the \$650MM API manufacturing facility in Cruiserath, (Dublin) Ireland.
- Coordinated remediation of lengthy FDA 483, issued to BMS bulk manufacturing site, citing numerous observations relating to aseptic bulk manufacturing. FDA accepted corrective actions without issuance of a Warning Letter and follow-up inspection resulted in no FDA 483.

Director: Worldwide Compliance Services, Bristol-Myers Squibb: 1990 -1992

- Following the merger of Bristol-Myers with E. R. Squibb, assumed responsibility for five major functional areas: Domestic and International Pharmaceutical Product Complaints Investigation and Data Base, Domestic Annual Product Quality Review, Master Production Documentation System, Process and Equipment Validation Policy, Divisional Technology Transfer Project Management, and Technical Review and Support of Major Capital Construction Projects.
- Managed over 100 technology transfer projects in 23 locations worldwide.

Director: Compliance Services, Bristol-Myers: 1986 -1990

- Serving five domestic and international facilities, led group responsible for Microbiological Control and Service, Domestic-Market Product Complaint Investigation, Division Level Quality Assurance including Compliance Auditing and GMP training, Master Documentation system, Process and Equipment Validation Policy.
- Led coordination of validation and start up activities for two new manufacturing facilities in Puerto Rico.

Director: Compliance Assurance, Bristol-Myers: 1984 -1986

- Responsible for Divisional Compliance with applicable GMP, GLP, GCP, ASH, DEA and EPA regulations through internal audits performed by staff auditors and coordinated by the Department Manger.
- Chaired the division's validation committee and interdivisional systems task force.

Manager: Production, Bristol-Myers: 1981-1984

- Direct responsibility for four drug product production units producing liquid and dry powder antibiotic parenterals, veterinary antibiotic infusions, oral antibiotic suspensions and tablets.

Manufacturing Assurance Evaluator: Bristol-Myers: 1977 - 1981

- Performed technical inspections of all regulated company manufacturing facilities.
- Extensive foreign travel included Asia, Europe, and South America. Inspections covered manufacturing, material control, engineering and quality assurance operations in pharmaceutical food and medical device plant.

Manager: Technical Services, Ayerst Laboratories: 1975 -1977

- Responsible for all production scale up projects, technical and specification writing.
- Duties included supervision of technical training and resolving routine technical problems in production.
- Supervised a staff of three (3) salaried personnel and five (5) technicians.

Development Program, Ayerst Laboratories: 1970 -1975

- Held various positions of increasing supervisory responsibilities in tablet manufacturing, liquid compounding, lyophilized sterile products, packaging and production control.



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Military Service, 1968 -1970 (see below)

Chemist: Analytical Research and Development Laboratory, Ayerst Laboratories: 1967 -1968

- Duties involved developing and perfecting assays for routine use in Quality Control.
- Used various types of analytical instrumentation including: HPLC, UV, IR, and X-Ray Diffraction.

EDUCATION

M.S., Program SUNY, Plattsburgh, NY: 1971-1973

Major: Biochemistry

B.A., Middlebury College, Vermont: 1967

Major: Chemistry Minor: Mathematics

MILITARY EXPERIENCE

- Commissioned 2nd LT. USAR, Distinguished Military Graduate: 1967
- Graduate: Brooke Army Medical Center, Officers Basic Course & Battalion Surgeon's Assistant Course - Commandant's List: 1968
- Promoted 1stLT. US Army Vietnam, 25th Infantry Division: 1969
- Promoted Captain USAR (1973); served as Company Commander USAR: 1974-1977
- Awards and Decorations: Combat Medical Badge, Purple Heart Medal, Bronze Star w/ 'V' Device Medal, Army Commendation Ribbon, Vietnam Campaign Ribbon, Vietnam Service Ribbon, Presidential Unit Citation, National Defense Service Ribbon

PROFESSIONAL AFFILIATIONS

- Member: Parenteral Drug Association (PDA); Quality Assurance and Education Subcommittee, Science Advisory Board
- Member: International Society of Pharmaceutical Engineering (ISPE)
- Member: Pharmaceutical Research and Manufacturing Association (PhRMA) Bulk QA Workgroup (chair 2000-2003)

PRESENTATIONS

- Speaker: PDA Annual Meeting, Sterile Powder Filling (1985)
- Lecturer: CENTER for PROFESSIONAL ADVANCEMENT, Filtration Sterilization (1995)
- Section Leader: AAPS/FDA Meeting (BACPAC I) (1997)
- Lecturer: CENTER for PROFESSIONAL ADVANCEMENT, Filtration Sterilization (1998)

- Speaker: PDA Puerto Rico Chapter Process Simulation Testing, Sterile API (1998)
- Speaker: Pharma Conference, Process Simulation for Aseptic Bulk Manufacturing, (2005)
- Speaker: ISPE Conference, Conducting Simulation Runs for API Sterile Powders, Regulatory Expectations and TR 28 (2006)
- Lecturer: State University of New York (SUNY-ESF) Bioprocess Plant Design Course (2006-present)

PUBLICATIONS

K. L. Hofmann, “Sterile Powder Filling - The Learning Curve”, *PDA Journal of Parenteral Science and Technology*, **1986**, 140(5)

D. C. Fry and K. L. Hofmann, “Records and Reports”, Chapter in *Pharmaceutical Dosage Forms: Parenteral Medications*, Vol I, eds: K.E. Avis, L. Lachman, and H. Lieberman, Marcel Dekker, New York, **1993**

K. L. Hofmann, “Sterile Products Validation”, Chapter in *Pharmaceutical Process Validation*, 2nd Ed, eds: I. Berry and R. Nash, Marcel Dekker, **1993**

M. Lazar, K. L. Hofmann, et al. “Sterile Bulk Pharmaceutical Chemicals”, *Pharmaceutical Technology*, **1995** TR 28.

K. L. Hofmann et al., “Process Simulation testing for Sterile Bulk Pharmaceutical Chemicals” *Journal of Parenteral Science and Technology*, **1998**, 52(S3).

K.L. Hofmann and B. J. Evanoff; “Technology Transfer: Active Pharmaceutical Ingredients”. Chapter in *Validation of Active Pharmaceutical Ingredients*, 2nd Edition, eds: I. Berry and D. Harpaz, IHS@Health Group, Denver, CO, **2001**

J. Agalloco, K. L. Hofmann et al; “TR 28 rev. 1 Process Simulation testing for Sterile Bulk Pharmaceutical Chemicals”, *Journal of Parenteral Science and Technology*, (publication pending)

AWARDS

Elected to International Who's Who of Professionals (1997)

Awarded the 2004 Presidential Green Chemistry Challenge Award for "Development of a Green Synthesis for Taxol™ Manufactured via Plant Cell Fermentation and Extraction.