

JOHN Y. LEE

PROFESSIONAL EXPERIENCE

Executive Director Pharmaceutical Compliance Associates No. Massapequa, New York	8/91 - Present
Director, Quality Assurance Altana, Inc. Melville, New York	3/88 - 8/91
Quality Assurance Manager Organon, Inc. West Orange, New Jersey	4/85 - 3/88
GMP Compliance Associate Ortho Pharmaceutical Corporation Raritan, New Jersey	12/83 - 4/85
Consumer Safety Officer (Investigator) U.S. Food & Drug Administration East Orange, New Jersey	10/77 - 12/83

TECHNICAL EXPERIENCE

Extensive GMP auditing experience in bulk pharmaceutical chemicals and finished pharmaceuticals, with specialization in pre-approval inspection audits.

Active involvement in the design, renovation and validation of sterile and non-sterile pharmaceutical facilities.

Design of validation studies, preparation of validation documents, and coordination of validation projects for sterile and non-sterile operations.

Development and organization of Quality Assurance operations and programs including batch record review, product annual reviews, documentation control, quality assurance investigation, auditing, vendor qualification, GMP and technical training, validation, product stability, complaint investigations, etc.

Development and presentation of training programs for line personnel, supervisors and management on topics of GMP compliance, validation, quality assurance programs and sterilization science.

PUBLICATIONS

1. "FDA Compliance Issues For Cleaning Validation," *STP Pharma Pratiques*, 10(5): 292-295, September-October, 2000.
2. "Documentation Requirements for Preapproval Inspections," *Pharmaceutical Technology*, 17(3):154-164, March, 1993.
3. "Validation Organization and Documentation," *Pharm Tech Japan*, 9(2):151-161, February, 1993.
4. "Recent Trends in Process Validation," chapter in *Pharmaceutical Process Validation*, Marcel Dekker, Inc., New York, 573-586, 1993.
5. "Validation Terminology and Concepts," *Pharm Tech Japan*, 8(9):7-16, September, 1992.
6. "Sterilization Control and Validation for Topical Ointments," *Pharmaceutical Technology*, 16(3):104-110, March, 1992.
7. "Product Annual Review," *Pharmaceutical Technology*, 14(4):86-92, April, 1990.
8. "Investigating Sterility Test Failures," *Pharmaceutical Technology*, 14(2):38-43, February, 1990.
9. "Validating an Automated Filter Integrity Test Instrument," *Pharmaceutical Technology*, 13(10):48-56, October, 1989.
10. "Security for Pharmaceutical Audit Reports," *Pharmaceutical Production TechSource*, 4(6):3, June 1989.
11. "Auditing an Aseptic Filtration Process," *Pharmaceutical Technology*, 13(2):66-72, February, 1989.
12. "Environmental Requirements for Clean Rooms," *Bio-Pharm*, 1(7):40-43, 1988 reprinted 2(2):42-45, February, 1989.
13. "GMP Compliance for the Lyophilization of Parenterals: Part II," *Pharmaceutical Technology*, 12(11):38-42, November, 1988.
14. "GMP Compliance for the Lyophilization of Parenterals: Part I," *Pharmaceutical Technology*, 12(10):54-60, October, 1988.
15. "Essential Elements for Establishing and Performing an Internal GMP Audit," *Pharmaceutical Manufacturing*, 3(2):18-21, February, 1986.
16. "GMP Compliance for Clinical Packaging," *Pharmaceutical Manufacturing*, 2(9):34-38, September, 1985.

COURSES AND LECTURES

Course director, symposium chairman, moderator and speaker for professional organizations:

Parenteral Drug Association
Pharm-Tech Conference
PharmaNet, Inc.
Technomics
InfoScience

The Center for Professional Advancement
Medical Manufacturing TechSource
American Society for Microbiology
Institute for Applied Pharmaceutical Science
Technical Seminars

PROFESSIONAL AFFILIATIONS

Founder of the GMP Compliance Network; Former Vice President of the North Jersey Chapter of ISPE, and the GMP Education and Training Association. Member of the Parenteral Drug Association.

EDUCATION

Fairleigh Dickinson University
Teaneck, New Jersey
M.B.A.-Pharmaceutical Studies, 1991

New York University
New York, New York
B.A.-Biology, 1976