JOHN Y. LEE

PHARMACEUTICAL PROFESSIONAL EXPERIENCE

Executive Director 8/91 - Present
Pharmaceutical Compliance Associates
Massapequa, New York
Henderson, Nevada

Director, Quality Assurance and Quality Control 3/88 - 8/91
Altana, Inc.
Melville, New York

Quality Assurance Manager 4/85 - 3/88
Organon, Inc.
West Orange, New Jersey

GMP Compliance Associate 12/83 - 4/85
Ortho Pharmaceutical Corporation
(Div. Johnson & Johnson)
Raritan, New Jersey

Consumer Safety Officer (Investigator) 10/77 - 12/83
U.S. Food & Drug Administration
East Orange, New Jersey

PHARMACEUTICAL TECHNICAL EXPERIENCE

Extensive GMP auditing and consultation experience in active pharmaceutical ingredients (API) and finished pharmaceuticals, with specialization in FDA pre-approval inspection (PAI) audits and sterile products (aseptic processing, terminal sterilization, lyophilization).

100% success rate in assisting clients to secure approval at the initial FDA pre-approval inspection (PAI). PAI country clients include US, Europe (Germany, Italy, France, Denmark, Netherlands, Sweden, UK, Spain, Norway), China and Japan.

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

Designed validation studies, prepared validation documents, and coordinated validation projects for sterile and non-sterile operations.

Developed and organized Quality Assurance operations and programs including batch record review, product annual review, documentation control, quality assurance investigation, auditing, GMP and technical training, validation, product stability, complaint investigations, etc.

Developed and presented training programs for line personnel, supervisors and management, and senior executive management (e.g., CEO and Vice Presidents) on topics of GMP compliance, validation, quality assurance programs, and sterilization science and technology.

284 E Lake Mead Pkwy, Suite C, PMB 278
Henderson, NV 89015
www.gmpseminars.com
Tel.: (702) 558-0094
Fax: (702) 558-0079

PUBLICATIONS

1. “Checklist for Computer Software Validation,” *Pharmaceutical Technology,* February 2014.

2. “Change Management: Common Failures and a Checklist for Improvement,” *Pharmaceutical Technology Europe,* May 2010.

3. “Product Annual/Quality Review: US/EU Comparative Analysis and Interpretations,” *Pharmaceutical Technology,* 32(3): 88-104, March, 2008.

4. “Good Laboratory Practice (GLP) Regulations: Interpretation Techniques and Review of Selected Compliance Issues,” *Drug Information Journal*, 40(1): 33-38, 2006.

5. “FDA Compliance Issues For Cleaning Validation,” *STP Pharma Pratiques*, 10(5): 292-295, September-October, 2000.

6. "Documentation Requirements for Preapproval Inspections," *Pharmaceutical Technology*, 17(3):154-164, March, 1993.

7. "Validation Organization and Documentation," *Pharm Tech Japan*, 9(2):151-161, February, 1993.

8. "Recent Trends in Process Validation," chapter in *Pharmaceutical Process Validation,* Marcel Dekker, Inc., New York, 573-586, 1993.

9. "Validation Terminology and Concepts," *Pharm Tech Japan*, 8(9):7-16, September, 1992.

10. "Sterilization Control and Validation for Topical Ointments," *Pharmaceutical Technology*, 16(3):104-110, March, 1992.

11. "Product Annual Review," *Pharmaceutical Technology*, 14(4):86-92, April, 1990.

12. "Investigating Sterility Test Failures," *Pharmaceutical Technology*, 14(2):38-43, February, 1990.

13. "Validating an Automated Filter Integrity Test Instrument," *Pharmaceutical Technology*, 13(10):48-56, October, 1989.

14. "Security for Pharmaceutical Audit Reports," *Pharmaceutical Production TechSource*, 4(6):3, June 1989.

15. "Auditing an Aseptic Filtration Process," *Pharmaceutical Technology*, 13(2):66-72, February, 1989.

16. "Environmental Requirements for Clean Rooms," *Bio-Pharm*, 1(7):40-43, 1988 reprinted 2(2):42-45, February, 1989.

17. "GMP Compliance for the Lyophilization of Parenterals: Part II," *Pharmaceutical Technology*, 12(11):38-42, November, 1988.

18. "GMP Compliance for the Lyophilization of Parenterals: Part I," *Pharmaceutical Technology*, 12(10):54-60, October, 1988.

19. "Essential Elements for Establishing and Performing an Internal GMP Audit," *Pharmaceutical Manufacturing*, 3(2):18-21, February, 1986.

20. "GMP Compliance for Clinical Packaging," *Pharmaceutical Manufacturing*, 2(9):34-38, September, 1985.

COURSES AND LECTURES

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

Parenteral Drug Association	The Center for Professional Advancement
Pharm-Tech Conference	Medical Manufacturing TechSource
PharmaNet, Inc.	American Society for Microbiology
Technomics	Institute for Applied Pharmaceutical Science
InfoScience	Technical Seminars
Key to Compliance (Sweden)	AP3 (France)
Blue Bell Consulting (China)	China Food & Drug Administration (China FDA Inspectors)

PROFESSIONAL AFFILIATIONS

Founder of the GMP Compliance Network

Former Vice President of the North Jersey Chapter of the International Society for Pharmaceutical Engineering (ISPE)

Former Vice President of the GMP Education and Training Association

Member of the Parenteral Drug Association (PDA)

Member of the ISPE

EDUCATION

Fairleigh Dickinson University

Teaneck, New Jersey

Master of Business Administration (MBA) -Pharmaceutical Studies, 1991

New York University

New York, New York

B.A.-Biology, 1976